



### Patton Healthcare Consulting Newsletter November 2015

#### NEWS FROM TJC

##### **Perspectives and the Portal for EC/LS**

The November issue of Perspectives doesn't have any really new information or requirements to worry about or make changes in preparation for new requirements. This month's edition of their "clarifications and expectations" column has a reminder about the useful content on the ASHE/TJC portal for environment of care and life safety code. The portal does sound worthwhile, yet thus far we are not seeing clients really maximizing the benefit from this resource. While everyone is busy, this is one resource we would suggest that the quality department might want to schedule, in conjunction with facilities, a demo, review and discussion about how all can utilize this portal to help create an environment that heads off some of the more common EC/LS findings.

##### **Executive Briefings 2016**

Joint Commission executives did complete their round of Executive Briefings for 2016. There were presentations on the most frequently scored clinical standards and most frequently scored EC/LS standards. In the articles published in Perspectives about the top 10 most frequently scored standards, it is always a commingling of clinical and non-clinical and it is nice to see beyond just those few frequent fliers. In the clinical realm IC.02.02.01, dealing with high level disinfection and sterilization, is the most frequently scored and they had multiyear graphs demonstrating how this standard "frequency of being scored" has skyrocketed in the past few years. We will talk more about preparing for this

standard later on in this newsletter. Other frequently scored clinical issues we have not reported on this year, because they did not make the top 10, include MS.01.01.01, which is an open book test and can be easily self assessed. Being scored deficient on this is really inexcusable. Our advice here is to verify that your medical staff bylaws really do have all the required content as specified in MS.01.01.01 and tab that content for your surveyors to find easily. Your chance of success is much greater if you can find it, and you tab it. If you make the surveyor sit down for 2 hours to read the bylaws, they may not find all the required elements and in a hurried discussion with the surveyor you may not find it either.

##### **Plan of Care Challenges & Suggestions**

PC.01.03.01 dealing with care plans made the list of most frequently scored clinical standards, but not the top ten overall. One issue we have seen TJC score frequently and, at the same time, seen very limited to nonexistent functionality in the EMR, is a pathway to accommodate EP 5 requiring timeframes for patient goals. Most EMR's appear to set everything up to be closed on the day of discharge and this EP appears to look for incremental progress to be documented, rather than just a miracle on the day of discharge. Recently, TJC leadership acknowledged in a conference call with consultants, including Patton HC, that they are working to educate surveyors to have a broader view of what the plan of care should look like in the EMR. Patton HC has helped guide the discussion by advocating that in our view the

entire EMR constitutes the plan of care. The plan of care does not have to be limited to a single tab or screen within the EHR, but rather, you could decide that additional components of the patient's medical record comprise a part of the patient plan of care, including but not limited to: medications ordered/ administered; physician orders; plan for medical care; progress notes; consults; assessments/reassessments for rehabilitation, dietary, and discharge planning needs; restraint flow sheets (if applicable), I&O flowsheets, and vital sign flowsheets.

Upon admission the initial nursing assessment is always completed. The care planning process includes diagnoses, outcomes identification (goals), and the planning of care with the patient or their representative. The nursing process continues with the nurse implementing actions to provide care for the patient based on the plan and the physician orders. Additional screening triggers or physician orders may cause other disciplines to become involved with discipline-specific assessments and the provision of care, treatment or service. Ongoing reevaluations measure the patient's progress against the expected outcomes and the plan of care is adjusted accordingly.

The timeframes associated with the timing of interventions and goal achievement is assumed to be by the time of patient's discharge or as otherwise specified in the electronic healthcare record and plan of care. For example:

- For a patient that is determined to be at high risk for a fall the plan might specify the goal is to prevent a fall during this inpatient admission\* and the intervention to achieve the goal is to conduct hourly\* rounding.
- For a patient at risk for pain for whom pain control is the goal the plan might specify the goal is to manage and minimize pain prior to discharge\* by performing twice per shift\* pain assessments or assessments whenever\* pain is reported along with orders for analgesics or

other non-pharmaceutical interventions that include (for medications) an administration frequency\* and an expectation for reassessment at defined intervals\*.

- For a patient in non-violent, non-self destructive (NV/NSD) restraint the goals and timeframes are contained within the order (understood as release as soon as possible, though must be renewed every X days/hours)\* and nursing documentation of each q2 hour\* evaluation conducted while the patient is in restraint.
- For the NPO tube-fed diabetic patient the plan might specify a goal to maintain glycemic control during the inpatient admission and the order/intervention is to perform q 6 hour\* capillary blood glucose levels with insulin administered per sliding scale.

Note that all underlined/italic/asterisked words or phrases are in fact timeframes associated with the problem and goal identified in the patient's plan of care.

### Other Top Scored

There are of course the classics like medication storage issues and pre-anesthesia assessments being incomplete. One surprise on the list is PC. 02.01.11, which is about resuscitation services, but this is where they can ding you for missing a crash cart check. This may also be where some are scoring issues about not doing your defibrillator or suction machine checks per manufacturers guidelines or checking the time for accuracy. Since we have just switched to standard time from daylight savings time we would encourage all readers to verify the accuracy of the clock on their defibrillator. MM. 04.01.01 dealing with medication orders and compliance is on the clinical list and a lot of this is likely problems with drip titrations which are not being documented consistently with respect to physician orders for monitoring the physiological parameter pertinent to the drip. For example, each heparin drip rate change should tie to a PTT value and each Propofol drip

rate change should tie to a RASS score.

MM.05.01.01 dealing with un-stratified therapeutic duplication is on the list. This has been a difficult issue for decades and few hospitals have been able to eliminate it adequately and some we see on mock events seem to have stopped trying.

### Alarm Management

Executive Briefings also had a nice reminder about the changes in the NPSG for alarm management that go into effect in January 2016. This safety goal was implemented in a phased in process, but 2016 is when everything should be up and running completely. They reminded attendees that come January 2016 surveyors will be looking to see policies and procedures identifying:

- Who is authorized to change alarm signals or alarm parameters or set to off?
- What are the monitoring and response expectations?
- Has there been a check of alarms for adequate settings, proper operation and detectability?
- Have staff and LIP's been educated about proper use of alarm systems?

### EC/LS Tool

During the discussion of the most commonly scored EC/LS findings a new required document list and review tool was distributed and discussed. It lists 7 of the most difficult and frequently scored standards, EP by EP, and this allows the hospital and surveyor to focus on the most challenging aspects of the document review. Using this as a self assessment tool and a tool to help you organize your documents is highly recommended.

### Infection Control

There was also a special session dedicated to infection control issues, which are becoming as challenging as EC and LS. In particular the subject of high level disinfection and sterilization

practices was reviewed in detail. Given the previously mentioned growth in scoring on these issues and the fact that these are usually going to be CoP Condition-level scores should lead everyone to focus and improve readiness here. Some of the frequent problems TJC reported with high level disinfection included:

- Failure to measure enzymatic cleaner to water ratios
- Hand carrying dirty scopes to decontamination; missing biohazard labeling
- Failure to ID your clinical practice guideline for HLD
- No oversight of HLD by infection control
- Process flow mixing clean and dirty instruments
- No temperature monitoring of chemical used in HLD
- Failure to document competency

The failures they identified for sterilization practices included:

- Failure to pre-clean instruments at the point of use
- Leaving hinged items in the closed position during sterilization
- No documentation of washer and sterilizer PM and cleaning
- Failure to document biological indicators
- Use of double peel packs where inner pack is folded over
- Premature release of IUSS
- Failure to document competency

Since this is such an area of focus and the impact will likely be at a Medicare CoP level, what are you going to do to get ready? Our suggestion is to get the reference materials the Joint Commission surveyors have and develop the same degree of expertise the Joint Commission surveyors have developed. This means purchasing, analyzing and implementing the practices spelled out in the AAMI reference books. This is becoming analogous in the Joint Commission process to the need for knowledge about NFPA reference materials. We have seen many, many findings

from TJC this year with the most minute details from one of the AAMI references quoted and the identified failure point spelled out in the surveyor's observation. So if you don't have these AAMI references, make it a point to buy them soon. No we are not receiving a commission from AAMI, but we have learned as consultants we need to become more aware of this minutia also. So the suggestion we are making is to obtain:

- ST 79 Steam Sterilization 2013 update
- ST 91 Flexible scope processing 2015
- ST 58 Chemical sterilization and HLD 2013
- ST 41 Ethylene oxide sterilization 2010 (if you use ETO)

Then after you obtain these references you want someone to review them in as much detail as a college student would. Underline, analyze, and understand the gaps at your hospital and plan out how you can become compliant. Last thought on this is to the extent you can centralize these functions, the higher your chance of success. If you have one department of experts with all the references it is easier to be compliant than if you try to perform sterilization and HLD in 10 different areas of your hospital.

## CMS UPDATE:

### **Sterile Compounding & USP chapter 797**

CMS did post a new Survey and Certification memo to it's website on October 30, 2015, their first of the new federal fiscal year. Its SC 16-01 and addresses requirements relative to compounding of medications needed by hospital patients. This memo somewhat brings an issue relative to USP 797 to a conclusion more than a decade after TJC and hospitals began to first discuss these requirements. Readers might remember that back in 2003 Joint Commission announced that they were going to evaluate hospitals against what was then the brand new requirements of USP 797. This caused considerable distress in the hospital industry and TJC began to back off of that initial position,

to instead only require a gap analysis, then in 2006 TJC backed off further basically only evaluating USP 797 compliance if the state board of pharmacy had approved USP 797 requirements as state regulatory requirements. By 2015 many states have done this, but not all. Well CMS has just drawn the big red line in the sand nationally stating that sterile compounding must be compliant with USP chapter 797. There is no longer any ambiguity. CMS state on page 7 of the memo: "Hospitals must ensure that they meet all currently accepted standards for safe preparation and administration for compounded sterile products (CSP's), whether they are the type of CSP that must be compounded in an aseptic pharmacy location that meets USP 797 standards for low, medium or high risk CSP's or are immediate use CSP's prepared outside the pharmacy.

So lets talk about low risk compounding, defined as a simple transfer of not more than 3 commercially manufactured, non hazardous sterile products, and not more than 2 entries into any one container. The bottom line requirement on this type of compounding is that:

- The product must be hung on the patient or administered to the patient within 1 hour of preparation
- There shall be no advanced preparation of such products for more than one hour outside of a sterile pharmacy compounding area.
- Additionally they state that unless the product is immediately and completely administered by the person who prepared it, the CSP must be labeled with patient ID, names and amounts of all ingredients, the name or initials of the preparer, and the exact one hour beyond use date/time.

### **Contracted Compounding Pharmacy**

If you purchase compounded sterile products from a contracted pharmacy or compounder there are new Federal regulations for these compounders to register with the FDA and state their compliance with good manufacturing

principles and agree to be subjected to FDA inspection. The FDA has recommended that hospitals purchase CSP's from these registered or 503B vendors. There are also other vendors, usually external pharmacies that do not register with the FDA. In these cases you are not prohibited from purchasing from them, but CMS would expect that you have access to quality assurance data verifying the vendor is adhering to USP 797 requirements and the hospital can verify that it obtains and reviews such data. Additionally your contract should establish a requirement for that vendor to meet all the requirements of Section 503A of the FDA concerning compounding of CSP's. Our suggestion would be to also have your pharmacy director do an onsite inspection of the facility since it was previously reported that the "quality data" distributed by New England Compounding Center was questionable given what the FDA found during their inspection.

This CMS memo also describes the requirements for compounding when done by your hospital pharmacy and establishes an expectation that all sterile compounding be done by the hospital pharmacy, "except when not feasible," for example emergencies and short stability products. Our observation is that this is usually the case in hospitals today, however the CMS memo also describes this responsibility for "baths, and soaks for live organs and tissues, and irrigations for wounds and body cavities." It is our observation that some of these are compounded in procedural settings, not the sterile pharmacy compounding area. When compounding in your hospital pharmacy the CMS memo would also call for adherence to the requirements for medium risk compounding or high risk compounding if done or use a beyond

Best Regards,

*Kurt A. Patton MS RPh*  
[Kurt@PattonHC.com](mailto:Kurt@PattonHC.com)

*Jennifer Cowel, MHA*  
[JenCowel@PattonHC.com](mailto:JenCowel@PattonHC.com)

*John R. Rosing, MHA*  
[JohnRosing@PattonHC.com](mailto:JohnRosing@PattonHC.com)

*Mary Cesare-Murphy, PhD*  
[MCM@PattonHC.com](mailto:MCM@PattonHC.com)

use shelf life no greater than 12 hours.

Since the publication of USP 797, most, but not all hospital pharmacies have implemented media fill testing and finger tip testing to assess employee techniques. These will now become mandatory expectations.

### **Automatic Stop Orders**

Lastly this memo contains a lot of content pertinent to the CoPs including a reminder about a real "oldie" that has fallen into disuse. Many years ago TJC and CMS used to focus on automatic stop order policies. This was back in the day when patients had really long lengths of stay and it was intended to stop and reconsider some medications prescribed earlier in the hospitalization that may no longer be needed. With today's shorter length of stay and the diminished focus, this has to a large extent been forgotten about or not even programmed into your EMR. Well on page 40 of this memo, it is back. Section 482.25(b)(5) describes stop order policy and the next section in red is guidance for surveyors to "ask unit staff what happens in the case of drugs with no stop date or prescribed number of doses? Are they aware of the automatic stop order policy? Can they describe how it is enforced?"

So readers, you will want to have this memo analyzed thoroughly by your pharmacy and therapeutics committee to determine what changes may be needed in your hospital. Those states where the state board of pharmacy had earlier adopted USP 797 as state regulations will have a head start on this process.

### **Have a great Thanksgiving!**

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