Approved: New Antimicrobial Stewardship Standard

The Joint Commission recently announced a new Medication Management (MM) standard for hospitals, critical access hospitals, and nursing care centers. Standard MM.09.01.01 addresses antimicrobial stewardship and becomes effective January 1, 2017.

Current scientific literature emphasizes the need to reduce the use of inappropriate antimicrobials in all health care settings due to antimicrobial resistance. According to the World Health Organization (WHO): “Antimicrobial resistance threatens the effective prevention and treatment of an ever-increasing range of infections caused by bacteria, parasites, viruses and fungi.”1 The Centers for Disease Control and Prevention (CDC) identified that 20%–50% of all antibiotics prescribed in US acute care hospitals are either unnecessary or inappropriate.2 The CDC has also stated: “Antibiotics are among the most commonly prescribed medications in nursing homes. Up to 70% of long-term care facilities’ residents receive an antibiotic every year.”3

On June 2, 2015, The Joint Commission participated in the White House Forum on Antibiotic Stewardship. The Joint Commission joined representatives from more than 150 major health care organizations, food companies, retailers, and animal health organizations at the forum to express commitment for implementing changes over the next five years to slow the emergence of antibiotic-resistant bacteria, detect resistant strains, preserve the efficacy of existing antibiotics, and prevent the spread of resistant infections.4

Subsequently, The Joint Commission developed the antimicrobial stewardship standard for hospitals, critical access hospitals, nursing care centers, ambulatory care organizations, and office-based surgery practices and conducted a field review in November and December 2015. Prior to and during the field review, Joint Commission staff conducted stakeholder calls on the proposed antimicrobial stewardship standard with several governmental and professional organizations, including the Centers for Medicare and Medicaid Services, the American Society for Healthcare Epidemiology of America, the Infectious Disease Society of America, the National Association of Workforce Boards, and the American College of Healthcare Executives.

Continued on page 3
In Sight

This column lists developments and potential revisions that can affect accreditation and certification and tracks proposed changes before they are implemented. Items may drop off this list before the approval stage if they are rejected at some point in the process.

APPROVED STANDARDS

- New Medication Management (MM) Standard 09.01.01, EPs 1–8, regarding antimicrobial stewardship for critical access hospitals, hospitals, and nursing care centers (see article on page 1)

CURRENTLY IN FIELD REVIEW

- Proposed new Human Resources (HR) Standard HR.02.01.03, EP 37, for ambulatory care organizations that provide sleep study services (field review ends July 6, 2016)
- Proposed new and revised requirements for laboratories that address the following: molecular and genetic testing, clinical chemistry and toxicology, and aligning various requirements with Clinical Laboratory Improvement Amendments (CLIA) Interpretive Guidelines (field review ends July 6, 2016)
- Proposed revisions to clarify language of several requirements for behavioral health care organizations (field review ends July 20, 2016)

Note: Please note that field review dates are tentative and subject to change. To participate in or read more about field reviews, please visit The Joint Commission website at http://www.jointcommission.org/standards_information/field_reviews.aspx.

CURRENTLY IN DEVELOPMENT STANDARDS

- Proposed deletion of 51 additional elements of performance for hospitals as Phase II of the EP Review Project component of Project REFRESH
- Proposed revisions to Care, Treatment, and Services (CTS) Standard CTS.03.01.09 requirements for behavioral health care organizations regarding the assessment of outcome measures
- Proposed revised and new requirements for Advanced Certification for Inpatient Diabetes Care in the disease-specific care program
- Proposed expansion of the Integrated Care Certification program option for ambulatory care organizations, hospitals, and critical access hospitals to include home care organizations and nursing care centers as partners along the post-acute care continuum
- Proposed new Comprehensive Cardiac Center advanced certification option for accredited hospitals

FSA Tool Temporarily Offline for July 2016 Standards Update

Starting June 30, 2016, at 5:00 p.m. central time (CT), the Focused Standards Assessment (FSA) tool on the Intracycle Monitoring (ICM) Profile will be offline for the July 2016 standards update. The tool will resume July 11, 2016, at 8:00 a.m. CT. An extension date will be applied for accredited organizations with a scheduled ICM submission due date between July 1st and July 11th to allow additional time to review any changes made to standards displayed in the open FSA tool. The extension due date will be set to Monday, July 25, 2016.

Questions may be directed to your organization’s designated Account Executive at 630-792-3007.
& Medicaid Services (CMS), the CDC, and the Society for Healthcare Epidemiology of America (SHEA).

There was significant support for the antimicrobial stewardship standard for the hospital, critical access hospital, and nursing care center accreditation programs. Additionally, CMS is in the process of developing a Condition(s) of Participation (CoP) on antimicrobial stewardship for the hospital and nursing home settings, which therefore aligns the Joint Commission’s standard with CMS’s plans for a CoP(s) in this area. In the meantime, the antimicrobial stewardship standard for Joint Commission–accredited ambulatory care organizations and office-based surgery practices is still in development.

The approved antimicrobial stewardship standard and EPs are shown in the box that begins below and will also be displayed on The Joint Commission website at http://www.jointcommission.org/standards_information/prepublication_standards.aspx. In addition, the requirements will be posted in the fall 2016 E-dition® update and published in the 2017 Comprehensive Accreditation Manual for the Critical Access Hospital, Hospital, and Nursing Care Center Accreditation Programs.

Questions regarding the new antimicrobial stewardship standard may be directed to Kelly Podgorny, DNP, CPHQ, RN, project director, Department of Standards and Survey Methods, The Joint Commission, at kpodgorny@jointcommission.org.

References

The Joint Commission Perspectives
July 2016
http://www.jointcommission.org

New Antimicrobial Stewardship Standard (continued)

4. The [critical access] hospital has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting:
   - Infectious disease physician
   - Infection preventionist(s)
   - Pharmacist(s)
   - Practitioner

   **Note 1:** Part-time or consultant staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.

   **Note 2:** Telehealth staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.

5. The [critical access] hospital’s antimicrobial stewardship program includes the following core elements:
   - Leadership commitment: Dedicated necessary human, financial, and information technology resources.
   - Accountability: Appointing a single leader responsible for program outcomes. Experience with successful programs shows that a physician leader is effective.
   - Drug expertise: Appointing a single pharmacist leader responsible for working to improve antibiotic use.
   - Action: Implementing recommended actions, such as systemic evaluation of ongoing treatment need, after a set period of initial treatment (for example, “antibiotic time out” after 48 hours).
   - Tracking: Monitoring the antimicrobial stewardship program, which may include information on antibiotic prescribing and resistance patterns.
   - Reporting: Regularly reporting information on the antimicrobial stewardship program, which may include information on antibiotic use and resistance, to doctors, nurses, and relevant staff.
   - Education: Educating practitioners, staff, and patients on the antimicrobial program, which may include information about resistance and optimal prescribing. (See also IC.02.01.01, EP 1 and NPSG.07.03.01, EP 5)

   **Note:** These core elements were cited from the Centers for Disease Control and Prevention’s Core Elements of Hospital Antimicrobial Stewardship Programs (http://www.cdc.gov/getsmsart/healthcare/pdfs/core-elements.pdf).

6. The [critical access] hospital’s antimicrobial stewardship program uses organization-approved multidisciplinary protocols (for example, policies and procedures).

   **Note:** Examples of protocols are as follows:
   - **Antibiotic Formulary Restrictions**
   - **Assessment of Appropriateness of Antibiotics for Community-Acquired Pneumonia**
   - **Assessment of Appropriateness of Antibiotics for Skin and Soft Tissue Infections**
   - **Assessment of Appropriateness of Antibiotics for Urinary Tract Infections**
   - **Care of the Patient with Clostridium difficile (c.-diff)**
   - **Guidelines for Antimicrobial Use in Adults**
   - **Guidelines for Antimicrobial Use in Pediatrics**
   - **Plan for Parenteral to Oral Antibiotic Conversion**
   - **Preauthorization Requirements for Specific Antimicrobials**
   - **Use of Prophylactic Antibiotics**

7. The [critical access] hospital collects, analyzes, and reports data on its antimicrobial stewardship program.

   **Note:** Examples of topics to collect and analyze data on may include evaluation of the antimicrobial stewardship program, antimicrobial prescribing patterns, and antimicrobial resistance patterns.

8. The [critical access] hospital takes action on improvement opportunities identified in its antimicrobial stewardship program. (See also MM.08.01.01, EP 6)

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**APPLICABLE TO NURSING CARE CENTERS**

**Effective January 1, 2017**

**Medication Management (MM)**

**Standard MM.09.01.01**
The organization has an antimicrobial stewardship program based on current scientific literature.

**Elements of Performance for MM.09.01.01**

1. Leaders establish antimicrobial stewardship as an organizational priority. (See also LD.01.03.01, EP 5)

   **Note:** Examples of leadership commitment to an antimicrobial stewardship program are as follows:
   - Accountability documents

Continued on page 8
**PROJECT REFRESH: Restraint and Seclusion Standards Deletions**

As previously announced (see May 2016 Perspectives, page 5, and the related article below), The Joint Commission is conducting a multiphase review project to streamline the accreditation requirements for hospitals. This initiative examines standards and elements of performance (EPs) to identify those that were considered necessary to evaluate on survey when they were introduced years ago but that have now become part of routine hospital practice.

The first phase of this project resulted in the deletion of 225 EPs. A majority of these deletions—131—are **effective July 1, 2016**. The remaining 94 EPs address restraint and seclusion and are scheduled for deletion, as discussed below, because they are duplicative of other standards; these deletions become **effective January 1, 2017**.

**Streamlining from Two Sets to One**

The Joint Commission currently has two sets of standards that address restraint and seclusion:

1. **Non-Deemed Standards**—The Joint Commission’s original restraint and seclusion standards, these currently apply only to hospitals that are not seeking accreditation for deemed status purposes. These requirements comprise Provision of Care, Treatment, and Services (PC) Standards PC.03.02.01 through PC.03.03.31.

2. **Deemed Standards**—These standards, which align with Centers for Medicare & Medicaid Services (CMS) requirements, must be followed by hospitals seeking accreditation for deemed status and are covered in Standards PC.03.05.01 through PC.03.05.19.

Because these two sets of restraint and seclusion standards are largely duplicative of each other, The Joint Commission decided to delete the first set and use only the second set. Therefore, as of January 1, 2017, all hospitals—regardless of whether or not they seek accreditation for deemed status purposes—will be required to follow Standards PC.03.05.01 through PC.03.05.19.

**Similarities and Differences**

There are similarities and differences between what is required by the two sets of standards. Both sets of standards require, for example, that hospitals do the following:

- Clinically justify the use of restraints
- Use physician orders for restraints
- Limit the use of restraints to situations when they are needed to protect the patient and others
- Limit the amount of time patients are kept in restraint; discontinue restraints as soon as possible
- Monitor patients in restraints
- Make sure staff are competent to use restraints
- Use the least restrictive method of restraint that is possible
- Follow policies on the use of restraints

Among the several differences between the two sets of standards, one is that while Standards PC.03.02.01 through PC.03.03.31 (those being deleted effective January 1, 2017) require hospitals to determine whether the need for restraints is for behavioral or medical reasons, Standards PC.03.05.01 through PC.03.05.19 (those aligned with CMS requirements) do not specify that hospitals are required to make this distinction. In addition, while the deleted standards require the debriefing of individuals who have been placed in restraints, this is not specified in the CMS-related requirements. Despite these differences, hospitals are free to continue to follow the processes in Standards PC.03.02.01 through PC.03.03.31 even though they are not required within Standards PC.03.05.01 through PC.03.05.19.

For more information regarding the multiphase EP review project, please contact Maureen Carr, MBA, project director, Department of Standards and Survey Methods, The Joint Commission, at mcarr@jointcommission.org.
Laboratory Accreditation Program Granted Deeming Authority for Licensure in California

Effective May 23, 2016, The Joint Commission has received deeming authority for licensure for California clinical laboratories from the California Department of Public Health’s Laboratory Field Services. California clinical laboratories are now able to demonstrate compliance with federal and state laws and regulations through The Joint Commission Laboratory Accreditation Program.

Laboratories meeting the conditions set forth in the California Business and Professions Code (BPC) 1223 and All Clinical Laboratories Letter (ACLL) 16-01 may now apply for a certificate of deemed status from the California Department of Public Health with The Joint Commission as the laboratory’s accrediting organization. Laboratory Field Services, which retains its authority to conduct complaint investigations and validation surveys, also requires submission of proficiency testing results to ensure compliance with state standards.

“The Joint Commission’s deemed-status approval to oversee California clinical laboratories expands the laboratory program’s initiative to continuously improve patient quality and safety by ensuring that laboratories nationwide comply with both federal and specific state laws,” says Stacy Olea, MBA, MT(ASCP), FACHE, executive director, Laboratory Accreditation Program, The Joint Commission. This approval confirms that Joint Commission laboratory standards and survey process meet all specific requirements unique to the California clinical laboratory law.

Many states recognize and rely upon The Joint Commission’s Laboratory Accreditation Program as an important component of their quality oversight activities. The Joint Commission has accredited hospital laboratory services since 1979 and freestanding laboratories since 1995. More than 1,500 organizations currently maintain Laboratory Services Accreditation from The Joint Commission.

For more information or to register for free 60-day trial access to the laboratory accreditation standards, visit https://www.jointcommission.org/accreditation/laboratory.aspx.

SAFETY FOCUS: Capturing Medical Device UDIs in the Electronic Medical Record

The US Food and Drug Administration (FDA) and the Office of the National Coordinator for Health Information Technology (ONC) are taking steps to make the unique device identifier (UDI) system work as a patient safety tool. A UDI is a unique numeric or alphanumeric code labeled on a medical device that acts as a key to certain basic identifying information about the device.

Background
Almost six years after the FDA Amendments Act (H.R. 3580) was signed into law, requiring the FDA to publish regulations that create a medical device identifier system to track adverse events related to medical devices, the FDA released a final rule¹ in 2013 requiring medical device manufacturers to include a UDI on the medical device label and each piece of a medical device package. Two years later, in 2015, ONC issued a final rule² addressing a standard for capturing the medical device UDI in the electronic medical record. Additionally, the FDA’s rule requires medical device manufacturers to enter device information into a publicly available database, the Global Unique Device Identification Database (GUDID).³ Clinicians and hospitals can use the GUDID to obtain critical information about the device by entering the UDI into the database to retrieve the information about the device.

The Role of the UDI System in Patient Safety
The mandatory UDI system, which makes it easier to identify devices on the market as well as certain characteristics of the devices, also provides more readily available information about a patient’s implantable device that may not otherwise be easily identified. For example, during surgery for a total hip replacement, the clinical staff in the operating room will scan the implantable hip device UDI into the hospital inventory management system and the electronic medical record. The electronic medical record system queries the GUDID system to return characteristics of the hip implant, such as whether the device is MRI safe or latex free. The UDI and the characteristics of the device are then part of the patient’s electronic medical record for future reference.

UDIs make it possible to track a device throughout the

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Nursing Care Center Accreditation Program Observes 50th Anniversary

This year The Joint Commission commemorates the 50th anniversary of its Nursing Care Center Accreditation Program. The Joint Commission currently accredits more than 1,000 nursing homes that provide nursing care, treatment, and services to more than 100,000 patients and residents every day in the United States.

The program was founded in 1966 as the Long Term Care Accreditation Program. In 2013 it was reinvented to address the increasing levels of complex care provided to patients and residents and formally renamed as the Nursing Care Center Accreditation Program. In addition, the program now offers organizations the opportunity to achieve specialty certifications that recognize advanced care competencies in post–acute care and memory care–related services.

“We are proud to celebrate the half century of this program because it serves such an important goal of improving the quality and safety of care provided to thousands of residents and patients in Joint Commission–accredited nursing care centers and other long term care facilities,” says Gina Zimmermann, executive director, Nursing Care Center Accreditation, The Joint Commission. “Over the years, we’ve continuously looked for ways to evolve and advance the program as the complexity of nursing home care has increased. True recognition goes out to the leaders and staff who commit to improving patient safety and quality together with The Joint Commission. It’s your passion, dedication, and tenacity that ultimately helps us to improve patient and resident care in the nursing home setting.”

When the program was founded, representatives from the American Association of Homes for the Aging and the American Nursing Home Association provided The Joint Commission Board of Commissioners with a voice on issues related to long term care. Today, Connie March-Curtis, RN, MSN, who has held clinical and executive health care leadership positions for more than 30 years, serves on the board as a representative of nursing care centers.

“I congratulate The Joint Commission for being a true asset to nursing care centers over the past 50 years,” says March-Curtis. “The seven years that I have served on the board has been a very exciting time to be part of the re-creation and expansion of the Nursing Care Center Accreditation Program and its specialty certifications. Specialty certifications, such as post–acute care, memory care, and integrated care certifications, are bringing renewed focus to the expanding needs of patients, consumers, and providers. It has been exhilarating to see the improvement in safety and quality at organizations that go through Joint Commission accreditation and certification processes.”

Fifty years ago, organizations applying for accreditation with The Joint Commission followed an eight-page standards manual. Today organizations follow standards in the Comprehensive Accreditation Manual for Nursing Care Centers, which is accessible electronically (as well as in print) and includes discussion prompts, documentation checklists, and action planning tools. Foundational accreditation standards and optional specialty certification standards are developed and continuously renewed with the input of consumers, government agencies, health care professionals and providers, and subject matter experts to help organizations measure, assess, and improve performance.

For more information, please contact the Nursing Care Center Business Development team at 630-792-5020 or ncc@jointcommission.org or visit https://www.jointcommission.org/accreditation/nursing_care_centers.aspx.

Delayed Implementation of Removing Ban on Secure Text Orders Until September 2016

The Joint Commission has determined that additional guidance is required to ensure a safe implementation involving the secure texting of orders for those organizations desiring to employ technology supporting this practice. The Centers for Medicare & Medicaid Services (CMS) will collaborate with The Joint Commission on the development of additional guidance for text orders to ensure congruency with the Medicare Conditions of Participation. The Joint Commission and CMS will develop a comprehensive series of Frequently Asked Questions (FAQ) documents to assist health care organizations with the incorporation of text orders into their policies and procedures. This guidance information is designed to supplement the recommendations in the May 2016 Perspectives article permitting the use of secure text messaging platforms to transmit orders. As an update to the May 11, 2016, issue of Joint Commission Online, the goal for this additional guidance is a release date by late September 2016.
New Antimicrobial Stewardship Standard (continued)

- Budget plans
- Infection prevention plans
- Performance improvement plans
- Strategic plans
- Using the electronic health record to collect antimicrobial stewardship data

2. The organization educates staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire or granting of initial privileges and periodically thereafter, based on organizational need.

3. The organization educates residents, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics. (For more information on patient and resident education, refer to Standard PC.02.03.01)

   Note: An example of an educational tool that can be used for patients and families includes the Centers for Disease Control and Prevention’s Get Smart document, “Viruses or Bacteria—What’s got you sick?” at http://www.cdc.gov/getsmart/community/downloads/getsmart-chart.pdf.

4. The organization has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting:
   - Infectious disease physician
   - Infection preventionist(s)
   - Pharmacist(s)
   - Practitioner

   Note 1: Part-time or consultant staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.

   Note 2: Telehealth staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.

5. The organization’s antimicrobial stewardship program includes the following core elements:
   - Leadership commitment: Demonstrate support and commitment to safe and appropriate antibiotic use in your facility.
   - Accountability: Identify physician, nursing, and pharmacy leads responsible for promoting and overseeing antibiotic stewardship activities in your facility.
   - Drug expertise: Establish access to consultant pharmacists or other individuals with experience or training in antibiotic stewardship for your facility.
   - Action: Implement policy or practice changes to improve antibiotic use.
   - Tracking: Monitor and measure the use of antibiotic use and at least one outcome from antibiotic use in your facility.
   - Reporting: Regularly reporting information on the antimicrobial stewardship program, which may include antibiotic use and resistance, to physicians and other practitioners, nurses, and relevant staff.
   - Education: Provide resources to physicians and other practitioners, nursing staff, residents, and families about antibiotic resistance and opportunities for improving antibiotic use. (See also IC.02.01.01, EP 1)

   Note: These core elements were cited from the Centers for Disease Control and Prevention’s The Core Elements of Antibiotic Stewardship for Nursing Homes (http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html). The Joint Commission recommends that nursing care centers use this document when designing their antimicrobial stewardship program.

6. The organization’s antimicrobial stewardship program uses organization-approved multidisciplinary protocols (for example, policies and procedures).

   Note: Examples of protocols are as follows:
   - Antibiotic Formulary Restrictions
   - Assessment of Appropriateness of Antibiotics for Community-Acquired Pneumonia
   - Assessment of Appropriateness of Antibiotics for Skin and Soft Tissue Infections
   - Care of the Long Term Care Patient with a Urinary Tract Infection
   - Care of the Patient with Clostridium difficile (c.-diff)
   - Facility Guidelines for Antimicrobial Use in Adults
   - Plan for Parenteral to Oral Antibiotic Conversion
   - Preauthorization Requirements for Specific Antimicrobials

7. The organization collects, analyzes, and reports data on its antimicrobial stewardship program.

   Note: Examples of topics to collect and analyze data on may include evaluation of the antimicrobial stewardship program, antimicrobial prescribing patterns, and antimicrobial resistance patterns.

8. The organization takes action on improvement opportunities identified in its antimicrobial stewardship program. (See also MM.08.01.01, EP 6)
**UPDATE: Standards Changes for Providers of Diagnostic Imaging Services**

In the March 2016 issue of *Perspectives*, The Joint Commission announced the addition of two new Human Resources (HR) elements of performance (EPs) for accredited hospitals, critical access hospitals, and ambulatory care organizations that provide diagnostic imaging services (including those ambulatory care organizations that have achieved Advanced Diagnostic Imaging certification). The new HR requirements, scheduled to become effective September 1, 2016, were designed to address expectations for technologists who perform computed tomography (CT) exams.

The first new EP, Standard HR.01.02.05, EP 19, includes a note communicating the expectation that CT technologists obtain advanced-level CT certification by January 1, 2018. The second new EP, Standard HR.01.05.03, EP 26, requires organizations to demonstrate that CT technologists participate in education that prepares them to achieve advanced-level CT certification by January 1, 2018.

Since the publication of these requirements, The Joint Commission has received significant feedback from rural and critical access hospitals that is focused primarily on the expectation to achieve advanced-level CT certification by January 2018. These customers communicated concerns about their ability to comply with the expectation for advanced-level CT certification and—if this were to be required by 2018—the potential negative impact on patient access to CT services.

Because of these factors, The Joint Commission has decided to delete Note 1 at Standard HR.01.02.05, EP 19, and suspend implementation of Standard HR.01.05.03, EP 26. The effective date for Standard HR.01.02.05, EP 19, is still scheduled for September 1, 2016.

The revisions, provided below (deleted language is crossed out), will also appear on The Joint Commission website at [http://www.jointcommission.org/standards_information/prepublication_standards.aspx](http://www.jointcommission.org/standards_information/prepublication_standards.aspx). The revisions will be posted in a future E-dition update and published in future updates of the Comprehensive Accreditation Manuals for the Ambulatory Care, Critical Access Hospital, and Hospital Accreditation Programs. Questions may be directed to Joyce Webb, RN, BSN, MBA, CMPE, project director, Department of Standards and Survey Methods, at jwebb@jointcommission.org.

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**Official Publication of Joint Commission Requirements**

**New and Revised Diagnostic Imaging Requirements**

**Applicable to Ambulatory Care, Critical Access Hospitals, Hospitals**

**Effective September 1, 2016**

**Human Resources (HR)**

**Standard HR.01.02.05**
The [organization] verifies staff qualifications.

**Element of Performance for HR.01.02.05**

A 19. Technologists who perform diagnostic computed tomography (CT) exams have advanced-level certification by the American Registry of Radiologic Technologists (ARRT) or the Nuclear Medicine Technology Certification Board (NMTCB) in computed tomography or have one of the following qualifications:

- State licensure that permits them to perform diagnostic CT exams and documented training on the provision of diagnostic CT exams or
- Registration and certification in radiography by ARRT and documented training on the provision of diagnostic CT exams or
- Certification in nuclear medicine technology by ARRT or NMTCB and documented training on the provision of diagnostic CT exams (See also HR.01.02.01, EP 1; HR.01.02.05, EPs 1–3; HR.01.02.07, EPs 1 and 2; and HR.01.05.03, EP 26)

**Note 1:** Effective January 1, 2018, all technologists who perform diagnostic computed tomography (CT) exams will be expected to have advanced-level certification in computed tomography.

**Note 12:** This element of performance does not apply to CT exams performed for therapeutic radiation treatment planning or delivery, or for calculating attenuation coefficients for nuclear medicine studies.

**Note 23:** This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

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SAFETY FOCUS: Capturing Medical Device UDIs in the Electronic Medical Record
(continued)
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device’s life cycle; in doing so, they allow for more accurate adverse event reporting and recall. In a recent study, a national sample of orthopedic surgeons stated that searching for a UDI first in a total joint arthroplasty registry and then in an electronic medical record is the preferred standard for identifying implants, saving time, and identifying recalled devices in patients.4

Requirements for UDI Documentation in the Electronic Medical Record
One challenge to fully implementing the UDI system is that, while the FDA has jurisdiction over medical device companies seeking approval of devices distributed in the United States, it has limited authority when it comes to requiring clinicians to document a UDI in a patient’s medical record. A UDI on a device implanted in a patient is meaningless if there is no documentation of the UDI in the medical record. In early 2016, US Department of Health & Human Services Secretary Sylvia Burwell stated that “when we think about why we want the UDIs in terms of having a place where one can go and find out if someone had something, if [hospitals] need to track back, having that be part of the individual’s record, we think, moves a long way with regard to the questions of ensuring and using this tool as a tool for safety.”

To improve post-market surveillance of medical devices and ensure that the UDI system works, ONC’s 2015 final rule established a standard for capturing the medical device unique identifier in the electronic medical record. Eligible health care providers, hospitals, and critical access hospitals must adhere to this standard to qualify for Medicare and Medicaid electronic medical record incentive payments. The final rule stated that “documentation of UDIs in a patient’s medical record and the inclusion of that data field with the CCDS [Common Clinical Data Set] requirements for the summary of care documents is a key step toward improving the quality of care and ensuring patient safety.” Also, in May 2016, Centers for Medicare & Medicaid Services (CMS) Acting Administrator Andy Slavitt stated that CMS supports the incorporation of UDIs in electronic health.7

Conclusion
The adoption of the UDI system in clinical documentation is necessary for the system to be effectively utilized for the intended benefit—patient safety. The UDI system is critical to tracing medical devices in the hospital system and those already implanted in patients.

Questions about this information may be directed to Kathryn Spates, JD, ACNP-BC, director, Federal Relations, The Joint Commission, at kspates@jointcommission.org.

Consistent Interpretation
Joint Commission Surveyors’ Observations on MM.03.01.03, EPs 1–3

The bimonthly Consistent Interpretation column is designed to support standards compliance efforts. Each column draws from a de-identified database containing surveyors’ observations—as well as guidance from the Standards Interpretation Group on how to interpret the observations—on one or more elements of performance (EPs) in the Comprehensive Accreditation Manual for Hospitals. This installation (the fourth in the series) highlights three of the four requirements for Medication Management (MM) Standard MM.03.01.03 (EPs 1–3).

Note: Interpretations are subject to change to allow for unique and/or unforeseen circumstances.

References

10 The Joint Commission Perspectives July 2016 http://www.jointcommission.org
Medication Management (MM) Standard MM.03.01.03: The hospital safely manages emergency medications.

EP 1: Hospital leaders, in conjunction with members of the medical staff and licensed independent practitioners, decide which emergency medications and their associated supplies will be readily accessible in patient care areas based on the population served.

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<th>Surveyor Observations</th>
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<td>There was no evidence that hospital leaders consulted with the medical staff to determine which emergency medications and supplies would be readily available for specific populations served, such as pediatrics.</td>
<td>“Readily available” items may be described as the specific medication(s) that, while they may not be on a crash cart, are available elsewhere and without delay. Organizations should consider conducting a risk assessment to ensure emergency medications are readily available when not contained within an emergency cart. The risk assessment should include staff knowledge as to where such medications are located.</td>
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EP 2: Emergency medications and their associated supplies are readily accessible in patient care areas. (See also PC.03.01.01, EP 8)

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<td>Staff were unable to articulate where the malignant hyperthermia cart containing dantrolene was stored and where additional vials of dantrolene or Ryanodex® could be obtained. In some cases, the organization had secured emergency medications on crash carts with combination or keyed padlocks. In other cases, expired dantrolene was noted in the malignant hyperthermia emergency box.</td>
<td>The organization should define and follow what is meant by “readily accessible.” These meds need not be on the crash cart, for example, but the Malignant Hyperthermia Association of the United States (MHAUS) does recommend having 36 vials of (unexpired) dantrolene available. Some health care organizations may be transitioning to a product called Ryanodex®, which is a concentrated, soluble form of dantrolene containing 50 mg/ml of the drug. Each vial contains 250 mg of dantrolene sodium in lyophilized powder form requiring 5 mL of sterile water for reconstitution. MHAUS recommends that health care organizations have three vials available. The vials may be divided between the obstetrics operating room and the main operating room with the understanding that the additional vials can be immediately available. The “associated supplies” addressed in this EP are specific to administration of emergency medications. For nonmedication-related emergency supplies, see Provision of Care, Treatment, and Services (PC) Standard PC.02.01.11, EP 2.</td>
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EP 3: Whenever possible, emergency medications are available in unit-dose, age-specific, and ready-to-administer forms.

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<th>Surveyor Observations</th>
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<tr>
<td>Multidose vials were observed in a crash cart when unit-dose vials were readily available. In addition, although infant-dose unit-dose vials of resuscitation medication were stocked, there were no pediatric-dose or unit-dose vials available where pediatric surgery or procedures were performed.</td>
<td>“Readily available” may signify that a specific medication in a multidose vial on the crash cart is available elsewhere within the health care organization as a unit-dose vial. Nonemergency medications are cited at Standard MM.03.01.01, EP 10. If multidose vials are used, the organization should be prepared to discuss the rationale behind not using unit-dose emergency medications.</td>
</tr>
</tbody>
</table>

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**UPDATE: Standards Changes for Providers of Diagnostic Imaging Services**

*Continued from page 9*

**New and Revised Diagnostic Imaging Requirements (continued)**

**Standard HR.01.05.03**
Staff participate in ongoing education and training.

**Element of Performance for HR.01.05.03**

C.26: Technologists who perform diagnostic computed tomography (CT) exams participate in education that prepares them to achieve advanced level CT certification by January 1, 2018.

**Note 1:** This element of performance does not apply to:

- GT exams performed for therapeutic radiation treatment planning or delivery, or for calculating attenuation coefficients for nuclear medicine studies.
- GT exams performed for diagnostic computed tomography (CT) imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

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