PATTON HEALTHCARE CONSULTING
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INSIDE THIS ISSUE

PERSPECTIVES

Deleted, Consolidated, and Revised EPs:

In the lead article in the July issue of *Perspectives* TJC gives itself a pat on the back for making your job easier by eliminating unnecessary elements of performance. Before you send them a thank you note, do go to the prepublication section of their website to download the deleted/consolidated and revised elements of performance for your accreditation program.

Some went away entirely because they are never scored. In many instances, however, elements of performance with a single expectation were combined into a "compound" element of performance. For example, when one EP says write a policy and a second EP says implement the policy, combining those two expectations into one EP doesn't mean you can stop doing something.

We looked at the changes for the hospital program and we counted nine (9) elements of performance that were consolidated into four (4) compound elements and another two (2) EPs that were actually deleted.

One of the two EPs that were deleted was LD.03.06.01, EP 4 which required leaders to evaluate the effectiveness of those who work in the hospital to promote safety and quality. We assume this was deleted because it is almost never scored, however it is a task you are likely to continue to perform because everyone has their job performance evaluated.

Healthcare Equity Certification Resource Center:

The July *Perspectives* describes new website content on the TJC site for resources regarding healthcare equity. While this relates to a new

optional certification program TJC has developed there are many useful resources on this site that may be helpful in implementing the healthcare equity national patient safety goal, formerly the healthcare equity standards in the leadership chapter.

We encourage readers to share this resource with their organization's identified leader on this issue. There is material and ideas on the website that may help get your program moving.

We should also mention that this month's *Consistent Interpretation* column discusses the nuances of scoring NPSG.16.01.01, where the healthcare equity requirements now reside.

Unfortunately, as these standards were just moved to the safety goal section of the accreditation manual on July 1, thus there is no actual scoring data under NPSG and TJC did not provide scoring data from when they were leadership standards.

There is still benefit to reviewing the "guidance/interpretation" section and we noted one issue under EP 2 regarding the assessment of health related social needs (HRSN) that may be easier than we would have guessed from reading the EP and its notes.

The guidance/interpretation section for this EP indicates that "it is acceptable to collect data as part of a pilot process in selected areas of the organization." Note 2 for this EP indicates that "HRSNs may be identified for a representative sample of the hospital's patients or for all the hospital's patients. The term representative sample in the note sounds much broader, or more comprehensive.

If you choose to perform a "pilot process in selected areas" of your organization, we encourage readers to retain this guidance from TJC should any scoring take place at a later time.

Medication Compounding:

The July *Perspectives* announces that the revised medication compounding requirements have been posted to the prepublication section of the TJC website. This includes the optional medication compounding certification requirements and the home care program standards. These revised requirements are effective January 2024, and the changes reflect the new expectations resulting from the final revisions to the USP chapters.

The expectations in both programs seem identical for sterile compounding (797), however the optional medication compounding certification standards only include requirements for sterile compounding (797), whereas the home care chapter also includes nonsterile compounding (795) and radiopharmaceutical compounding (825).

If you are thinking "*I don't have the optional certification and I don't have home care therefore I can skip to the next section of this newsletter*," we are recommending downloading and studying at least the sterile compounding requirements. While TJC has based their revised standards on the revised USP requirements we find the TJC format with discrete elements of performance very clear, instructive, and concise.

Self-evaluating individual elements of performance, with guidance advising which ones require documentation, which ones require a competency, frequencies for specific monitoring, and other activities is easier than trying to self-evaluate the lengthy narrative format in the USP chapters themselves.

Most, but not all of these new EPs have a required documentation icon, and this format makes ensuring you have the required evidence of compliance easier. If you don't have a home care program and you don't have the optional medication compounding certification you won't have access to these standards after they are removed from the prepublication portion of the TJC website, so access them now, while you can.

As you prepare for hospital surveys after the official applicability date of the new USP Chapters we know that TJC has committed to producing a revised version of its hospital sterile compounding tool. This tool crosswalks specific USP Chapter 797 requirements to more general medication management, human resources, environment of care, and infection prevention standards. But we still recommend reviewing the very detailed EP format of the medication compounding or home care standards for details.

Some readers questioned the reported non-applicability of USP Chapter 795 (nonsterile compounding) during Joint Commission hospital surveys. This was announced by the TJC speaker and in the literature during and after the American Society of Health Systems summer meeting last month. This announcement surprised us as well as there are multiple guiding principles that would indicate that USP Chapter 795 is applicable in the hospital industry.

One reference that might create enforcement authority for USP Chapter 795 is your own State Board of Pharmacy regulations. The National Association of Boards of Pharmacy (NABP) has a 2022 model pharmacy practice act on its website that is used by many states to develop their own regulations. The NABP template includes multiple references to official USP-NF requirements that may be embedded in your state regulations.

The CMS State Operations Manual also includes a requirement for adherence to accepted professional standards such as USP in A-0491, when they state:

> *"Interpretive Guidelines §482.25(a)*
> *Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations, such as those found in the U.S. Pharmacopeia/National Formulary (USP/NF)."*

Back in 2013, after the New England Compounding Center contamination problems Congress enacted the Drug Quality and Security Act (DQSA) to clarify the FDA's authority over drug compounding and reaffirmed USP's role under Section 503A. Following enactment of the DQSA, the FDA provided further clarification of its views on the application of USP standards to pharmacy compounding through a nonbinding guidance document entitled: FDA Guidance: Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug and Cosmetic Act.

This guidance states that compounded preparations made by a licensed pharmacist or physician qualify for an exemption from requirements of a new drug application if they are compounded in compliance with the USP chapters on pharmacy compounding using bulk drug substances and ingredients that comply with the standards of an applicable USP or NF monograph, if one exists. The guidance specifically references USP General Chapter <795> Pharmaceutical Compounding–Nonsterile Preparations and USP General Chapter <797> Pharmaceutical Compounding–Sterile Preparations.

In conclusion, not having TJC evaluate nonsterile compounding may avoid one additional learning hurdle in your Joint Commission preparation, however there are other important regulatory entities that likely will be expecting compliance with all USP requirements, so be prepared for those.

EC NEWS

Ambulatory Care Environmental Standards:
The lead article in this month's *EC News* discusses the most frequently scored environmental standards in organizations accredited using the ambulatory care manual. There are many comparable and problematic standards compliance issues shared in both hospitals and ambulatory care facilities. These include control of airborne contaminants including fumes, dust, air pressure relationships, air exchange rates, temperature, and humidity. We

also noted that ambulatory care facilities struggle with hazardous chemical situations as do hospitals. A key problem is availability of a fully functional eye wash where needed, with functionality tested on a weekly basis.

TJC's engineers provide background information and suggestions on managing these two problematic issues that may be useful to both hospital and ambulatory facilities managers. For example, on the issue of managing air pressure relationships each clinical location with unique requirements should have a method and frequency of monitoring the required pressure relationship. We still see many locations that should have pressures monitored but staff have no tool or process to do so.

Relative to hazardous chemicals, the authors remind us that formalin is a routine hazardous chemical and, if pouring from one container to another, requires spill preparation and an eyewash. The authors also warned about eyewash stations seen with only hot water plumbed, not the required tepid water (commonly defined as 60 – 100°F). If you are going to flush the eyes for 15-20 minutes the water can't be either too hot or too cold.

We did notice that improper maintenance of sterilizers made the top ten list in ambulatory care, and we have not seen that same level of scoring in hospitals. The authors provided guidance that the issues seen included the basic failure to document sterilizer maintenance, as well as failure to have an initial biomed evaluation of incubators use for biologic indicators, and lastly failure to perform the manufacturers required daily, weekly, or monthly maintenance on the sterilizer (MIFU).

Potential Summer Heat Emergencies:

The July issue of *EC News* has a timely reminder about potential summer heat emergencies and considerations in emergency management planning and facilities maintenance. One suggestion provided is to have a sample heat plan in your EOP if your organization is in an area where your HVA has rated the potential for a heat emergency as significant. The authors also highlighted specific NFPA 99-2012 requirements relative to essential utilities, exterior connections, generators, standby/stored power systems, power loss, and activation of emergency utility resources.

Failure to meet these known requirements could worsen the culpability exposure should your area and organization have a heat emergency. We suggest sharing this article with your EM and EOC teams for evaluation.

Environmental Tours:

EC News has run a monthly column including a sample tool or checklist for quite some time now and this month they provide a link to an environmental tour checklist. Environmental tours are a long-standing practice in health care facilities that used to be required, but in one of the prior rounds of EP evaluation and deletion, it went away. There was a perception at the time that this process was "hard wired" and no longer required a mandate from TJC.

Unfortunately, some organizations did eliminate the process and have since found the need to reinstitute the process as described in the post-survey ESC as a useful monitoring concept. If you have continued the practice, you likely already have a tool developed and modified over many years. You might want to take a look at the JCR tool to see if there is anything you want to add to your tool. If you stopped the process, you may want to consider restarting and using the JCR tool to help get restarted.

CMS

Hospital Discharges to Post-Acute Requirements:
During the past month CMS issued QSO-23-16 dated June 6th, 2023, which discusses some concerns CMS has relative to the information being shared by hospitals with post-acute care providers upon discharge from the acute hospital setting.

We noted CMS' concern about not sharing information about known behavioral health needs and/or the use of psychotropic medications. CMS also mentioned missing information relative to DME needs such as CPAP/BiPAP, high flow oxygen, or the presence of skin issues such as pressure ulcers.

The CMS memo is silent on whether or not they perceive these omissions as unintentional or part of the push/pull and resistance of trying to discharge patients to alternate care settings. They do however advise state agencies and accrediting organizations of the regulations for discharge planning. Thus, there may be somewhat of an uptick in examining these issues.

Eliminated Practices:
On June 16th, CMS sent a memo to all the accrediting bodies advising them of certain existing practices that must be eliminated no later than July 14th.

One existing practice that must be eliminated is the electronic notice that is sent prior to 8am, notifying organizations that their survey is going to start today, and posting the pictures and biographies of the surveyors. This practice was developed a few years after the 9/11 terrorism when unknown individuals, pretending to be surveyors started to appear at organizations seeking to "conduct a survey," and then ask to be escorted to certain sensitive locations within hospitals.

The perception at the time was that these unauthorized individuals were scouting out potential terrorist activities in hospitals. Some alternative arrangement will be needed to establish the bona fides of surveyors who show up at the beginning of the day or after hours requesting to see your liquid oxygen storage or nuclear medicine department's hot lab.

Another significant change outlined in the memo is the cessation of any communication between the accreditor and the organization within six months of the survey due date that may indicate an impending survey. This measure intends to eliminate any potential advance knowledge of an upcoming survey and level the playing field for all healthcare organizations.

CMS is also requiring the elimination of blackout date requests during the application process. These were useful for identification of religious holidays observed by key leaders, state-only holidays that the accreditor may not be familiar with, or even leadership and board retreats.

While patient care takes place every day not all leaders are present every day and accredited organizations will need to ensure that access to key survey materials or documents is always available through an identified back up.

Lastly, routinely accrediting organizations evaluate complaints about organizations that are directed to their attention. Sometimes these complaints are so well documented and significant that they result in an immediate "for cause" survey.

At other times they describe a lower-level concern that may or may not be real and the accreditor may call or email seeking details about the care. CMS has indicated that this too must stop. Lower-level issues can be deferred for follow up at the next survey but remote fact gathering is prohibited.

CONSULTANT CORNER

Dear Readers,

In the past few months, we have seen a substantial increase in adverse decisions across the country from CMS and The Joint Commission. Due to these unanticipated circumstances, we have been quite busy assisting our clients back into compliance.

Preliminary Denial of Accreditations (PDA), Conditional Level Deficiencies (CLD), CMS Medicare Termination, Immediate Jeopardies (IJ), Immediate Threat to Health & Safety (ITHS), Accreditation with Follow-Up Surveys (AFS), and CMS Systems Improvement Agreements (SIA) are all perilous and stressful situations to be involved in. All Adverse Decisions require an immediate response, and our expert consulting team is here to help.

If you don't want to be get caught off guard and be on the receiving end of one of these adverse decisions, schedule your mock survey or focused visit today to prepare your organization for success.

If you have received one of these critical decisions, we empathize with you, and we are here to get you out of this predicament.

We have a 100% success rate in all adverse decisions for every client that we have served.

We are responsive, experienced, and competent. Time is of the essence to respond to these decisions, so please contact our experts today. We will help you succeed in providing safe, compliant, and quality patient care and we will help you keep your doors open so you can continue to safely serve your community.

Don't wait, call us at 888-PHC-INC1 or Contact Us today!

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