SEPTEMBER 2019
PHC NEWSLETTER

PATTON HEALTHCARE CONSULTING, INC.

NEWS FROM CMS AND JOINT COMMISSION

INSIDE THIS ISSUE:

PERSPECTIVES

September has arrived, the weather is cooling, children are back in school, vacations are over, and we are resuming publication. We hope our readers had a pleasant summer, with some time off and are looking forward to another action-packed year of accreditation and regulatory compliance changes.

FPPE/OPPE Requirement Update:
The August issue of *Perspectives* contained a potentially very important update to the existing FPPE and OPPE requirements that would allow for the incorporation of external data to somewhat fulfill these requirements. Readers will note that we are not using clear and declarative language to describe these changes. This is because interpreting the medical staff standards in general, and OPPE and FPPE requirements more specifically is like interpreting ancient scripture. Every word, comma, bullet point and the multiple FAQ's that are being amended to catch up with this change have to be carefully evaluated.

One clear message in the *Perspectives* article is that "supplemental data may not be used in lieu of a process to capture local data." The term "supplemental data" refers to external data and what is clear here is that there must be a "process" to capture local data. By "process," we would advise ensuring that there is a policy and procedure for data collection that is fully operational. However, it appears that TJC is going to permit of external data to supplement your locally collected data. An important quote from TJC is, "The Joint Commission recognizes that, in rare situations, local data may be unavailable, and decisions must rely primarily on outside data." TJC qualifies this statement with the following, "However, it is important that the organized medical staff develop a process to make a good faith attempt to collect such data locally whenever possible."

This seems very reasonable. If there is any local performance you are capturing data relative to that performance, but if that volume is low, you may incorporate data from another Medicare certified hospital to conclude your evaluation.

Unfortunately, TJC then points to an existing, but recently modified FAQ that discusses OPPE, but points to the use of external peer recommendations for purposes of reappointment decision making. We say unfortunately because this opportunity has been out there for several years and reappointment is different than OPPE. We have seen organizations in the past being cited for the use of peer recommendations in fulfillment of their OPPE requirement when no data is available. Our hope is that this FAQ will be tweaked to make it clear that external data can be used for purposes of OPPE and FPPE and the discussion about peer recommendations will be moved to a separate FAQ on the reappointment process.

Perhaps the clearest and most succinct section of this article is Table 2, which appears to conclude that external data can be used as supplemental information for both OPPE and FPPE.

Table 1 in the article is interesting although it is entirely unrelated to the discussion of OPPE and FPPE. Table 1 identifies additional information that can shared among hospitals pertinent to the credentialing and privileging process such as general application data, verification of training if it was obtained through a primary source or a CVO, the physical ability to perform the privileges and peer or faculty recommendations.

We encourage readers to share this article with medical staff leaders and the office staff and if you believe this has utility at your organization you should develop policies and procedures on how you will obtain and utilize external data for OPPE or FPPE. In addition, keep scanning the FAQs as there are already changes and perhaps additional ones coming to help explain this issue. In addition, if your team has questions, these should be directed to the standards interpretation group at TJC. As always, we would advise that you retain any responses that you use in developing your policies and procedures in case questions arise on survey.

Sentinel Event Statistics:

The August *Perspectives* also includes data on the first 6 months of 2019's most frequently reported sentinel events. This data shows unintended retained foreign object (URFO) leading the way with 60, wrong site surgery second with 29, patient falls at 25, inpatient suicide at 21 and suicide off-site within 24 hours of discharge also at 21. While this was not published in *Perspectives*, at the August TJC Consultant Forum we were shown a multiyear comparison for these most frequently reported sentinel events.

In theory, numbers for the first 6 months of 2019 should be about half as many reported events as in prior full years unless some improvement is noted. Interestingly, falls, suicides, and wrong site surgery are less than half as great as prior years, so perhaps there is some improvement occurring. Unfortunately, URFO is already at 60 while the prior year was 111, so this 2019 number is outpacing prior years slightly. It could also be that the volume of reporting has increased. *Perspectives* reminds us that reported sentinel events are only the tip of the iceberg of total sentinel events, estimated at only 2% of the total.

HR Requirement for Fluoroscopy Deleted:

In January of this year, TJC had introduced a new requirement, HR.01.05.03, EP 15 for staff and physicians using fluoroscopy, to receive annual training in dose optimization techniques and tools as described in Image Gently and Image Wisely, as well as the required safe procedures for use of the equipment. Well, TJC has decided their requirement is redundant with other accreditation requirements and they are deleting the requirement effective immediately. Bear in mind that if you provide a printed version of the standards to department heads, this will still appear in printed versions, but it is deleted from the newest E Edition.

Frequently Scored Standards:

The lead article in the September edition of *Perspectives* is the listing of the most frequently scored standards through the first 6 months of 2019. As has been the pattern for many years now, most of the list is comprised of EC and LS standards although there has been some minor shifting in the scoring patterns; but basically, the same EC/LS standards continue to cause compliance difficulties.

When previously published in April 2019, there was only one clinical standard in the top 10—and that was IC.02.02.01. IC.02.02.01 is frequently cited relative to HLD and sterilization issues. Now there are two clinical standards in the top 10 with IC.02.01.01, joining IC.02.02.01. Data presented at the Consultant Forum revealed that the most frequently cited EP in IC.02.01.01 is EP 1. EP 1 says: The hospital implements its infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection. EP 1 is the grab bag of IC issues, low level disinfection dwell time, dust, supplies on the floor, etc. We see surveyors continue to expect hospitals to adhere to manufacturer instruction for use.

The one standard that fell out of the top ten since April is EC.02.02.01. This is the hazardous materials and waste standard dealing with a potpourri of hazardous items from eyewash requirements to hazardous medications to inspection of lead shields and dosimetry badges in radiology. Remember, while this standard may have fallen out of the top ten, it is by no means one that has stopped being scored frequently or one that we can be inattentive to. Number 10 on the September list is still scored in 64% of hospitals, while in April #10 was only cited in 62% of hospitals.

The September *Perspectives* article on the most frequently scored standards also includes a table for their optional medication compounding certification program. We would encourage our hospital readers to carefully review this listing and share it with their pharmacy leadership. At the moment hospitals are at somewhat of a disadvantage because there are very few published sterile medication compounding standards in the existing hospital manual, yet surveyors seem very astute at finding areas of noncompliance with USP Chapter 797. Looking at what is being scored most often in the medication compounding certification program provides very important clues on what hospitals should be concerned about when hospital surveyors visit your pharmacy compounding areas. USP Chapter 797 has included many policy, training and competency requirements that TJC can score, and this listing helps identify some of the most frequent problem areas.

New Standards for Perinatal Safety:

The September issue of *Perspectives* also introduces two new Provision of Care standards with 13 elements of performance that detail requirements for maternal safety. These new requirements take effect July 2020. The new standards are not published in *Perspectives*, but there is a link to the TJC website's prepublication standards and a new R3 report on this same subject. Much like this year's safety goal modifications on suicide prevention, these new standards require hospitals to select evidence-based tools, procedures, and guidelines to help shape your implementation of the new standards.

These new requirements certainly look like they will require a lot of thought, analysis, multiple drafts, edits and training. The R3 report issued August 21 on this issue is particularly helpful in that it identifies references TJC used in developing each of the new elements of performance and identifies with hyperlinks the membership of the technical advisory and standards review panels. Knowing who the physician and nursing leaders were who shaped these new requirements will likely be helpful in developing buy-in at your hospital. Many of the references in the R3 come from the American College of Obstetricians and Gynecologists. One reference comes from the California Department of Public Health. Of interest, the Joint Commission shared maternal mortality data at the Consultants Forum from 1999-2013 which highlighted that the improvements California has made in steadily reducing mortality rates. This is in contrast to the national data which shows rates rising in the US over that same period of time. The US has the highest maternal mortality rate of any other developed country and we are the only country with a rising death rate.

Hospital readers will have 10 months to get these new requirements up and running before the July deadline. Given the unpredictability of triennial survey scheduling and the risk of out of cycle, for-cause surveys, this is not an issue you want to be delayed in implementing. While 10 months may sound like a long way off, it is really not given the scope of these new requirements. We suggest you put together an implementation team now, share all of these materials and develop a timeline and work plan to bring your implementation to a conclusion prior to July 1, 2020. As with any good work plan and timeline, you also want to

ensure that deadlines are being met in accordance with senior leaderships expectations.

Sentinel Event #61 – Direct Oral Anticoagulants:
The September *Perspectives* has a reminder that TJC published a new Sentinel Event Alert on July 30th. There is a new class of anticoagulants called DOAC's, or direct oral anticoagulants and they can pose some new issues as not everyone is familiar with the names of these agents, their mechanism of action, and how to reverse bleeding complications.

The Sentinel Event Alert contains hyperlinks to the American College of Cardiology's 2017 Expert Consensus Decision Pathway on Management of Bleeding and a second link to a webinar TJC conducted on this subject. In the Sentinel Event Alert TJC published 6 specific recommendations and, while you are not mandated to implement all 6, there should be an appropriate committee or team evaluation of each with decisions reached about which ones you will implement as well as documented rationales on why you might not implement some.

The 6 recommendations are as follows:

1. Create name awareness for these new agents so that clinicians recognize the implications when doing patient evaluation and medication reconciliation.
2. For each type of anticoagulant use evidence-based protocols and practice guidelines for drug initiation, maintenance and reversal and management of bleeding.
3. Have written P+P for baseline and ongoing laboratory monitoring including these newer DOAC's.
4. Include the indication for use on the patient's prescription, instructions for use and the EMR so that all staff interacting with this patient can reinforce that education.
5. Address anticoagulation safety practices and monitor effectiveness, a usual performance improvement approach to enhancing safety.
6. Provide detailed drug specific patient education about each of these new agents.

TJC also supplied an informative side bar and a colorful graphic with thematically similar but not identical advice. The sidebar mentions one very practical recommendation about stocking the appropriate blood products and reversal agents, and we would add, even if you do not have each of these new agents on formulary. It is likely your emergency department will see patients on DOAC's that you do not have on formulary, but you may need to provide emergency treatment. The 2017 ACC Expert Consensus Decision Pathway does include a table identifying appropriate reversal agents and treatments.

Consistent Interpretation:
Both the August and September editions of *Perspectives* includes the ever-confusing column on consistent interpretation. Their usual format is repeated in the customary two column format with surveyor observations on the left and on the right guidance from SIG on the standard and EP that appears to have no direct correlation to the surveyors' observations. In the end it appears the surveyors have identified meaningful scoreable issues and SIG identifies even more meaningful scoreable issues that could fall under this same element of performance. Unfortunately, it remains unclear if anything included in the surveyor observations is a misinterpretation of a requirement.

CONSULTANT FORUM

Scoring Patterns:
At the August Consultant Forum hosted by TJC, data was presented on accreditation outcomes and standards compliance. The 2019 data is, of course, only for the first half of the year, but the adverse outcomes of preliminary denial of accreditation (PDA) and accreditation with follow up survey (AFS) are at this point occurring less often than in 2018. We can determine this because the half-year data is less than half the prior years' experience. For example, PDA through June was only 26, whereas the full year 2018 was 88. Similarly, AFS thus far is 29, whereas in 2018 it was 77. The immediate-Threat-to-Health and Safety (ITHS) outcome appears very similar to the prior year, however. So far in 2019 they have seen 14 ITHS, and in the full year 2018 it was 29, so this is tracking very closely to the prior years' experience.

Medicare condition level findings appear to be up in acute care hospitals as compared to 2018. In 2018 50% of hospitals had COP level findings and in the first half-year of

2019 57% are receiving condition level findings. The total number of RFI's is also up slightly from an average of 32.4 last year to 33.7 RFI's this year.

The bottom-line consideration from these scoring patterns is to set expectations at a practical level. You are going to have more requirements for improvement, and you are more likely to have a Medicare condition level finding after your survey. Not mentioned in this article, but an issue we have observed is that you are also going to have many more observations of noncompliance to address under a specific element of performance. We believe that most surveyors avoided citing an issue over and over again, however that does not appear to be the case any longer. Compliance gaps observed in multiple locations of the organization are all likely to be noted in your report making analysis of findings and planning for corrective action more complex.

EC NEWS

Time Limited Waiver:
The August and September editions of EC News were both very lengthy. The lead article in August was particularly helpful in that it described the process for requesting a "time limited waiver" in response to findings issued on survey that cannot be completed within the expected 60 days. Searching the Joint Commission public website for this content has proven difficult for our consulting clients and us, so this article should be shared with your facilities and quality teams that will have to respond to survey findings.

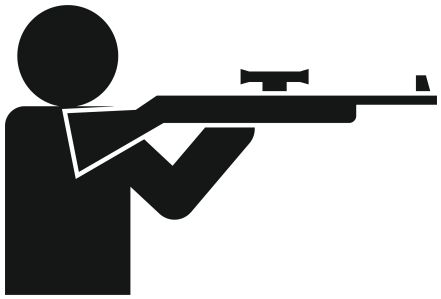
This article describes the path to accessing the request form via the secure extranet site, not the public website. There is also a nice flow chart that depicts the process steps, which includes TJC needing to obtain CMS regional office approval before granting any time-limited waivers. The most important concept in the article is that the waiver request must be submitted within 30 days of your survey. This gives TJC and CMS time to complete their analysis of your request before you hit the 60-day submission deadline for the ESC. There is also helpful advice from TJC that denials are often due to incomplete submissions and/or missing attachments. We would encourage readers to obtain the appropriate documents from the TJC extranet and review the process. If you received LS findings from us or other consultant firms in a mock survey that you believe cannot reasonably be corrected in 60 days, it might be good practice to draft a really good waiver request to use in the event TJC notices the same issue on actual survey.

Mold is on the Radar:
The August issue of EC News has a 10-page article on mold. We have been reading and hearing a lot more coming out of TJC relative to mold in hospitals this past year. Dedicating 10 pages on this subject is just another indicator that this is becoming increasingly important and it should be on your radar screen. The article has a nice description of action steps you can take to contain or prevent mold contamination. They have also reprinted two different tables from the CDC, one on mold pathogens and how they get into the environment, and a second on infection prevention and control measures for construction. At a minimum this should be shared with facilities and infection prevention staff and a gap analysis performed to determine your relative risks and readiness for preventing or managing mold.

Construction Compliance:
The August mold article is followed by a second article on "Tips for Maintaining Compliance During Construction" and the September EC News has an article entitled "Construction Safety Considerations." Both articles are very useful reading for staff involved in preconstruction risk assessments (PCRA), infection control risk assessments (ICRA) and interim life safety code risk assessments (ILSM).

There are 9 best practices published in the September article, one of which is the recommendation to post the PCRA, ICRA and ILSM evaluations in the job site. This is a recommendation we have made for years in that it allows administrative and quality staff, as well as area clinical staff, to see what enhanced safety measures should be in place, and to determine if they really are in place adequately. These two construction related articles should be shared with your facilities, quality and infection prevention teams and the best practices and recommendations analyzed to determine what modifications you need to make to enhance your management of construction projects.

Active Shooter Drills:
The August edition of EC News has an article on active shooter drills which recommends a formal large-scale drill as well as brief mini drills conducted in departments and units to help get staff prepared for the larger scale drill. The September edition then has an article discussing what to do if your hospital is the crime scene and managing that process from the perspective of working with law enforcement and media. Both articles should be analyzed and incorporated as needed into your emergency management plan.



ASHE Conference – 6 Commonly Scored:
The September EC News has an article highlighting content delivered by Joint Commission speakers at this year's ASHE Conference entitled "What Joint Commission Surveyors Want you to Know." This article provides details about 6 very commonly scored survey issues that we see popping up over and over again in survey reports. These include:

1. Relocatable power taps
2. Remote stop station for emergency generators
3. Alcohol-soaked materials in the OR
4. Medical gas distribution and labeling
5. Kitchen fire safety
6. Spare sprinkler heads

These issues have loomed large on survey because many organizations did not catch up with changes that resulted from conversion to the 2012 Life Safety Code. The remote stop station for the emergency generator we see scored very often simply because it is often located not the least bit remote from the generator. The alcohol-soaked materials proved controversial because CMS initially wanted them removed from the OR before the case started. Discussion with AORN and others has modified this position and apparently this will be changed in the 2021 edition of NFPA 99. For the time being, just making sure the alcohol prep has dried appropriately and moving the materials away from the table is sufficient. It looks like TJC will be an early adopter of this modified position.

Medical gas labeling we usually see scored for failures or mislabeling of the emergency shut off valves. This tip includes guidance that the piping itself, both horizontally and vertically must also be labeled at intervals of every 20 feet.

The kitchen fire safety issue involves the need to separate the kitchen fryer by at least 16 inches from any flame-based cooking surface, unless a tempered glass baffle plate is installed between those 2 devices. This one reads like TJC had not been applying this requirement, but they now will begin to do so. Thus, you will want to inspect your own kitchen to determine if you are compliant.

The spare sprinkler head issue we have seen scored steadily for at least 2 years now. Apparently NFPA 13-2010 requires at least 6 spare sprinkler heads of each type used in the hospital to be available as spares. However, if you have between 300-1000 total sprinklers, you need to have 12 spares on hand; and for more than 1000 sprinklers, you have to have at least 24 spares. This has surprised many hospitals, but we also have seen the second aspect of this get scored and that is storage. These sprinkler heads must be stored below 100 degrees F. We have seen facility shops that operate without air conditioning get scored on the temperature issue, too.

CMS

EMTALA Memos:
CMS issued two EMTALA related memos as QSO memoranda this summer. The first published on June 27th is a reissuance and revision of a memo from 2005 on EMTALA protections for infants born alive. We know that this subject has been a hot political discussion item this year and without joining that hot political conversation, we would simply advise printing the memo, sharing it with your hospital counsel, and asking for advice on your current practices or changes needed, if any.

The second memo, QSO 19-15, issued July 2 has a very limited target audience of just psychiatric hospitals, and among those hospitals just the ones that meet the threshold for what EMTALA considers a "dedicated emergency department." The memo includes 7 responses to what CMS calls frequently asked questions about the responsibilities of psychiatric hospitals to perform medical screening of emergency patients. The FAQ's are informative and attempt to explain current CMS policy, not new requirements. The bottom line is that if your organization meets this dedicated emergency threshold then yes you have to do medical

screenings in accordance with state law and scope of practice rules. If you are one of these unique type of facilities, you will want to review this memo in detail and determine if you are compliant with the FAQ guidance.

IN OTHER NEWS…

FDA Dispute:
Shortly before going to print, we saw news that the FDA and the manufacturer of the One Tray system, Innovative Sterilization Technologies are in dispute about how the device should be marketed and used. We have no insight into how this disagreement will be concluded, nor have we seen any actions taken by TJC as of yet. However, readers should be aware of the issue and determine if they want to make any changes by reading the notices of both the FDA and the manufacturer. Here are the links:

FDA:
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/innovative-sterilization-technologies-llc-524761-03202019

CONSULTANT CORNER

Dear Readers,

We hope you enjoyed the remainder of your summer! There was a lot of update since we published last, so we hope this issue finds you well.

We want to remind you that we are here to help you respond to and recover from any Immediate Jeopardy finding. It is an unfortunate circumstance that our team of experts will guide you through.

Contact us today to learn more about how our experts can help you!

Thank you,

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