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PERSPECTIVES

Standards Revisions:
There was one new set of standards revisions announced in *Perspectives* this month, in preparation for the implementation of the new USP Chapters. TJC modified the hospital and critical access hospital standard MM.05.01.07 and made a minor edit to NPSG.03.04.01. The changes for the hospital program are as follows:

MM.05.01.07
EP 1: "A pharmacist supervises all compounding, packaging, and dispensing." This brings in the concept from the new USP Chapter 797 of a "designated person" to supervise all compounding activities. We had read in the USP FAQs and other literature that some organizations were interested in having a lead technician as their designated person. However, we note in this revised EP the supervision for Joint Commission accredited organizations must be from a pharmacist.

EP 2: "The hospital develops and implements policies and procedures for sterile compounding…." You likely already have policies and procedures but given the very frequent reference in the new USP chapters to SOPs (Standard Operating Procedures) we would encourage readers to verify that they have policy content for each SOP expectation. If you print to file the new USP chapter, you can use the PDF search feature to find all the exact references to SOP. Probably due to copyright protection features the search results look like gibberish, however, if you click on each it will actually bring you to SOP requirements.

EP 3: "The hospital assesses competency of staff who conduct sterile medication compounding…." The one nuance in the new USP Chapter 797 that may require some policy changes are that the

frequency of competency assessment does ramp up based on the "category" of sterile compounding you perform. The former low, medium, and high-risk compounding categories are gone. The new categories 1, 2, 3 are derived based on the planned expiration dating and, as you would expect, if you want longer dating for products there is a corresponding increase in the frequency of competency assessment for many activities.

EP 4: "The hospital conducts sterile medication compounding … within a proper environment." This brings in all the USP expectations for air pressure relationships, air exchanges, ISO certification, cleaning requirements, and air and surface sampling.

EP 5: "The hospital properly stores compounded sterile preparations… and labels them with beyond use dates…." The new USP categories of sterile compounding have different BUDs based on storage at room temperature, refrigeration, or freezer, and longer still if you perform terminal sterilization on products. Hospitals may need to change standardized dates built into labeling software to accommodate the new requirements.

EP 6: "The hospital conducts quality assurance of compounding sterile products…." Section 18 of the new USP Chapter 797 details their expectations for quality assurance and assigns oversight of QA activities to the "designated person" you assign to supervise sterile compounding. The USP expects the designated person to have "a formal, written QA and QC program that establishes a system of:

1. Adherence to procedures
2. Prevention and detection of errors and other quality problems
3. Evaluation of complaints and adverse events
4. Appropriate investigations and corrective action."

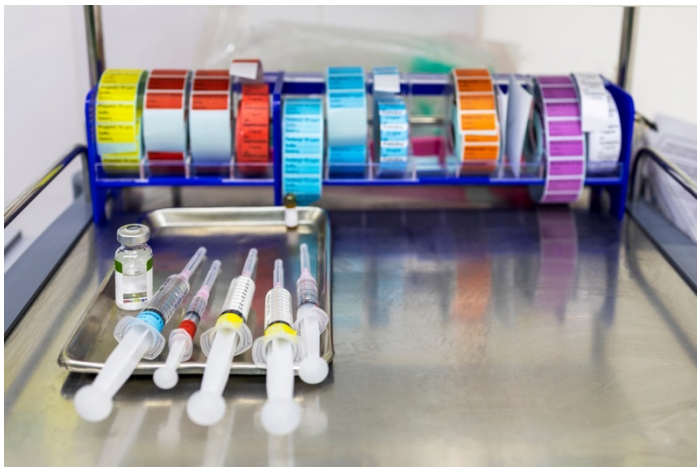
It is likely that hospitals already use their incident reporting mechanism for products that reach the floors where issues are detected. The first issue listed above may require some thought to capture issues identified during observations and daily work process activities in the sterile compounding room(s).

EP 7: This one is not really new, but rather renumbered from EP 6. It still requires the preparation of radiopharmaceuticals to be under the supervision of an appropriately trained pharmacist or physician.

NPSG.03.04.01

EP 3: This one is not substantively changed, but it may require a little policy refinement to be compliant. Currently, this perioperative safety goal requires an expiration date and time on pharmaceuticals when not used within 24 hours. The new EP just requires date and time, period. But then there is a new note that says, "Date and time are not necessary for short procedures, as defined by the hospital." So, you may need to create a policy that defines short procedures, thus exempting drugs prepared for short procedures from the timing label requirement.

These new changes take effect January 1, 2024. We are hearing that TJC is nearing completion of their new surveyor sterile compounding review tool. The tool has been undergoing revision as a result of the new USP chapters. Be on the lookout for it over the coming month. The earlier version was very useful for internal evaluation of sterile compounding compliance, and we expect the revised tool to be as useful.



Applicability of USP:

As we approach the November implementation date for the new USP chapters, some may be questioning, "*who is this USP group and why is The Joint Commission evaluating compliance with their requirements?*"

USP was started back in 1820 by physicians with concerns about the quality of medicines in the US. By 1848, Congress passed The Drug Importation Act, drawing upon guidance from USP, for drugs to be imported into the US. By 1906, Congress' passage of the Pure Food and Drug Act made the USP reference standards official in the US and later many countries around the world also adopted the USP reference standards. More recently, Congress passed the 2013 Drug Quality and Security Act to identify the FDA and USP's roles in drug compounding under sections 503A and 503B of the Act.

Today, most states have adopted USP's sterile compounding expectations as regulations, and some states even have specific

sterile compounding inspection surveys. CMS no longer specifically states a compliance expectation with USP requirements, but they have broadened their position to require compliance with nationally accepted clinical practice standards, including USP. But USP is not an inspection agency, but other interested parties such as CMS, accreditors, state boards of pharmacy, and even the FDA may evaluate compliance with USP's standards.

New Hospice EM Requirement:
This month's *Perspectives* also announced a new emergency management requirement for hospice providers. The applicability statement indicates it is applicable to "home care providers and hospices that provide care in a patient residence." The pertinent standard is EM.12.02.05, EP 4. Basically, it requires procedures to develop a patient's personal emergency management plan based on their needs and discussion with the family.

We turned to the listed CMS reference to learn more about the requirement, 42 CFR §484.55, but we only learned about the requirements for documenting a detailed assessment, which now should include this personal EM plan. We did find more information on the ASPR Tracie website for emergency management, Home Health Agency Requirements, under Tag 0017.

Because CMS is requiring this change, the new EP took effect August 27th, which means was already in effect by the time we were writing this issue.

New Resuscitation Standards:
This month's *Consistent Interpretation* column discusses the new resuscitation standards that became effective in January 2022. The scoring at this time is miniscule, less than 1%, and the guidance section does not seem very enlightening due to the very limited findings. But if you struggled in implementing these standards, you might want to take a look at this column.

EC NEWS

Environment of Care Data Collection:
This month's issue of *EC News* has a good article on data collection in the Environment of Care. From a performance improvement perspective, we often immediately think of incident reports and clinical PI measures, but there are very substantial PI data collection expectations in the EC Chapter also. We know that organizations often struggle to conduct their annual evaluations of the EC management plans, but if you have a thorough set of performance measures being collected, this provides you with the ability to more effectively conclude how well your EC management plans worked.

The authors advise data collection for injuries to patients served, occupational injuries for employees, incidents of damage to organization or personal property, safety and security incidents, hazardous material spills and exposures, fire safety management problems, medical and laboratory equipment malfunctions, and utility system problems. The article is definitely worth sharing with your Environment of Care Committee for discussion and possible identification of all the EC related performance measures you collect at this time to determine if it is thorough enough.

Managing Mass Casualties:

EC News also contains a summary of a presentation from JCR's 2023 Emergency Management Conference on managing mass casualties that will be of interest to your EM committee. A key point made by the presenters is to have a tiered response comparable or tailored to the scope of the mass casualty event. There is a diagram of a football type single page playbook that was developed to help guide the response that may be of interest to some. Some may find it overwhelming, but it may be well received by emergency management teams.

CMS

New SOM Appendix A Manual:

There were no new QSO memos of importance to our readers published this past month. CMS did issue a new State Operations Manual, SOM, also known as Appendix A for Hospitals, that you will want to be sure to download.

The last version that was available was dated 2/21/20. Since then, there have been many new QSO memos and that content, where still current and appropriate, has been added to the new SOM. The usual CMS format with red text for new content continues in this edition and we did notice some red edits in the section on ligature hazards and some new reference material.

As a PDF document, the State Operations Manual is easily searchable using key words for your search criteria. In addition, the SOM format often makes use of lengthy narrative explanations, background information and references which is useful to understanding the requirements.

Hospice Billing Investigation:

CMS also published CMS is Taking Action to Address Benefit Integrity Issues Related to Hospice Care on August 22nd describing an oversight and enforcement action against some hospice providers

who may be inappropriately billing and inadequately serving patients in need of hospice services.

As a result, CMS has conducted visits to over 7,000 hospice providers and they anticipate there will be regulatory changes proposed to better manage the hospice industry. The investigative focus of potential fraud has been in Arizona, California, Nevada, and Texas.

Fentanyl Handling and Exposure:
We recently had a client ask us about procedures for handling illicit fentanyl that may be brought into a healthcare facility by a patient. A quick search did find two guidance documents that recommended worker precautions and the use of PPE that you would use for other hazardous chemical or drug spills; the CDC's Preventing Occupational Exposure to Fentanyl and the DEA's Fentanyl: Safety Recommendations for First Responders.

As our search engine cranked away looking for this guidance, we did come across what we would call contrary advice from the *Health and Justice Journal*, Can touch this: training to correct police officer beliefs about overdose from incidental contact with fentanyl.

We found similar contrary guidance from some major media outlets. Because these are consumer publications, we have not included these links, but you will see them as you analyze your own situation and needs. We also looked at the safety data sheet for pharmaceutical grade fentanyl and it contains multiple skull-and-crossbones pictures and advises workers to wear appropriate PPE as described in the CDC guidance document.

We know that OSHA, NIOSH, and The Joint Commission all discuss employer responsibilities for worker protection from hazardous materials. Given where we are as a society today, if this has not already come up at your organization it likely will in the near future. Developing guidance on appropriate clean up procedures for spills and contamination sounds like a worthwhile, pro-active planning effort.

CONSULTANT CORNER

Dear Readers,

The departure of a leader, especially an unplanned one, is a critical time that doesn't just impact processes and revenue, it becomes a matter of patient safety. We can provide interim staffing for any Quality or Regulatory healthcare professional.

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