MARCH 2018
PHC NEWSLETTER

PATTON HEALTHCARE CONSULTING, INC

NEWS FROM CMS AND JOINT COMMISSION

INSIDE THIS ISSUE:

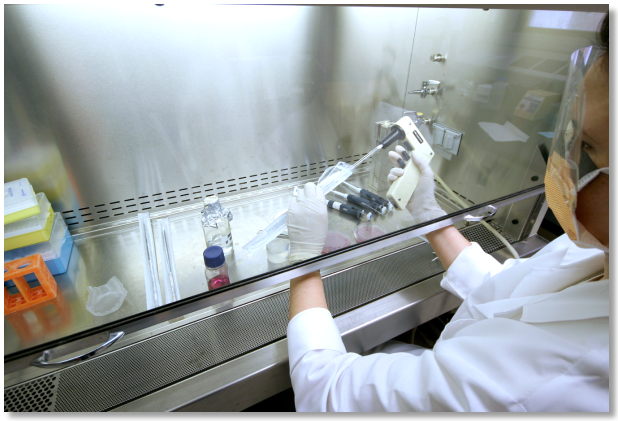
PERSPECTIVES

Suicide Prevention:
The lead article in this month's edition of *Perspectives* discusses the fourth meeting of their expert panel on suicide prevention. This meeting was to have discussed and provided guidance to the field on "Suicide Risk Assessment" (and we presume here this may have been a two-pronged topic – one, coming to a conclusion on which of the several physical environment risk assessment tools that are available for hospitals to use is the tool that TJC is going to suggest or sanction be used, and two, which of the several available patient suicide risk assessment tools is recommended for use) and two, guidance on the "key components for safe monitoring of high-risk patients." We presume this latter topic would delve into the acceptable techniques for mitigating suicide risk, such as a 1:1 direct observation, or an order for q 15-minute checks. Both topics are of vital importance to hospitals who are trying to thread the compliance needle and avoid Condition Level or worse accreditation decisions following survey. We continue to see surveyor variation on what physical environment risk tool they find acceptable (e.g., the "VA tool" seems favored by some), along with whether hospitals must use the seemingly favored "Columbia" patient suicide/self-harm risk assessment scale or may an alternative or even home-grown scale be used.

Field Review for New Standards:
The article states that this meeting was different in that it led to discussion of potential new standards rather than interpretation of existing standards. Unfortunately, the article does not provide any hints as to what they were suggesting for future standards development, so stay tuned for a potential field review of draft standards in the future. While we are discussing that subject, there are three current field reviews posted on the TJC website at this time and available for you to provide feedback. The content addresses credentialing and privileging requirements for contracted services, pediatric emergency equipment and supplies, and newborn identification. Two of the field reviews will close prior to the end of March so if you want to have an opportunity to affect the process before publication take a look and provide feedback.

Clinical Contract for Pharmacies is Focus of Increased Attention:
In previous issues of our newsletter, we have discussed the enhanced emphasis on sterile compounding and the more rigorous evaluation of compliance with USP Chapter 797. This month, the "Consistent Interpretation" column discusses the leadership contracting standards and the requirements for hospitals to evaluate clinical contractor pharmacies and it somewhat raises the bar yet again for hospital oversight of these contractors.

There are two types of pharmacies you may be contracting with; those providing services under a Federal definition as a 503A pharmacy and those providing services as a 503B pharmacy. These two terms define pharmacies that are solely licensed by the state boards of pharmacies to provide patient specific compounding (503A), and those both licensed by the state board and have agreed to be subject to the FDA's good manufacturing principles with an inspection process by FDA, conducted on a frequency based on risk assessment (503B). Previously, the clearest guidance to hospitals on the required evaluation of such contracted services was provided by CMS in their SC memo 16-01 on Pharmaceutical Services. In that memo CMS described the rigor of the FDA oversight process for 503B pharmacies and then described the additional oversight steps hospitals must take if they chose to contract with a 503A pharmacy rather than a registered 503B outsourcing facility. These steps included contractual obligations to submit to the hospital QA data on compliance with USP chapters 797 and 795 and requiring the vendor to meet the FDA requirements for 503A pharmacies. Our interpretation of this CMS guidance was that the hospital had to evaluate the quality of the 503A pharmacy and the FDA was responsible for evaluating the quality of the 503B registered outsourcing pharmacy.



In the Consistent Interpretation column from TJC this month, TJC indicates that the hospital's contractual use of either a 503A and 503B pharmacy needs to be evaluated, and the contract with the 503A pharmacy must stipulate that the vendor will comply with USP chapters 797 and 795. The TJC advice on 503B vendors is described in its discussion of EP's 5 and 6 for LD.04.03.09. In the discussion of EP 5 (the communicating expectations EP) TJC states that: "if the organization utilizes a 503B pharmacy, quality metrics should be submitted to the compounding pharmacy in writing to ensure appropriate compliance with sterile compounding practices." Whereas additional TJC advice for EP 5 stated that if the hospital uses a 503A pharmacy "it should ensure compliance by requesting in writing the receipt and ongoing testing and certification performed in the compounding pharmacy to include appropriate testing of the engineering controls and taking appropriate action when testing components do not meet minimum requirements."

In the discussion of EP 6, (leaders monitor compliance with expectations) TJC states that if the hospital uses a 503B pharmacy "quality metrics should be monitored to ensure appropriate compliance with sterile compounding practices." This seems to us like a new and expanded requirement that is redundant with what the FDA already does with 503B pharmacies. Additionally, TJC state that if the hospital utilizes a 503A pharmacy, "it should ensure compliance with USP chapter 797 and have documentation of receiving qualitative data and evaluating the results."

By now most readers we assume are somewhat confused by all this and wondering, "what do I have to do now?" We recommend 3 specific actions to take at this time.

1. Look at your list of clinical contractors and ask your pharmacy leadership if they use any offsite compounders that are registered as either 503A or 503B vendors. If you use such compounders, then they should be added to your list of clinical contractors. In particular we believe it is likely that you may be using 503B vendors who were previously not included in your list because CMS treated them more like a drug manufacturer than an offsite pharmacy.
2. Look at your written contracts for the services with both 503A and 503B vendors and verify that those with 503A vendors state they will be compliant with USP chapters 797 and 795 and require the vendor to submit evidence of the evaluation of the engineering controls for the compounding environment and actions taken if any deficiencies are found. If you contract with a 503B vendor, quality metrics that you determine must be included in the contract.
3. Verify you have an evaluation of the contractor's performance during the prior year and that the performance evaluation has been reviewed and approved by senior leaders and medical staff.

Lastly since this column expands the potential applicability of the contracting standards beyond existing CMS and TJC requirements and has some redundancy with FDA responsibilities for the 503B vendors, there may be some push back and revision to these expanded requirements. Again, stay tuned.

Deletion of Old EP Regarding the Patient's Right to Pain Management:

The March issue of *Perspectives* also has a brief article on the deletion of RI.01.01.01, EP 8 which stated the "hospital respects the patient's right to pain management." The article states that this EP could be deleted because the new pain management standards, which became effective January 1, include leadership, medical staff and patient involvement in treatment planning, making this requirement unnecessary. While not stated, changing times, politics and the national opioid crisis may also have played a role in the decision to delete this patient rights requirement.

Additional Detail on New EC Requirements:

Perspectives also includes a very brief article on two new EC requirements which have already taken effect as of March 11, however the article says nothing about the content of these new requirements. The first change occurs with EC.02.03.05, EP 25, where the EP remains as it was previously, however there are now 3 notes attached to help explain the applicability of the EP. EP 25 addresses the requirement to annually inspect fire door assemblies. The new note 1 states that nonrated doors including corridor doors and patient room doors are exempt. Note 2 states that nonrated doors should still be inspected and maintained in accordance with the hospitals facility maintenance program. Note 3 identifies multiple references from NFPA 101, 80 and 105 that detail the expectation for inspections.

EC.02.05.01, EP 27 is a new EP stating that areas designated for general anesthesia, specifically inhaled anesthetics using medical gases or vacuum, are maintained in accordance with ASHRAE 170 and that medical supply and equipment IFU's are considered before reducing humidity levels to those allowed by ASHRAE. Previously this was explained through an FAQ. In addition, this new EP discusses maintenance and venting of smoke control systems in this setting.

EC NEWS

Documentation Checklist Required by the Life Safety Code Surveyors:
The lead article this month is about building services and the requirements of LS.02.01.50. The article includes the full text of the standard as well as some discussion about the codes that form the basis of for the requirements under the standard. It is informative and should be reviewed by facilities leadership, however this is not a frequently scored or problematic standard nor are there any new revelations about compliance.

EC News also includes a reprint of the documentation checklist that is required by the life safety code surveyors. This is an excellent tool to help get organized and verify that you have all the required documentation in a readily retrievable fashion. Problems with missing documentation, missed tests or inspections, or just the ability to find the documents requested is a continuing problem on survey for many hospitals. Proper use of this tool using a simple "show me" technique where one staff person asks to see the documentation and the individual who is responsible to keep them organized and retrieve them brings the proper document forward. This type of rehearsal can be very valuable for a successful survey.

CMS UPDATE

There were no new QSO (Quality, Safety and Oversight) group memos issued to the hospital industry this month. However, we have seen correspondence from Congress to CMS and the accrediting bodies about an analysis Congress will be doing on CMS' oversight of the deemed status organizations in the hospital industry.

ADDITIONAL RESOURCES

We have been reading a newsletter called Sterile Compounding Pearls of Knowledge published by a firm called Critical Point for some time now. In February they published an article on choosing the right media for staff and environmental monitoring as required by USP 797. While microbiology is a course many healthcare professionals took in college, it was not the major for most of us. This article was particularly enlightening given the TJC focus on USP 797 and the need for staff fingertip sampling and media fill testing. They also describe the different media needed for environmental sampling and sterility testing. Rather than try to explain the intricate details we are encouraging our readers to become regular readers of this newsletter. Like ours, their newsletter is provided free of charge by going to their website to subscribe. Their newsletters are archived on the website https://www.CriticalPoint.info/signup.

CONSULTANT CORNER

Are you worried about your next survey? Many hospitals had long reports and were frequently cited with Condition Level Deficiencies or had adverse outcomes last year. A mock survey will highlight crucial areas and provide your team with comprehensive education on compliance.

Check out the services we offer and please give us a call today!

Thank you,

Jennifer Cowel, RN, MHSA
JenCowel@PattonHC.com

Kurt Patton, MS, RPh
Kurt@PattonHC.com

John Rosing, MHA
JohnRosing@PattonHC.com

Mary Cesare-Murphy, PhD
MCM@PattonHC.com