Quality Tip



Multi-Use Vial Expiration Dates:

The Joint Commission (TJC) has clarified its requirements for multi-use vial expiration dates. According to TJC, the clarified requirements correspond with recent guideline revisions from Association for Professionals in Infection Control and Epidemiology (APIC) and the United States Pharmacopeia (USP).

Once a multi-dose vial is opened or punctured, unless otherwise clarified by the manufacturer, TJC requires a 28-day expiration date.

This requirement is effective immediately and applies to the ambulatory care, behavioral health, critical access hospital, home care, hospital, long term care, and office-based surgery accreditation programs.

TJC further notes the following:

- If a manufacturer has determined an original expiration date that is earlier than the revised expiration date, the earlier date must be used.
- Manufactures, per FDA regulations, may offer extended dating for a product if they have performed testing that goes beyond the 28-days.
- Whenever there is a question about sterility, multi-dose vials should be immediately discarded.
- Vaccines that are a part of the Centers for Disease Control and Preventions immunization programs are not subject to the dating expectation reviewed in this notice.

For complete details, see The Joint Commission Online, June 9, 2010 publication (attached).

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Accreditation

Telemedicine requirements for hospitals and CAHs are delayed until March 2011

The Centers for Medicare & Medicaid Services (CMS) has delayed The Joint Commission's requirement to implement CMS telemedicine standards for both general and critical access hospitals until March 2011. Until receipt of this extension from CMS, Joint Commission accredited hospitals were expected to implement by July 15, 2010 new elements of performance to conform to Medicare's credentialing and privileging requirement for telehealth services. Therefore, hospitals now do not need to make changes to their telemedicine process by the July 15, 2010 date as was previously communicated. The extension was granted by CMS because CMS has issued a new proposed regulation on telemedicine, which will ultimately affect Medicare's credentialing and privileging standards, but this regulation will not be finalized until sometime in the future. The Joint Commission plans to comment on the proposed rule by the July 26 deadline and urges hospitals to do the same. Look for more information in an upcoming issue of *The Joint Commission Perspectives*.

As background on this issue, the required changes to the telemedicine standards were part of The Joint Commission's application to CMS for continued hospital deeming authority. This required The Joint Commission to add specificity to its standards as a way to demonstrate equivalency with the Medicare hospital requirements. The changes made to the standards relating to credentialing and privileging by proxy were announced in September 2009. Since that time, The Joint Commission has engaged CMS and members of Congress regarding the issue of credentialing and privileging by proxy as it relates to telemedicine providers and users. The Joint Commission believes that there would be an adverse effect on the access to some telehealth services if organizations are not allowed to comply with the original Joint Commission requirements addressing credentialing and privileging by proxy. The Joint Commission also believed that the CMS requirements placed an undue burden on many organizations without improving the quality of services, provider accountability and the effectiveness of the credentialing and privileging processes. (Contact: Margaret VanAmringe, mvanamringe@jointcommission.org)

Multi-dose vials: Discard 28 days after first use

Effective immediately, The Joint Commission has clarified its requirements for ambulatory care, behavioral health, critical access hospital, home care, hospital, long term care, and office-based surgery programs regarding the use of multi-dose vials and their expiration dates. The clarification aligns with recently revised guidelines from the Association for Professionals in Infection Control and Epidemiology (APIC) and the United States Pharmacopeia (USP). Medication Management standard MM.03.01.01 element of performance 7 (for OBS, MM.03.01.01 EP 8) requires organizations to store all medications labeled with the expiration date. The Joint Commission defines "expiration date" as the last date that the product is to be used. The manufacturer bases the expiration date on the fact that the product has not been opened. Once a vial cap is removed or the vial is punctured, the expiration date is no longer valid and a revised expiration date (also called the "beyond-use date" in pharmaceutical terminology) needs to be identified.

The Joint Commission requires organizations to re-label multi-dose vials with a revised expiration date (beyond-use date) once a multi-dose vial is opened or punctured. USP and APIC now recommend that opened or punctured multi-dose vials be used for no more than 28 days unless the manufacturer specifies otherwise. Therefore, The Joint Commission requires a 28-day expiration date for multi-dose vials from the date of opening or puncture, unless the manufacturer specifies otherwise. The Joint Commission bases this 28-day time frame on the fact that manufacturers are required by law to test the effectiveness of the bacteriostatic agent used in the multi-dose vial for a period of 28 days.

The FDA allows manufacturers to provide extended dating in the package insert if they have conducted testing beyond the minimum 28 days. However, if the manufacturer identifies an original expiration date earlier than the revised expiration date, then the earlier date must be used. Also, if sterility is questioned or compromised, the multi-dose vial should be immediately discarded. This dating expectation does not apply to vaccines in the Centers for Disease Control and Prevention and state immunization programs, which have separate requirements for when multi-dose vials must be discarded. (Contact: Pat Adamski, padamski@jointcommission.org)

RPI process focuses on high-value standards; eliminates 16 hospital EPs

Effective July 1, 2010, The Joint Commission will eliminate 16 elements of performance for the hospital program. The eliminated EPs underwent an extensive evaluation process as part of The Joint Commission's internal Robust Process Improvement (RPI) project. Using RPI processes, The Joint Commission established a measurement ranking scale against which all standards for all programs will be evaluated going forward. As part of this initial evaluation, hospitals were asked for their perceptions of what constitutes a "valuable" standard and which standards they felt contributed the least value toward quality and safety. A valuable standard is defined as one that:

- Supports a health care priority that affects patient safety or quality of care
- Has a solid evidence base or an iron-clad rationale
- Has a strong relationship to clinical care
- Supports the organization's attainment of patient safety and quality care
- Judiciously uses an organization's resources (that is, the benefit of implementing a requirement outweighs the cost of doing so)

Input from more than 300 hospitals identified 52 EPs of questionable value. The Joint Commission reviewed the 52 requirements against these value criteria and made a recommendation to keep, revise, combine or delete the requirement. Their recommendations were presented to the Hospital Professional and Technical Advisory Committee and to the Standards and Survey Procedures Committee for approval. The determination resulted in:

- The elimination of 16 EPs: EC.02.06.01 EPs 4,5,6,18; LD.02.04.01 EP 3; LD.03.02.01 EP 2; LD.03.03.01 EP 2; LD.03.04.01 EP 2; LD.03.05.01 EP 2; LD.03.06.01 EP 2; MM.07.01.01, EPs 1,2; PC.02.03.03 EPs 1,2,5; RI.01.06.05 EP 1
- EPs 1-5 under standard RI.01.07.07 that are currently applicable to all hospital settings that provide longer term care (more than 30 days) are revised to apply only to psychiatric hospitals that provide longer term care.
- A note is being added to PC.01.02.01 EP 1 to capture concepts from deleted standard MM.07.01.01.
- The remaining EPs will be further reviewed to clarify intent and increase value to our customers.

See the June issue of *The Joint Commission Perspectives* for the full text of the eliminated and revised requirements. The Joint Commission's internal RPI initiative started in mid-2008 with the goals to improve the efficiency and effectiveness of internal processes and to better meet customers' needs and expectations of value. The Joint Commission's RPI "toolkit" includes a variety of methodologies, including Lean Six Sigma and change management. RPI is enterprisewide, encompassing The Joint Commission and its affiliates, Joint Commission Resources and the Center for Transforming Healthcare. (Contact: Amy Panagopoulos, mpanagopoulos@jointcommission.org)

Reminder: Interim staffing effectiveness requirements go into effect July 1, 2010

On July 1, 2010, interim requirements to the staffing effectiveness standards will go into effect for hospitals and long term care organizations. The interim standards will remain in effect while The Joint Commission continues to research staffing effectiveness issues. While the survey of the original, problematic hospital staffing effectiveness standard PI.04.01.01 remains suspended, beginning July 1, The Joint Commission will begin assessing organization compliance with the interim staffing effectiveness requirements (the last bullet under LD.04.04.05 EP 13 and PI.02.01.01 EPs 12,13,14). The interim staffing effectiveness requirements were based on input from hospitals and other stakeholders during two field reviews: the first in June 2009 and the second in September 2009. The interim requirements were included in the first manual update for 2010; the E-dition (electronic manual) will be updated in July. To see the interim requirements, see the December 16, 2009 issue of <u>Joint Commission Online</u>. (Contact: Laura Smith, <u>Ismith@jointcommission.org</u>)

WARNING: Deceptive mailing should be disregarded

Hospitals are alerted to disregard a deceptive mailing using The Joint Commission's name to sell antibacterial nasal cannulas. There are no Joint Commission standards mandating the use of these devices. The Joint Commission has no relationship, nor had any knowledge of the entity offering to sell the products. That entity is "Ford Health International," located in Humble, Texas. Ford is the last name of the individuals The Joint Commission believes are responsible for the mailing. The Joint Commission is communicating with law enforcement authorities and will pursue appropriate legal remedies. (Contact: Hal Bressler, hbressler@jointcommission.org)

Patient safety

Sentinel Event Alert: Violence Rising at Health Care Facilities

A new Joint Commission <u>Sentinel Event Alert</u> warns that health care facilities today are being confronted with steadily increasing rates of crime, including assault, rape and murder. The *Alert* urges greater attention to the issue of violence and to controlling access to facilities to protect patients, staff and visitors, noting that assault, rape and homicide are consistently in the top 10 types of serious events reported to The Joint Commission. The *Alert* cautions that the actual number of violent incidents is significantly underreported and advises organizations to mandate the reporting of all real or perceived threats. To prevent violence in health care facilities, The Joint Commission's *Sentinel Event Alert* newsletter suggests that facilities take a series of 13 specific steps, including evaluating the facility's risk for violence, examining the campus, reviewing crime rates and surveying employees about their perceptions of risk.

"Health care facilities should be places of healing, not harm. But, unfortunately, health care settings are not immune from the types of violence that are found in the other areas of our lives," says Mark R. Chassin, M.D., M.P.P., M.P.H., president, The Joint Commission. "The recommendations in this *Alert* give health care institutions and caregivers specific strategies to take action that will keep everyone safer." In addition to the specific recommendations contained in the *Alert*, The Joint Commission urges hospitals to comply with the requirements described in its accreditation standards to prevent violence. The standards require accredited health care facilities to have a security plan as well as conduct violence risk assessments, develop strategies to prevent violence and have a response plan when a violent episode occurs. The Joint Commission's standards also are clear that patients have a right to be free from neglect, exploitation, and verbal, mental, physical and sexual abuse. (Contact: Cathy Barry-Ipema, cipema@jointcommission.org)

People

JCR names Nurse Safety Scholar-in-Residence sponsored by Hill-Rom

Diane Whitworth, R.N., CWOCN, has been named the Nurse Safety Scholar-in-Residence by Joint Commission Resources and Hill-Rom. Whitworth is a certified wound, ostomy and continence nurse with more than 30 years of clinical experience. She is currently responsible for the wound care team at Bon Secours St. Mary's Hospital, a 391-bed acute care hospital and Magnet designated facility in Richmond, Va. Recognizing the important role that nurses play in translating evidence-based findings into excellent

care at the patient's bedside, the Nurse Safety Scholar-in-Residence program was initiated through funding by Hill-Rom, and is in its second year of a three-year project, focuses on developing tools and best practices to maintain skin integrity and to prevent pressure ulcers. Whitworth, the second nurse to be named in this program, will serve a six-month appointment as Patient Safety Nurse Scholar-in-Residence. During her term, which ends September 30, 2010, she will work closely with JCR experts to achieve the goals of the program:

- To foster the professional development of expert nurse clinicians and scholars to become translators of evidence into practice
- To disseminate best practice processes associated with providing safe care for specific clinical problems
- To continue the work of a hospital-based collaborative project focused on the implementation of pressure ulcer reduction strategies

For more information about the program, visit the JCR Web site. (Contact: Nanne Finis, nfinis@jcrinc.com)

Learn more about Joint Commission Resources' education programs and publications at http://www.jcrinc.com/? or call (877) 223-6866

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