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PHC NEWSLETTER



NEWS FROM CMS AND
JOINT COMMISSION

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PERSPECTIVES

The Pendulum Swings: More Changes for High Level Disinfection & Sterilization:

Last month we wrote an article in this newsletter entitled “The pendulum swings, we think.” Well, our conclusion, and yours after reading the October issue of *Perspectives* will be that there definitely is a new orthodoxy at Joint Commission regarding requirements for high level disinfection and sterilization. The new belief system is much more nuanced and will require much more precise documentation from surveyors to score a requirement for improvement and much more nuanced policy and procedure creation by hospitals. If you read nothing else this month, be sure to read the 10 pages of guidance in the Consistent Interpretation column. Oddly, the article is written not from the perspective of providing instruction to those of us in the field, but rather, it provides instruction to surveyors on how they are to now score or not score certain observations. Some of these instructions are a 180-degree reversal of what they have scored in the past. Reading as if through the eyes of the surveyor, what we find generally speaking is there will be a much greater reliance on manufacturer’s instructions for use effective September 1. This may pose a continuing problem for organizations as staff’s understanding of each IFU that may be applicable in each circumstance (e.g., IFU for the sterilizer, the washer, the chemical or biological indicator, the high-level disinfectant sterilant, the test strips, the endoscope, the cannulated instrument, etc., etc.), coupled with their ability to access the IFU for all devices in use is often beyond challenging. A second

new surveyor requirement is that when citing a clinical practice guideline (CPG) it must be verified that your organization has adopted that CPG, and the specific reference should be quoted. Just saying per AAMI without stating the specific AAMI manual and the fact that the organization had adopted it is insufficient. Some frequently scored “gotchas” are also eliminated. For example, the gotcha about finding a closed pair of scissors in a peel pack that is in storage, ready for use will no longer be scored. The surveyor must find this flaw prior to sterilization or find staffs inability to describe what is done to keep these instruments open to allow complete sterilization to score this. Another eliminated gotcha is when the surveyor picks up an instrument tray that feels heavy and asks the organization to test it on their scale and there is no scale. Now the mere absence of a scale is not score-able, or the fact that the tray feels heavy is not score-able. The surveyor must drill down to discover the organizations process to prevent instrument trays from being excessive. Surveyors may quickly adapt to this nuanced approach and it may be as frequently scored in a few months as it previously was, it will just require a little more effort to do so.

When to Document the Biologic Indicator & Re-usable Brushes:

There is also an extensive section on biologic indicator use and new guidance to not score organizations for failure to document lot numbers of biologic indicators, unless the indicator IFU, or clinical practice guideline or hospital policy mandate such documentation. There is equally complex new guidance on the process for disinfecting re-useable brushes used in the decontamination process. The new guidance states that surveyors should not score a failure to document lot number and expiration date of the disinfectant solution if the IFU itself does not require this documentation. However, the very next bullet point advises the surveyors to score failure to document lot number and expiration date of the disinfectant if the organization follows AAMI or AORN, if the IFU is not available, or if the organization is using a manual method to disinfect those brushes. Sadly, this sounds confusing and you can engineer out a lot of that confusion by using single use brushes.

Cleaning Ultrasound Transducers:

There is also an interesting section on regular ultrasound transducers and how to clean them if they come in contact with non-healthy skin or mucus membranes. This happens to be a controversial subject

right now, with some strongly advocating high-level disinfection and others stating it is not required. (See the American Institute for Ultrasound in Medicine website) <https://www.aium.org/officialStatements/57>

Regardless of the controversy, TJC advises surveyors on two areas of inquiry. First is to ask what established process the organization has to perform high level disinfection for transducers, following possible contamination. Second is: “are staff knowledgeable about how and when the probe may require high level disinfection?” In addition, you want to carefully review your transducer manufacturers IFU to determine what if any guidance they have provided on this subject.

Keeping Instruments Moist – Simplified:

We have examined report after report the past few years where organizations are hit with the mandate to use an enzymatic product during the pre-cleaning phase and dinged for failure to apply that product in the patient care area. Both of those prior mandates are now officially ended by TJC. This issue of *Perspectives* now states: “There is no requirement that an enzymatic product must be used...” They also state, “Application of a spray, or other method used to keep instruments moist, may occur once the instruments reach a soiled utility area rather than in the procedure room to avoid patient exposure to spray...” Information provided at Executive Briefings indicate that the manufacturers IFU should be used for keeping instruments moist, but absent specific advice you could choose the inexpensive option of a moist towel.



Probably the most important new requirement is on the last page of this article and it stipulates a requirement for surveyors. Surveyors must state the specific regulation, manufacturer’s IFU, or evidence-based guideline adopted by the organization, then include specific examples of noncompliance with those guidelines. That level of detail will by itself help to reduce inappropriate RFI’s where organizations go searching for some reference that states what the surveyor stated. The good news is that going forward

the 74% scoring rate for IC.02.02.01 reported in the September issue of *Perspectives*, should go down significantly. We actually saw the first report in a long time with no RFI's at that standard this week. At the same time this new approach may anger some other readers who have had an adverse decision of some sort with the old orthodoxy. It is definitely a fresh approach and will likely lead to much better documentation and clarity of findings in the future.

TJC Webinar on Sterilization/HLD:

This more recent guidance was also discussed by Joint Commission's new infection control expert at this month's Executive Briefings sessions. If you did not already get a chance to hear her describe these changes first hand, we would highly suggest you participate in a JCR webinar planned for October 31. No standards have been more problematic for the past 5 years than the ones regarding high-level disinfection and sterilization. Since it involves a change in belief systems that we have all acquired due to historical scoring patterns, it is best to hear it directly from the source, so there is no ambiguity.

Correction: No Need to Update the Address to TJC Office of Quality on your Posters:

We also learned at the Executive Briefings session that the announcement placed in the September issue of *Perspectives* regarding the need to update your public postings with the new non-telephonic methods of reaching the Office of Quality and Patient Safety was published prematurely. So, if you have not started to change your posters yet, you can choose to leave them alone for the present time. If you already changed them, you are ahead of the game.

Incidence and Method of Suicide in Hospitals:

The October issue of *Perspectives* has a summary of a larger article published in the Joint Commission *Journal on Quality and Safety* describing the incidence and methods used by patients who commit suicide in hospitals. Here is a link to the article:



They estimate that there are between 49-65 inpatient suicides each year and that 70% of them are death by hanging, thus the very intense focus on ligature hazards. They also identify the locations for these suicides with half occurring in the bathroom, another third in the bedroom and 4% in a closet, 4% in a shower and 8% in some other location. Again, it is easy to understand the Joint Commission's focus of attention on the bedrooms and bathrooms. We continue to see on both mock and actual Joint Commission survey reports findings for unrecognized ligature fixation points in psychiatric bedrooms and bathrooms that have either not been removed or identified in a risk assessment. Even when ligature risks in the environment are identified in a risk assessment, direct care givers are at times not apprised of them and thus don't know that they are to implement any risk mitigation steps. This *Perspectives* article on suicide also mentions in a very general sense plans to modify the existing National Patient Safety Goal 15.01.01, but without the specific new language. One topic they do mention will be addressed is "documentation of patient's overall level of risk for suicide and the plan to mitigate the risk for suicide." This is a great point for consideration. We do see suicide screenings taking place in the ED, on the psychiatric floor at admission, and by multiple staff periodically, but trying to identify the conclusions drawn from these screening processes and the mitigation strategy or level of precautions placed as an end result is often very difficult. The actual suicide risk assessment, the conclusion from that assessment and the actions taken are often scattered in different parts of the chart if present at all. So, stay tuned for more on this soon.

New CMS Requirements in Standards:

Perspectives has a brief article on new elements of performance that CMS is requiring them to add to the standards manual. The article refers you to the prepublications webpage maintained by Joint Commission.

Change Needed to Fire Response Plan:

The first change is at EC.02.03.01, with a small addition to EP 9 that discusses the fire response plan. As of January 1, 2019, you will want to add content to the plan stating that staff have been informed of their duties under the fire response plan, including "cooperation with firefighting authorities." The existing training you do for new hires and any annual training planned for 2019 will want to educate staff that they should cooperate with firefighting authorities.

Periodic Conversation Between Board and Lead of Organized Medical Staff Needed:

There is also a new element of performance at LD.01.03.01, EP 13. This will require the “governing body to consult directly with the individual assigned responsibility for the organization and conduct of the hospital’s medical staff, or designee.” They further require that “at a minimum this consultation occurs periodically throughout the fiscal or calendar year and includes a discussion of matters related to the quality of medical care provided to patients of the hospital.” If you are part of a multihospital system with a single governing body and multiple medical staffs, Joint Commission/CMS will require that the “multihospital governing body consults directly with the individual responsible for the organized medical staff or designee, of each hospital within its system.” You might remember the genesis of this requirement from the 2012 revision of the COP’s that initially called for each hospital to have a physician leader on the governing body, then in the final iteration released in SC 14-45 on September 15, 2014 CMS called for this consultation with the medical staff leader. You can also read more about this requirement in your State Operations Manual from CMS under tag A-0053. The Joint Commission also threw an interesting wrinkle in here by using two terms that sound synonymous but have two different meanings in their glossary. The first sentence of the EP uses the term “medical staff,” which is all practitioners with privileges. The last sentence uses the term “organized medical staff,” which is the voting members only. Since the identification of who represents the medical staff may prove controversial, as some hospitals may want to appoint their VPMA or CMO, this concept of the “organized medical staff” makes it appear to us that TJC is leaning toward the elected officer of the medical staff. This may require eventual posting of an FAQ to clarify this potential ambiguity. The new requirement may require some discussion; planning and logistics so take a look and start now.

The third change is at LD.04.03.01 which has been around forever and identifies the required services TJC expects from a hospital. Two new notes, note 2 and 3, for the EP have been added. Note 2 states that the hospital has to comply with the requirements of 42 CFR 482.55, which is the emergency services COP. This will require compliance with tags A-1101-A-1112. Note 3 then states that the diagnostic radiology services and staff qualifications must meet professionally approved standards. Neither of these changes should require much effort for most hospitals.

An RN Needs to Supervise Perioperative Services:

LS.01.01.01, EP 1 has Note 2 added, which simply states that in some states approved by CMS, the state’s fire and safety codes may apply rather than the 2012 life safety code. PC.03.01.01 is also changed by adding a note to EP 5. EP 5 had stated that a registered nurse needed to supervise perioperative services. The note now states that this individual should be immediately available to respond to emergencies and may delegate circulatory duties to LPN’s and surgical technicians in accordance with law and regulation. The last new change is at PC.03.01.01, EP 8 and is somewhat amusing. This new EP was added in 2018 and it identified a list of equipment that must be available in the OR suite. We had mentioned we had to look up some of the terms used for mandatory equipment in an old medical terminology dictionary. Well, the EP now includes parentheses with 21st century translations.



EC NEWS

Frequently Scored EC/LS Standards Graphically Displayed:

The lead article in this month’s EC News discusses the most frequently scored EC/LS standards in all accreditation programs and they include a graphical representation of scoring patterns. You should note the huge increase in the slope between 2016 and 2017, and we see continued but more gradual growth in 2018. The percentage of hospitals getting hit with these findings is huge, from 88% at number 1-61% at number 10. Clearly these scoring patterns point to the value of rigorous self-assessment before TJC finds these defects.

TJC has also included some useful checklists for inspection, testing and maintenance requirements that sometimes fall through the cracks. Many of these tests fall under EC.02.03.05, which from the above mentioned most frequently scored standards is #7 with 63% of hospitals failing to meet all the requirements under this standard. So, these checklists may prove helpful to just keeping the schedule for formal tests on

track. There is one aspect of scoring EC.02.03.05 that we have been seeing in many survey reports this year and that is EP 28 which requires each test to include the NFPA reference for the test. Hospitals struggled with this for many years and in most cases, vendors now include the references, or the hospital has developed a cover page for the file that includes the reference. However, the references in many cases now need to be updated. Vendors still have the older references from companion references from NFPA's 2001 LSC. Now the 2012 LSC has updated references to newer companion NFPA manuals. This is easy to update, however, in that TJC has included the newer references with each EP, just update your cover page or get your vendors to update their documents.

TJC Defines Timeframes in Standards:

Lastly, EC News included a graphic defining the timeframes which they will apply in determining compliance. These definitions are also in the introduction to the EC chapter as follows:

- Weekly = once each calendar week
- Monthly/30 day = 12 times a year, once each calendar month
- Quarterly = Every 3 months plus or minus 10 days
- Every 6 months/semi-annual = 6 months plus or minus 20 days
- Annually = one year from the last event plus or minus 30 days
- Every 36 months/3 years = 36 months from the last event, plus or minus 45 days.



CMS UPDATE

Important New Memo from CMS - Complaint Surveys Published & New Validation Survey Pilot

CMS did issue an important new memo QSO-19-01 that accomplishes 3 things. First it identifies a new website where consumers can locate information and survey findings from CMS complaint surveys. Second, the memo includes this year's annual report to Congress on the validation survey findings. Lastly the memo

discusses a new method being piloted for performing validation surveys, which involves simultaneous teams, or concurrent teams from the accrediting body and CMS surveying.

Find the memo at:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-01-RTC.pdf>

Readers should look at the new database CMS has created of survey findings. This may be concerning because it is easily navigable. Consumers and reporters with basic Internet skills will be able to quickly find readable version of any complaint surveys found at your organization. In prior editions of this newsletter we have discussed the American Health Journalists website and the CMS quarterly spreadsheet of all findings. Neither of these were as easily navigated as this new website. Hospital leaders should be aware that complete findings from the CMS 2567 will be publicly posted after a complaint survey, thus a communications or media strategy should be developed simultaneously with your plan of correction. The link to this website is in the CMS QSO memo.

The origin of this new CMS website service was described in the Wall Street Journal Friday October 5th as an outgrowth of their article in 2017. In 2017 WSJ had identified that the Joint Commission "took no action" when CMS conducted complaint surveys and found serious deficiencies. While true, this conclusion was also misleading in that TJC did not know conditions had changed and that CMS had found deficiencies due to missed or delayed sharing of information. CMS has found a way to share the information in a timelier basis by displaying it on a public website instead of pushing the information directly to TJC. Now TJC and the individual hospital can be publicly embarrassed together. We assume TJC will monitor this public website for new reports and they can potentially send out their own teams to investigate why these deficiencies are being found.

The report to Congress summarizes what CMS has found during its validation surveys at various types of organizations accredited by a deemed status accrediting body. The introduction to this report is very informative in that CMS states it views its complaint surveys as part of the validation process. This helps to explain why CMS and WSJ were incensed by serious

findings in accredited hospitals during complaint surveys. We had assumed that in a three-year accreditation cycle conditions can change, and issues identified today may not have been identified 3 years ago because this did not exist when the accreditor was present. The statement that CMS also views the complaint survey findings as a component of the validation process implies that they believe such conditions should never be found throughout the three-year accreditation cycle if the accreditor truly has their finger on the pulse of the organization. It will be interesting to see where this leads, but it may lead to a concept discussed by TJC many years ago of smaller footprint surveys conducted much more frequently. CMS also states that in its 2017 report to Congress it did not actually include the complaint survey findings in the mathematical calculation of disparity rates.

Most of the report to Congress discusses what CMS found that accreditors did not and provides feedback on more routine performance measures and expectations such as accreditors sharing schedules and survey reports with CMS in a timely basis. These performance measures are, for the most part, adequate for

information sharing from the accreditor to CMS. There is no performance measure for CMS sharing information with the accreditor. The more important part of the report is the discrepancies noted when CMS and the accreditors survey the same institution within 60 days of each other. Based on their analysis of 2016 surveys CMS is finding a discrepancy rate for hospitals accredited by TJC of 44%. This is equally split between physical environment and clinical findings. You might remember in past years most of the disparity was mainly in the physical environment; but given the increased days for TJC life safety code surveyors and the huge numbers of EC/LS findings, this has improved. The discrepancy in clinical findings is reported in infection control, governing body, QAPI, and nursing. This means CMS surveyors are finding more condition level issues in these 4 areas than is TJC. We have all certainly see lots of TJC scoring in IC and LD these past few years, but perhaps the number of condition level findings is going to have to increase even more to reduce the disparity rate. QAPI and nursing may be more of a struggle, as the PI and NR chapters are not scored very frequently. TJC may need to develop a strategy for secondary hits in those chapters, similar to what they already do with LD.

CONSULTANT CORNER

Dear Readers,

Keeping track of the ongoing TJC and CMS changes and updates is really difficult. That's why we take pride in our monthly newsletter and weekly blog to help to sort through the details. We would be honored to have our Newsletter be shared with other healthcare professionals to help keep everyone in our industry maintain compliance and enhance patient safety.

Thank you,

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