

**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 1: Leadership Structures and Systems</b>                      Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served.</p> <p><b>Applicable Clinical Care Settings</b>                      This practice is applicable to Centers for Medicare &amp; Medicaid (CMS) care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/ hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 1 from 2009 Consensus Report).</b></p>	<p><b>Awareness Structures and Systems:</b> Structures and systems should be in place to provide a continuous flow of information to leaders from multiple sources about the risks, hazards, and performance gaps that contribute to patient safety issues. <a href="#">[Botwinick, 2006]</a></p> <ul style="list-style-type: none"> <li>▪ Identification of Risks and Hazards: Governance boards and senior administrative leaders should be regularly and thoroughly briefed on the results of activities undertaken as defined by the <i>Identification and Mitigation of Risks and Hazards</i> safe practice. <a href="#">[Botwinick, 2006; Reason, 1997; Morath, 2006; IHI, 2009]</a></li> <li>▪ Culture Measurement, Feedback, and Intervention: Governance boards and senior administrative leaders should be regularly and thoroughly briefed on the results of culture measurement and performance improvement initiatives addressed in the <i>Culture Measurement, Feedback, and Intervention</i> safe practice. <a href="#">[Botwinick, 2006; Conway, 2008]</a></li> <li>▪ Direct Patient Input: A structure and system should be established to obtain direct feedback from patients about the performance of the organization. Information from satisfaction surveys is not enough – patients and/or patient families representing the population served should be included in the design of educational meetings or should participate on formal committees that provide input to the leadership on the management of safety and quality issues within the hospital. <a href="#">[Rider, 2002; IHI, 2009]</a></li> <li>▪ Governance Board and Senior Management Briefings/Meetings: Patient safety risks, hazards, and progress toward performance improvement objectives should be addressed at every board meeting and should be documented by meeting agendas and minutes. <a href="#">[IHI, 2009a]</a> Such meetings and documentation systems should ensure that organizational leadership is kept knowledgeable about patient safety issues present within the organization and is continuously involved in processes to ensure that the issues are appropriately addressed and that patient safety is improved. <a href="#">[Conway, 2008]</a></li> </ul>

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<p><b>Safe Practice 2: Culture Measurement, Feedback, and Intervention</b></p> <p>Healthcare organizations must measure their culture, provide feedback to the leadership and staff, and undertake interventions that will reduce patient safety risk. <a href="#">[Note 2-1; Note 2-2; Note 2-3]</a></p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 2 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ At least annually, leaders should assess the organization’s safety and quality culture using a survey tool that is selected with consideration of validity, consistency, and reliability in the setting in which it will be applied and that is conceptualized around domains that are applicable to performance improvement (PI) initiatives/efforts such as teamwork, leadership, communication, and openness to reporting. <a href="#">[Deilkas, 2008; Relihan, 2009; Note 2-4]</a> <ul style="list-style-type: none"> <li>• Survey a census of units or service areas that in aggregate deliver care to more than 50 percent of the patients receiving care.</li> <li>• Measure service lines or units where there is a high patient safety risk.</li> <li>• Identify and prioritize culture PI targets; provide adequate resources to address performance gaps over a specified period of time. <a href="#">[Fei, 2008; Smith, 2009]</a></li> <li>• Survey a valid sample to allow unit-level analysis and facilitate improvement.</li> </ul> </li> <li>▪ Critical care areas and services and high-volume and high-risk areas should be surveyed (e.g., emergency department, outpatient surgical services, diagnostic centers) and should include, in the aggregate, ambulatory totals to determine which of these areas should be targeted initially. <a href="#">[Donnelly, 2009; Kaafarani, 2009; Pater, 2009]</a></li> <li>▪ The results of the culture survey process should be documented and disseminated widely across the enterprise in a systematic and frequent manner. <a href="#">[Audet, 2008; Chadwick, 2009; Hutchinson, 2009]</a> The interventions component of this safe practice will be satisfied if the survey findings are documented and have been used to monitor and guide performance improvement interventions. <a href="#">[Pringle, 2009; Pronovost, 2005; Sexton, 2006; Sexton, 2007]</a></li> <li>▪ The organization should document that the results of the survey process, as defined in the <i>Leadership Structures and Systems</i> safe practice and by the activities defined in the <i>Teamwork Training and Skill Building</i> and the <i>Identification and Mitigation of Risks and Hazards</i> safe practices, have been provided to governance and senior medical leaders. <a href="#">[Note 2-5]</a></li> </ul>

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<p><b>Safe Practice 3: Teamwork Training and Skill Building</b>                      Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients.  <a href="#">[Note 3-3; Note 3-4; Note 3-5]</a></p> <p><b>Applicable Clinical Care Settings</b>                      This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 3 from 2009 Consensus Report).</b></p>	<p><b>Effective Team Leadership:</b> Training programs should systematically address and apply the principles of effective team leadership and team formation. <a href="#">[Salas, 2008]</a> Leadership at all levels of an organization should be fostered.</p> <p><b>Effective Teamwork Training:</b> Every organization should provide teamwork and communication training through basic and detailed programs. <a href="#">[Salas, 2008; Clark, 2009]</a></p> <ul style="list-style-type: none"> <li>▪ <b>Basic Teamwork Training:</b> Basic training should be provided annually to governance board members, senior administrative leaders, medical staff (both those who are independent and those who are employed by the organization), midlevel management, and front-line nurses. The subject matter should include sources of communication failures, hand-offs, and team failures that lead to patient harm. The length and modality of training should be established by the organization. Participation should be documented to verify compliance. <a href="#">[Salas, 2009]</a></li> <li>▪ <b>Detailed Teamwork Training:</b> All clinical staff and licensed independent practitioners should receive detailed training consisting of the best available teamwork knowledge; however, staff of clinical areas that are deemed to be at high risk for patient safety issues should receive such training first. The clinical areas that are prioritized should focus on specific patient safety risks. The subject matter should include the principles of high reliability, human factors applied to real-world care processes, interpersonal team dynamics, hand-offs, and specific communication methods. [Frankel, 2006; <a href="#">McKeon, 2009</a>] Focus should be placed on the development and application of structured tools. Detailed training should include a specified period of combined instruction and interactive dialogue about the application of the knowledge determined and documented by the organization. If all staff cannot be trained within one year, a goal should be set to train all clinical service area staff and caregivers over multiple years.</li> <li>▪ <b>Effective Teamwork Skill Building:</b> To develop the characteristics of “team-ness,” <a href="#">[Note 3-6]</a> individuals should build their teamwork and communication skills by establishing a shared mental model, using structured and critical language, understanding communication hand-off methods, and using effective assertion behaviors such as “stop-the-line” methods. Individuals and teams also should develop the skills necessary to monitor team performance continuously over time. Organizations should employ methods to verify the demonstration of teamwork skills. <a href="#">[Manser, 2009]</a> A specified number of care units or service line areas and length of training should be set and documented by organization leadership each year with initiatives for building and measuring teamwork skills.</li> </ul>

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<p><b>Safe Practice 3: Teamwork Training and Skill Building</b>                      Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients.                      (continued)</p>	<p><b>Effective Team-Centered Interventions:</b> In order to generate the greatest impact, team-centered performance improvement initiatives or projects should target the work “we do every day.” The units and service lines selected should be prioritized based on the risk to patients, which in turn should be based on the prevalence and severity of targeted adverse events. The interventions should address the frequency, complexity, and nature of teamwork and communication failures that occur in those areas. Each year, every organization should identify a specific number of teamwork-centered intervention projects it will undertake, such as those cited below and in the Example Implementation Approaches section. Ideally, team-centered interventions should be undertaken in all areas of care. <a href="#">[Note 3-7]</a></p> <ul style="list-style-type: none"> <li>▪ <b>Specific Team Performance Improvement Projects:</b> Organizations should select high-risk areas for performance improvement projects; these include emergency departments, labor and delivery, intensive care units, operating rooms, ambulatory care, and other procedural care units. Performance targets and strategies to close known performance gaps should be identified. Such performance improvement initiatives should have the components of education, skill building, measurement, reporting, and process improvement. <a href="#">[Note 3-8]</a></li> <li>▪ <b>Rapid Response Assessment:</b> Annually, organizations should formally evaluate the opportunity for using rapid response systems to address the issues of deteriorating patients across the organization. <a href="#">[Kaplan, 2009; Bellomo, 2003; IHI, N.D.; Note 3-9]</a></li> <li>▪ <b>Internal and External Reporting:</b> The performance improvement that is generated by team-centered interventions should be reported to governance boards and senior administrative management. Depending on the projects selected, the organization should submit the information to the appropriate external reporting organizations. <a href="#">[Drozda, 2008]</a></li> </ul> <p><b>Minimum Requirements of Practice 3:</b> To meet the minimum requirements of this safe practice, an organization can satisfy the Detailed Teamwork Training, Effective Teamwork Skill Building, and Effective Team-Centered Interventions requirements, defined above, by targeting an organization-determined number of units or service lines initially and additional new units each year, if the Effective Team-Centered Interventions requirements are satisfied, because it is expected that those involved would receive the required training and skill-building experiences. The requirements of the interventions component of the <i>Culture Measurement, Feedback, and Intervention</i> safe practice also will be met if improvement of the culture survey scores is an aim of the specific performance improvement projects that are undertaken.</p> <div data-bbox="1464 1208 1850 1332" style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice                      Red Text = Deleted Text                      Blue Underlined Text = New Text</p> </div>

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<p><b>Safe Practice 4: Identification and Mitigation of Risks and Hazards</b></p> <p>Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm.</p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 4 from 2009 Consensus Report).</b></p>	<p><b>Identification and Mitigation of Risks and Hazards</b></p> <ul style="list-style-type: none"> <li>▪ Risk and Hazard Identification Activities: Risks and hazards should be identified on an ongoing basis from multiple sources, including independent retrospective, real-time and near real-time, and prospective views. The risk and hazard analysis should integrate the information gained from multiple sources to provide organization-wide context. <a href="#">[AHRQ, 2009a]</a> The organizational culture should be framed by a focus on system (not individual) errors and blame-free reporting and should use data from risk assessment to create a just culture. <a href="#">[Nuckols, 2009; Pronovost, 2009b; Note 4-8]</a></li> <li>• Retrospective Identification: Organizations should use a number of retrospective measures and indicators to identify risk and contributing factors from historical data. Specific steps should be taken to ensure that the lessons learned are communicated across the organization and that they are applied in other care settings, where applicable. Some retrospective identification and analysis activities are triggered by adverse events; <a href="#">[Nuckols, 2009]</a> however, ideally the retrospective identification of risks and hazards should occur regularly, and progress reports should be generated as frequently as they are needed within each year. At least annually, a summary of progress based on an evaluation of the effectiveness of all of the relevant retrospective identification activities/tools listed below should be documented.             <ol style="list-style-type: none"> <li>1. <a href="#">Serious Reportable Events. Processes for identifying, managing, and analysis of events should be defined and implemented for every such event to identify patterns and opportunities for improvement.</a> <a href="#">[Levinson, 2008b; McDonald, 2009; Note 4-9; Note 4-10]</a></li> <li>2. <i>Sentinel Event Reporting and Analysis.</i> Processes for identifying, and managing, and analysis of events should be defined and implemented for every such event to identify patterns and opportunities for improvement. <a href="#">[Note 4-9; Note 4-10; Note 4-11]</a></li> <li>3. <i>Adverse Event Reporting.</i> <a href="#">Processes for identifying, managing, and analysis of events should be defined and implemented for every such event to identify patterns and opportunities for improvement.</a> <a href="#">[Note 4-9; Note 4-10]</a> A systematic approach to the assessment of adverse events should be undertaken. Such events may include the NQF-endorsed serious reportable events.</li> <li>4. <i>Root Cause Analysis.</i> The root cause analysis process for identifying the causal factors for events, including sentinel events, should be undertaken. <a href="#">[AHRQ, 2009b; Gupta, 2009; Note 4-12]</a></li> <li>5. <i>Closed Claims Analysis.</i> This analysis should be undertaken. <a href="#">[Richman, 2009]</a></li> <li>6. <i>Enterprise Systems Failures.</i> People systems, technology systems, and quality systems failures beyond those resulting in adverse outcomes should be evaluated.</li> <li>7. <i>Skill Mix.</i> Because the proportion between highly trained and less-qualified staff can have an impact on patient safety, the organization must regularly review for, evaluate, and address any imbalance. <a href="#">[Rodriguez-Paz, 2009]</a></li> <li>8. <i>Patient Safety Indicators.</i> Patient safety indicators should be used to generate hypotheses and guide deeper investigation. <a href="#">[Note 4-13]</a></li> <li>9. <i>Retrospective Trigger Tools.</i> Such tools should be used retrospectively through chart review and real-time or near real-time reviews as mentioned below. <a href="#">[Note 4-13]</a></li> <li>10. <i>External Reporting Source Input.</i> Such information should be an input to risk-assessment activities. <a href="#">[Reason, 2000]</a></li> </ol> </li> </ul> <div data-bbox="1464 1208 1850 1332" style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice  Red Text = Deleted Text  Blue Underlined Text = New Text</p> </div>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 4: Identification and Mitigation of Risks and Hazards</b></p> <p>Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm. (continued)</p>	<p>This organization-wide risk-assessment information should be provided to the governance board and senior administrative leadership continuously. The output of the activities of this element should be provided as an input to the activities articulated in the <i>Leadership Structures and Systems</i> safe practice.</p> <ul style="list-style-type: none"> <li>• Risk Mitigation Activities: Every organization has a unique risk profile and should carefully design performance improvement projects that target prioritized risk areas. An ongoing, proactive program for identifying and reducing unanticipated adverse events and safety risks to patients should be defined, documented, and implemented. <a href="#">[Damiani, 2009]</a></li> <li>• Performance Improvement Programs: The organization should provide documentation of performance improvement programs that bear evidence of the actions taken to close patient safety gaps identified in the <i>Identification and Mitigation of Risks and Hazards</i> safe practice. Such performance improvement programs should include education, skill building, measurement, reporting, and process improvement. <a href="#">[Denham, 2009a]</a> <ol style="list-style-type: none"> <li>1. <i>Targeted Performance Improvement Projects</i>: Specific patient safety risks and hazards identified by the activities described above should be targeted through performance improvement projects. <a href="#">[Warve, 2009]</a> Every organization should document the outcome, process, structure, and patient-centered measures of these projects. Organizations should document the projects' patient safety aims and regularly chart progress toward those aims. Such progress should be reported regularly to governance board members and senior administrative leaders as addressed in the <i>Leadership Structures and Systems</i> safe practice.</li> <li>2. <i>Systems Solutions</i>: Products, services, and technologies that enable the use of best practices in people systems, technology systems, and quality/safety systems should be considered in order to reduce the potential for patient harm. Performance improvement projects targeting these systems should be documented, and the progress of such projects should be charted and regularly reported to and through senior administrative leaders to governance board members.</li> <li>3. <i>Senior Leadership and Governance Engagement</i>: The direct participation of governance board and senior, midlevel, and line managers in monitoring the progress of all patient safety performance improvement programs should be documented. [Note 4-17; Denham, 2005; <a href="#">Pronovost, 2009a</a>] Tools such as summary reports, dashboards, or scorecards should be used to ensure that the most important messages are made as clear as possible and that information overload is minimized. Senior administrative leaders and governance board members should be involved in the selection of these monitoring tools for the organization. <a href="#">[Denham, 2009a]</a></li> </ol> </li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 4: Identification and Mitigation of Risks and Hazards</b></p> <p>Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm. <i>(continued)</i></p>	<ul style="list-style-type: none"> <li>• Specific Risk-Assessment and Mitigation Activities: The organization should provide documentation that bears evidence of high performance or of actions taken to close common patient safety gaps for the patient safety risk areas listed below. <a href="#">[Weingart, 2009]</a> <ol style="list-style-type: none"> <li>1. <i>Falls</i>: The organization should monitor the effectiveness of fall reduction programs, including risk reduction strategies, in-services, patient/family education, and environment of care redesign. [Note 4-18]</li> <li>2. <i>Malnutrition</i>: The organization should monitor its effectiveness in identifying malnutrition and in taking actions to reduce the potential adverse events that can result from malnutrition. For example, each patient should be evaluated upon admission, and periodically thereafter, for the risk of malnutrition. Clinically appropriate strategies should be employed to prevent malnutrition.</li> <li>3. <i>Pneumatic Tourniquets</i>: The organization should monitor its effectiveness in reducing the harm that can accompany high-risk procedures, including the use of pneumatic tourniquets (if they are used in the organization). For example, whenever a pneumatic tourniquet is used, the patient should be evaluated for risk of ischemia and/or thrombotic complication, and the appropriate prophylactic measures should be utilized.</li> <li>4. <i>Aspiration</i>: Upon admission and regularly thereafter, each patient should be screened for the risk of aspiration. An aspiration risk and prevention plan should be documented in the patient's record.</li> <li>5. <i>Workforce Fatigue</i>: Because workforce fatigue can have a direct impact on patient safety, every organization should be cognizant of the issue and should include aspects of precursors and alleviation in an annual review of patient safety risk in the organization.</li> </ol> </li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 5: Informed Consent</b>            Ask each patient or legal surrogate to “teach back,” in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.  <a href="#">[Pizzi, 2001; IHI, 2009]</a></p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 5 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ At a minimum, patients should be able to explain, in their everyday words, <a href="#">[Shaw, 2009]</a> the diagnosis/health problem for which they need care; the name/type/general nature of the treatment, service, or procedure, including what receiving it will entail; and the primary risks, benefits, and alternatives. This safe practice includes all of the following elements:               <ul style="list-style-type: none"> <li>• Informed consent documents for use with the patient should be written at or below the 5th-grade level and in the <b>primary preferred</b> language of the patient. <a href="#">[Garcia, 2008; Shaw, 2009]</a></li> <li>• The patient, and, as appropriate, the family and other decision-makers, should be engaged in a dialogue about the nature and scope of the procedure for which consent is being sought.</li> <li>• A qualified medical interpreter or reader should be provided to assist patients with limited English proficiency, limited health literacy, and visual or hearing impairments.</li> <li>• The risk that is associated with high-risk elective cardiac procedures and high-risk procedures with the strongest volume-outcomes relationship should be conveyed. [Note 5-1] <b>This information should include comparative hospital mortality and volume of esophagectomy and pancreatectomy for hospitals in the patient’s medical service area by those providers with the lowest volumes.</b> <a href="#">[Grumbach, 1995; Dardik, 1998; Birkmeyer 2000a; Birkmeyer 2000b; Birkmeyer, 2002; Chang, 2002; Dimick, 2006; Synnes, 2006]</a></li> </ul> </li> </ul>

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<p><b>Safe Practice 6: Life-Sustaining Treatment</b>            Ensure that written documentation of the patient's preferences for life-sustaining treatments is prominently displayed in his or her chart. <a href="#">[Cerminara, 2008]</a></p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 6 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>Organization policies, consistent with applicable law and regulation, should be in place and address patient preferences for life-sustaining treatment and withholding resuscitation. [Note 6-1; <a href="#">Note 6-2</a>; <a href="#">Note 6-3</a>]</li> </ul>

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<p><b>Safe Practice 7: Disclosure</b>            Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.  <a href="#">[MCPME, 2006; UMich, 2009; IHI, 2009]</a></p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 7 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ The types of serious unanticipated outcomes addressed by this practice include, at a minimum: a) sentinel events; <a href="#">[TJC, 2009b]</a> b) serious reportable events; <a href="#">[NQF, 2002]</a> and c) any other unanticipated outcomes involving harm that require the provision of substantial additional care (such as diagnostic tests/therapeutic interventions or increased length of stay) or that cause the loss of limb or limb function lasting seven days or longer. <a href="#">[TJC, 2009a]</a></li> <li>▪ Organizations must have formal processes for disclosing unanticipated outcomes and for reporting events to those responsible for patient safety, including external organizations, where applicable, and for identifying and mitigating risks and hazards. <a href="#">[Kussman, 2008]</a></li> <li>▪ The governance and administrative leadership should ensure that such information is systematically used for performance improvement by the organization. Policies and procedures should incorporate continuous quality improvement techniques and provide for annual reviews and updates. <a href="#">[Sorensen, 2008]</a></li> <li>▪ Adherence to the practice and participation with the support system is expected and may be considered as part of credentialing.</li> <li>▪ <b>Patient Communication <a href="#">with patients, their families and caregivers</a></b>, should include or be characterized by the following:               <ul style="list-style-type: none"> <li>• the “facts”—an explicit statement about what happened that includes an explanation of the implications of the unanticipated outcome for the patient’s future health, an explanation of why the event occurred, and information about measures taken for its preventability; [Fein, 2007; <a href="#">Holden, 2009]</a></li> <li>• empathic communication of the “facts,” a skill that should be developed and practiced in healthcare organizations;</li> <li>• an explicit and empathic expression of regret that the outcome was not as expected (e.g., “I am sorry that this has happened.”);</li> <li>• a commitment to investigate and as possible prevent future occurrences by collecting the facts about the event and providing them to the organization’s patient safety leaders, including those in governance positions;</li> <li>• feedback of results of the investigation, including whether or not it resulted from an error or systems failure, provided in sufficient detail to support informed decision-making by the patient; <a href="#">[O’Connell, 2009]</a></li> <li>• “timeliness”—the initial conversation with the patient and/or family should occur within 24 hours, whenever possible. Early and subsequent follow-up conversations should occur, both to maintain the relationship and to provide information as it becomes available;</li> <li>• an apology from the patient’s licensed independent practitioner (LIP) and/or an administrative leader should be offered if the investigation reveals that the adverse outcome clearly was caused by unambiguous errors or systems failures;</li> </ul> </li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 7: Disclosure</b></p> <p>Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.</p> <p><i>(continued)</i></p>	<ul style="list-style-type: none"> <li>• an apology from the patient’s licensed independent practitioner (LIP) and/or an administrative leader should be offered if the investigation reveals that the adverse outcome clearly was caused by unambiguous errors or systems failures;</li> <li>• emotional support for patients and their families by trained caregivers should be provided; <a href="#">[HBQI, 2008; Iedema, 2008]</a> and</li> <li>• a disclosure and improvement support system should be established and maintained to provide the following to caregivers and staff that includes:             <ul style="list-style-type: none"> <li>– emotional support for caregivers and administrators involved in such events by trained caregivers in the immediate post-event period that may extend for weeks afterward,</li> <li>– education and skill building about the concepts, tools, and resources that produce optimal results from this practice, centered on systems improvement rather than blame, and with a special emphasis on creating a just culture, <a href="#">[Frankel, 2006; Sorensen, 2008; Gallagher, 2009b]</a></li> <li>– 24-hour availability of advisory support to caregivers and staff to facilitate rapid responses to serious unanticipated outcomes, including “just-in-time” coaching and emotional support, and</li> <li>– education of caregivers on the importance and technique of disclosure to care teams of errors or adverse events when they happen. <a href="#">[Keller, 2009; Shannon, 2009]</a></li> </ul> </li> <li>▪ Healthcare organizations should implement a procedure to ensure and document that all LIPs are provided with a detailed description of the organization’s program for responding to adverse events, including the full disclosure of error(s) that may have caused or contributed to patient harm. This is done with the expectation that <a href="#">the healthcare organizations and/or the</a> LIPs will provide this information to their individual medical malpractice liability carriers in the event that they are provided liability coverage from entities outside of the organization. All new employees should also receive this information.</li> <li>▪ A process should be in place to consider providing information to a Patient Safety Organization that would provide a patient safety evaluation program to protect privileged and confidential information. [AHRQ, 2008; Public Law 109-41]</li> <li>▪ A process should be in place to consider early remediation and the waiving of billing for care services provided during the care episode and for subsequent treatment if the event was due to unambiguous systems failures or human error.</li> </ul>

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<p><b>Safe Practice 8: Care of the Caregiver</b></p> <p>Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events.            [Frankel, 2006; <a href="#">Note 8-1</a>; <a href="#">Note 8-2</a>; <a href="#">Note 8-3</a>]</p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 8 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Indications               <ul style="list-style-type: none"> <li>• At a minimum, the types of serious unanticipated outcomes addressed by this practice include a) sentinel events; b) serious reportable events; or c) any other unanticipated outcomes that involve harm and require substantial additional care (such as diagnostic tests/therapeutic interventions or increased length of stay) or cause loss of limb or limb function lasting seven days or longer. (This definition of events triggering the implementation of this practice is identical to that in <i>Safe Practice 7: Disclosure</i>.) [NQF, 2003; <a href="#">Note 8-4</a>]</li> <li>• For the purposes of this practice, caregivers shall mean clinical providers, staff, and administrators “involved” in adverse events as defined above. Involvement is defined as being directly involved AND indirectly involved in the event. Those who were directly involved may be those whose activities had a direct bearing on the systems failures or error that led to patient harm. Those who were indirectly involved may be individuals who have been impacted by the event and who may be only tangentially involved in the error chain or systems failure that led to the event.</li> </ul> </li> <li>▪ Formal structures, systems, and policies should be established so that administrative leaders have direct authority and accountability 24/7/365 to ensure that caregivers, staff, and administrators receive: [Denham, 2008d]               <ul style="list-style-type: none"> <li>• Treatment That Is Just: A well-organized, evidence-based process should be followed to assess the behavior of individuals directly involved in an adverse event to identify issues of substance abuse, intentional harm, illness, reckless violations of clear policies and procedures, and/or gross negligence, in order to avoid inappropriate blame. [Marx, 2007; Reason, 1997; Frankel, 2006; <a href="#">Wachter, 2009</a>] Those who were involved in an incident that is the result of systems faults or predictable human performance factor failure should be clearly designated as free from direct personal blame by a senior administrative leader in a manner that is visible to the entire organization. This process should be undertaken within 24 hours of having enough factual information to support it. [Denham, 2007; Denham, 2008b; <a href="#">McDonald, 2009</a>] If, after an event investigation, the organization is contemplating a corrective action that could result in a serious loss of livelihood of an individual, [<a href="#">Dunbar, 2009</a>] that individual should be notified of the potential action, and he or she should be advised that he or she may want to exercise the opportunity to seek the advice of legal counsel before providing a formal statement about the corrective action.</li> <li>• Respect: A formalized process should be followed by designated administrative senior leaders immediately after an incident to ensure that the individuals who are directly or indirectly involved are treated with respect and dignity. This process should outline who will interact with directly involved individuals and should recognize that these individuals may be undergoing extreme stress and discomfort. As those who interact with directly involved individuals address issues such as continued work, communication with co-workers, and follow-up investigations, they should treat the individuals as they themselves would wish to be treated had they unintentionally harmed a patient. Individuals should be treated as innocent of intentional or reckless harm until proven otherwise. By whatever means will best reach the organization, senior administrators should publicly request that all involved caregivers be treated with respect and dignity. [Marx, 2007; Reason, 1997; Denham, 2007; Denham, 2008b; Denham, 2008d; Denham, 2008a] (See Implementation Example Approach.)</li> </ul> </li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 8: Care of the Caregiver</b>            Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events.  <i>(continued)</i></p>	<ul style="list-style-type: none"> <li>• Understanding and Compassion: A formalized process should be followed by a designated administrative leader to invite co-workers to express personal understanding and compassion to those directly and indirectly involved in such events as defined above. Designated administrative leaders should be trained in the critical importance of forgiveness and the provision of personal support to individuals involved in unintentionally and seriously harming others. [Denham, 2008b; Berlinger, 2007; Purtilo, 2005]</li> <li>• Supportive Care: Caregivers, staff, and administrators directly involved in serious unintentional harm as defined above must be considered “patients requiring immediate and ongoing care.” A process must be established and regularly updated that must be led by a designated team or leader to ensure that all individuals directly involved and indirectly involved in the incident have the opportunity to receive appropriate professional care and are assessed for fitness for work to ensure their safety, that of their co-workers, and that of the patients they will serve in the future. Such a process should include a structure and system for all who are directly and indirectly involved in an incident to voluntarily request such supportive care, and a structure, system, and accountability should be established for mandatory “fitness for work” assessments of individuals directly involved in events. Such assessments and supportive care should also be considered for “near misses” that are reported to the organization.</li> <li>• Transparency: Those individuals who are directly or indirectly involved in events should be invited to fully participate in the investigation and analysis of the incident unless, through the process defined above, they were found to have been engaged in substance abuse or gross negligence, or their behavior was found to have intentionally induced harm. [Denham, 2007; Denham, 2008b; Denham, 2008e; Denham, 2006b; <a href="#">McDonald, 2009</a>]</li> </ul> <ul style="list-style-type: none"> <li>▪ Formal structures, systems, and policies should be established to educate senior administrators, caregivers, and staff about the vulnerabilities of caregivers who have been involved in unintentional harm and to provide “just-in-time” coaching to administrative leaders who are accountable for executing the actions defined in this practice. [Boothman, 2009]</li> <li>▪ The governance and administrative leadership should ensure that the information captured during the administration of this practice is systematically used for performance improvement by the healthcare organization. Policies and procedures should incorporate continuous quality improvement techniques and should provide for quarterly reviews and updates.</li> <li>▪ A process should be in place to consider providing information to a Patient Safety Organization that would provide a patient safety evaluation program to protect privileged and confidential information. [AHRQ, 2008; Public Law 109-41]</li> </ul> <div data-bbox="1464 1208 1850 1329" style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice            Red Text = Deleted Text            Blue Underlined Text = New Text</p> </div>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 9: Nursing Workforce</b>            Implement critical components of a well-designed nursing workforce that mutually reinforce patient safeguards, including the following:</p> <ul style="list-style-type: none"> <li>▪ A nurse staffing plan with evidence that it is adequately resourced and actively managed and that its effectiveness is regularly evaluated with respect to patient safety; [IOM, 2004; <a href="#">Rother, 2009</a>]</li> <li>▪ Senior administrative nursing leaders, such as a Chief Nursing Officer, as part of the hospital senior management team; [IOM, 2004; <a href="#">Laschinger, 2009</a>; <a href="#">Simpson, 2009</a>]</li> <li>▪ Governance boards and senior administrative leaders that take accountability for reducing patient safety risks related to nurse staffing decisions and the provision of financial resources for nursing services; [IOM, 2004]</li> <li>▪ Provision of budgetary resources to support nursing staff in the ongoing acquisition and maintenance of professional knowledge and skills. [IOM, 2004; <a href="#">Rafferty, 2009</a>]</li> </ul> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 9 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Implement explicit organizational policies and procedures, with input from nurses at the unit level, on effective staffing targets that specify the number, competency, and skill mix of nursing staff needed to provide safe, direct care services. [<a href="#">Smith, 2009</a>; Note 9-1]</li> <li>▪ Ensure that the governance board and senior, midlevel, and line managers are educated about the impact of nursing on patient safety.</li> <li>▪ Conduct ongoing organization-wide patient safety risk assessments to identify patient safety risks related to nurse staffing, nurse work hours, temporary nurse coverage, and other areas related to the prevention of patient harm. [<a href="#">Note 9-2</a>; <a href="#">Seago, 2001</a>] This assessment must be reviewed by senior administrative management and the governance board at least annually to ensure that resources are allocated and performance improvement programs are implemented.</li> <li>▪ Use the data collected and analyzed from the daily monitoring of actual unit-specific nurse staffing levels to identify and address potential patient safety-related staffing issues. [Note 9-3] Such data should include, but not be limited to, nursing hours per patient day as defined in the NQF report, <i>National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set</i>. [Note 9-3]</li> <li>▪ Provide regular reports, at intervals determined by leadership, of unit-specific, potential patient safety-related staffing issues to senior nursing leadership, the governance board, and senior administrative leaders. [Note 9-4]</li> <li>▪ Put in place and document performance improvement programs that include the elements of education, skill building, measurement, reporting, and process improvement, and provide evidence of the actions taken to close patient safety gaps related to nursing services. [<a href="#">NWMH, 2003</a>]</li> <li>▪ Provide reports at least annually to the public through the appropriate organizations.</li> <li>▪ Ensure, through ongoing assessments by managers/leaders in the practice environment, that all nurses are oriented and competent to provide safe care to the patients to whom they are assigned, including nurses who are new to the organization, temporary staff, float pool nurses, contract staff, and temporarily assigned nurses. [Note 9-5; <a href="#">IHI, 2003</a>] Ongoing education must be provided through in-services, training, and other activities to maintain and improve the competencies specific to the assigned duties [<a href="#">Duffield, 2008</a>] and job responsibilities related to patient safety, infection control, and the population served. [Note 9-6]</li> </ul>

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<p><b>Safe Practice 10: Direct Caregivers</b>            Ensure that non-nursing direct care staffing levels are adequate, that the staff are competent, and that they have had adequate orientation, training, and education to perform their assigned direct care duties.</p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 10 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Establish a staffing plan that is adequately resourced and actively managed, and the effectiveness of which is regularly evaluated with respect to patient safety. <a href="#">[NWMH, 2003; IHI, 2007]</a></li> <li>▪ Conduct ongoing patient safety risk assessment to identify the patient safety risks related to non-nursing direct care worker staffing, work hours, temporary staff coverage, and other areas related to the prevention of patient harm. [Note 10-1] This assessment must be reviewed by senior administrative management and the governance board at least annually to ensure that resources are allocated and performance improvement programs are implemented.</li> <li>▪ Senior administrative management and the governance board should ensure that resources are allocated and performance improvement programs are implemented based on their review of patient risk assessments related to non-nursing direct care worker staffing. Ideally all non-nursing direct care staff areas are assessed; however, at a minimum, the categories of direct care staff that in aggregate have direct contact with patients must be assessed.</li> <li>▪ Establish and consistently implement explicit policies and procedures to ensure that effective staffing targets are met. These should specify the number, competency, and skill mix of staff related to safe care, with input from front-line staff at the unit level.</li> <li>▪ Put in place and document performance improvement programs that include the elements of education, skill building, measurement, reporting, and process improvement, and provide evidence of the actions taken to close the patient safety gaps that are related to non-nursing direct caregiver services.</li> <li>▪ Provide reports, at least annually, about the impact of non-nursing direct caregivers on patient safety to the governance board and senior administrative leaders.</li> <li>▪ Ensure, through ongoing assessments by managers/leaders in the practice environment, that all staff are oriented and competent to provide safe care to the patients to whom they are assigned, [Note 10-2] including staff who are new to the organization, temporary staff, float pool staff, or contract staff, or those who are temporarily assigned. Ongoing education must be provided through in-services, training, and other activities to maintain and improve the competencies specific to the assigned duties and job responsibilities related to patient safety, infection control, and the populations served. <a href="#">[Clark, 2009; Regan, 2009;</a> Note 10-3]</li> </ul>

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<p><b>Safe Practice 11: Intensive Care Unit Care</b>                      All patients in general intensive care units (both adult and pediatric) should be managed by physicians who have specific training and certification in critical care medicine ("critical care certified").</p> <p><b>Applicable Clinical Care Settings</b>                      This practice is applicable to CMS care settings, to include inpatient service/hospital.</p> <p><b>Note: No material change to this practice (SP 11 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ A "critical care certified" physician is one who has obtained critical care subspecialty certification by the American Board of Anesthesiology, the American Board of Internal Medicine, the American Board of Pediatrics, or the American Board of Surgery, or has completed training prior to the availability of subspecialty board certification in critical care in his or her specialty, and is board certified in one of these four specialties and has provided at least six weeks of full-time intensive care unit (ICU) care annually since 1987. <a href="#">[TJC, 2009; Note 11-2; Note 11-3]</a></li> <li>▪ Dedicated, critical care certified physicians shall be present in the ICU during daytime hours, a minimum of eight hours per day, seven days per week, and shall provide clinical care exclusively in the ICU during this time.</li> <li>▪ When a critical care certified physician is not present in the ICU, such a physician shall provide telephone coverage to the ICU and return more than 95 percent of ICU pages within five minutes (excluding low-urgency pages, if the paging system can designate them). When not in the hospital, the critical care certified physician should be able to rely on an appropriately trained onsite clinician to reach ICU patients within five minutes in more than 95 percent of cases.</li> <li>▪ If it is not possible to have a dedicated, critical care certified physician in the ICU eight hours daily, an acceptable alternative is to provide exclusively dedicated round-the-clock ICU telemonitoring by a critical care certified physician, if the system allows real-time access to patient information that is identical to onsite presence (except for manual physical examination). [Rosenfeld, 1999; Rosenfeld, 2000]</li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 12: Patient Care Information</b>            Ensure that care information is transmitted and appropriately documented in a timely manner and in a clearly understandable form to patients <u>and appropriate family and caregivers</u>, and to all of the patient’s healthcare providers/professionals, within and between care settings, who need that information to provide continued care. [MCPME, N.D.]</p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 12 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>• Identify communication gaps and/or failures about critical test results, implement performance improvement programs to ensure timely closure of information loops, and report the gaps and improvement progress to senior leadership and the board of governance.</li> <li>• Implement a standardized process to ensure that critical results are communicated quickly to a licensed healthcare provider so that action can be taken. <u>[Note 12-1; Valenstein, 2008; Rensburg, 2009]</u> Values defined as critical by the laboratory must be reported to the responsible licensed practitioner within the timeframes established by the laboratory in cooperation with nursing and medical staff. <u>[Valenstein, 2008; Huang, 2009]</u></li> <li>• Put in place intra- and intercare setting processes to ensure that, when the patient’s responsible licensed practitioner is not available within the specified timeframes, there is a mechanism to report critical information to an alternate responsible practitioner. <u>[Note 12-2]</u> Also, include a process of how to communicate critical test results that are completed after the patient has been discharged from the organization.</li> <li>• Ensure that patients have access to their medical records, which should include, but not be limited to, medical histories and consultations, test results, including laboratory reports and imaging (including copies of imaging studies), medication lists, advance directives, and procedural reports, within 24 hours of a written request that includes the appropriate release documentation. Use technology to facilitate patient care information when possible. <u>[Matheny, 2007; Reid, 2008; Piva, 2009]</u></li> </ul>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 13: Order Read-Back and Abbreviations</b>                      Incorporate within your organization a safe, effective communication strategy, structures, and systems to include the following: <a href="#">[Note 13-2: Note 13-3: Note 13-5: Note 13-6]</a></p> <ul style="list-style-type: none"> <li>▪ For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and “read-back” the complete order or test result. [Note 13-1]</li> <li>▪ Standardize a list of “Do Not Use” abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization.</li> </ul> <p><b>Applicable Clinical Care Settings</b>                      This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 13 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ The process of verbal orders should be avoided except when it is impossible or impractical for the prescriber to write the order or enter it in the computer. <a href="#">[Baum, 2009]</a> Explicit organizational policies and procedures on verbal and telephone orders should include, at a minimum:                             <ul style="list-style-type: none"> <li>• strategies to minimize the use of verbal and telephone orders, [Note 13-2] and</li> <li>• the identification of items that cannot be ordered or reported verbally or by telephone.</li> </ul> </li> <li>▪ The receiver of verbal information writes down the complete order or test result or enters it into a computer.</li> <li>▪ The receiver reads back the order or test result.</li> <li>▪ The receiver receives confirmation from the individual who gave the order or test result.</li> <li>▪ Rigorously prohibit the use of terms known to lead to misinterpretation including, at a minimum, <i>u, IU, qd, qod, trailing zero, absence of leading zero, MS, MSO4, MgSO4</i>.</li> <li>▪ At a minimum, prohibit terms known to lead to misinterpretation from all orders and other medication- related documentation when handwritten, entered as free text into a computer, or on preprinted forms.</li> <li>▪ Use the metric system to express all doses on prescription orders, except for therapies that use standard units, such as insulin and vitamins.</li> <li>▪ Trailing zeros may be used in non-medication-related documentation when there is a clear need to demonstrate the level of precision, such as for laboratory values.</li> </ul>

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<p><b>Safe Practice 14: Labeling of Diagnostic Studies</b>            Implement standardized policies, processes, and systems to ensure accurate labeling of radiographs, laboratory specimens, or other diagnostic studies, so that the right study is labeled for the right patient at the right time. <a href="#">[Note 14-1; Note 14-2]</a></p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 14 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Label laboratory specimen containers at the time of use and in the presence of the patient. <a href="#">[Note 14-3]</a></li> <li>▪ Take the critical steps of identifying the individual and matching the intended service or treatment, including read-back, to that individual to prevent miscommunication or inaccurate labeling. <a href="#">[Note 14-4]</a></li> <li>▪ Use at least two patient identifiers (neither to be the patient’s room number or physical location) when taking blood samples or other specimens for clinical testing, imaging, or providing any other treatments and procedures. <a href="#">[Note 14-1; Note 14-5]</a></li> <li>▪ Label x-ray imaging studies with the correct patient information while in the darkroom or close to the imaging device.</li> <li>▪ Mark “left” or “right” on each radiographic image to prevent misinterpretation on the light box.</li> <li>▪ Monitor and report errors and harm related to mislabeling to the organization-wide risk-assessment activity as part of a performance improvement program that addresses mislabeling of specimens or diagnostic studies. <a href="#">[Note 14-6]</a></li> </ul>

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<p><b>Safe Practice 15: Discharge Systems</b></p> <p>A “discharge plan” must be prepared for each patient at the time of hospital discharge, and a concise discharge summary must be prepared for and relayed to the clinical caregiver accepting responsibility for post-discharge care in a timely manner. Organizations must ensure that there is confirmation of receipt of the discharge information by the independent licensed practitioner who will assume the responsibility for care after discharge. <a href="#">[Jack, 2009; Note 15-1]</a></p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 15 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Discharge policies and procedures should be established and resourced and should address: <a href="#">[Clancy, 2009; Note 15-2]</a> <ul style="list-style-type: none"> <li>• explicit delineation of roles and responsibilities in the discharge process;</li> <li>• preparation for discharge occurring, with documentation, throughout the hospitalization;</li> <li>• reliable information flow from the primary care physician (PCP) or referring caregiver on admission, to the hospital caregivers, and back to the PCP, after discharge, using standardized communication methods; <a href="#">[Sherman, 2009]</a></li> <li>• completion of discharge plan and discharge summaries before discharge; <a href="#">[Jack, 2009]</a></li> <li>• patient or, as appropriate, family perception of coordination of discharge care; and</li> <li>• benchmarking, measurement, and continuous quality improvement of discharge processes.</li> </ul> </li> <li>▪ A written discharge plan must be provided to each patient at the time of discharge that is understandable to the patient and/or his family or guardian and appropriate to each individual’s health literacy and English language proficiency. <a href="#">[Chugh, 2009; Were, 2009]</a> At a minimum, the discharge plan must include the following:           <ul style="list-style-type: none"> <li>• reason for hospitalization;</li> <li>• medications to be taken post-discharge, including, as appropriate, resumption of pre-admission medications, how to take them, and how to obtain them;</li> <li>• instructions for the patient on what to do if his or her condition changes; and</li> <li>• coordination and planning for follow-up appointments that the patient can keep and follow-up of tests and studies for which confirmed results are not available at the time of discharge. <a href="#">[Cook, 2009; Sherman, 2009]</a></li> </ul> </li> <li>▪ A discharge summary must be provided to the ambulatory clinical provider who accepts the patient’s care after hospital discharge. <a href="#">[Note 15-3]</a> At a minimum, the discharge summary should include the following:           <ul style="list-style-type: none"> <li>• reason for hospitalization;</li> <li>• significant findings;</li> <li>• procedures performed and care, treatment, and services provided to the patient;</li> <li>• the patient’s condition at discharge;</li> <li>• information provided to the patient and family;</li> <li>• a comprehensive and reconciled medication list; <a href="#">[Note 15-4]</a> and</li> <li>• a list of acute medical issues, tests, and studies for which confirmed results are unavailable at the time of discharge and require follow-up.</li> </ul> </li> <li>▪ Original source documents (e.g., laboratory or radiology reports or medication administration records) should be in the transcriber’s immediate possession and should be visible when it is necessary to transcribe information from one document to another.</li> <li>▪ The organization should ensure and document receipt of discharge information by caregivers who assume responsibility for post-discharge care. This confirmation may occur through telephone, fax, e-mail response, or other electronic response using health information technologies. <a href="#">[Zsenits, 2009]</a></li> </ul>

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<p><b>Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry</b></p> <p>Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure. <a href="#">[Alfreds, 2009; Note 16-1]</a></p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include inpatient service/hospital.</p> <p><b>Note: No material change to this practice (SP 16 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Providers enter orders using an integrated, electronic information management system that is based on a documented implementation plan that includes or provides for the following:           <ul style="list-style-type: none"> <li>• Risks and hazards assessment to identify the performance gaps to be closed, including the lack of standardization of care; high-risk points in medication management systems such as at the point of order entry and upon the administration of medications; and the introduction of disruptive innovations. <a href="#">[Singh, 2009]</a></li> <li>• Prospective re-engineering of care processes and workflow. [Note 16-2; <a href="#">Niazkhani, 2009]</a></li> <li>• Readiness of integrated clinical information systems that include, at a minimum, the following information and management systems: <a href="#">[Note 16-3]</a> <ul style="list-style-type: none"> <li>– Admit Discharge and Transfer (ADT).</li> <li>– Laboratory with Electronic Microbiology Output.</li> <li>– Pharmacy.</li> <li>– Orders.</li> <li>– Electronic Medication Administration Record (including patient, staff, and medication ID) (eMAR).</li> <li>– Clinical Data Repository with Clinical Decision Support Capability.</li> <li>– Scheduling.</li> <li>– Radiology.</li> <li>– Clinical Documentation.</li> </ul> </li> <li>• Readiness of hospital governance, staff, and independent practitioners, including board governance, senior administrative management, front-line caregivers, and independent practitioners. [Note 16-4; <a href="#">Note 16-5]</a></li> <li>• The following CPOE specifications, which: <a href="#">[Note 16-6]</a> <ul style="list-style-type: none"> <li>– facilitate the medication reconciliation process;</li> <li>– are part of an Electronic Health Record Information System or an existing clinical information system that is bi-directionally and tightly interfaced with, at a minimum, the pharmacy, the clinical documentation department (including medication administration record), and laboratory systems, to facilitate review of all orders by all providers;</li> <li>– are linked to prescribing error-prevention software with effective clinical decision support capability;</li> <li>– require prescribers to document the reasons for any override of an error prevention notice;</li> <li>– enable and facilitate the timely display and review of all new orders by a pharmacist before the administration of the first dose of medication, except in cases when a delay would cause harm to a patient;</li> <li>– facilitate the review and/or display of all pertinent clinical information about the patient, including allergies, height and weight, medications, imaging, laboratory results, and a problem list, all in one place;</li> <li>– categorize medications into therapeutic classes or categories (e.g., penicillin and its derivatives) to facilitate the checking of medications within classes and retain this information over time; and</li> <li>– have the capability to check the medication ordered as part of effective clinical decision support for dose range, dosing, frequency, route of administration, allergies, drug-drug interactions, dose adjustment based on laboratory results, excessive cumulative dosing, and therapeutic duplication.</li> </ul> </li> </ul> </li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 17: Medication Reconciliation</b>                      The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care.  <a href="#">[Note 17-1; Note 17-2; Note 17-3; Note 17-4; Note 17-5]</a></p> <p><b>Applicable Clinical Care Settings</b>                      This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 17 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Educate clinicians upon hire on the importance of medication reconciliation; frequency of ongoing education is based on the risk of noncompliance and adverse drug events as determined by the organization. <a href="#">[Note 17-6]</a></li> <li>▪ Providers receiving the patient in a transition of care should check the medication reconciliation list to make sure it is accurate and in concert with any new medications that are ordered/prescribed.</li> <li>▪ The list should include the full range of medications as defined by accrediting organizations such as The Joint Commission. At a minimum, the list should include the following:                             <ul style="list-style-type: none"> <li>• prescription medications;</li> <li>• sample medications;</li> <li>• vitamins;</li> <li>• nutraceuticals;</li> <li>• over-the-counter drugs;</li> <li>• complementary and alternative medications;</li> <li>• radioactive medications;</li> <li>• respiratory therapy-related medications;</li> <li>• parenteral nutrition;</li> <li>• blood derivatives;</li> <li>• intravenous solutions (plain or with additives);</li> <li>• investigational agents; and</li> <li>• any product designated by the Food and Drug Administration (FDA) as a drug.</li> </ul> </li> <li>▪ At the time the patient enters the organization or is admitted, a complete list of medications the patient is taking at home (including dose, route, and frequency) is created and documented. The patient, and family, as needed, are involved in creating this list.</li> <li>▪ The medications ordered for the patient while under the care of the organization are compared to those on the list created at the time of entry to the organization or admission. According to The Joint Commission's FAQ, organizations should keep two lists during the hospitalization. The "home medications" list should be maintained unchanged and available for subsequent use in the reconciliation process. The list of the patient's current medications while in the hospital is a dynamic document that will require updating whenever changes are made to the patient's medication regimen. Both lists should be considered whenever reconciliation is carried out. The reason for referring to the "home" medication list is that some "home" medications may be held when a patient is admitted or goes to surgery. They may need to be resumed upon transfer to a different level of care, return from the operating room, or at discharge. <a href="#">[Note 17-1]</a></li> <li>▪ Any discrepancies (i.e., omissions, duplications, adjustments, deletions, additions) are reconciled and documented while the patient is under the care of the organization.</li> <li>▪ When the patient's care is transferred within the organization (e.g., from the ICU to a floor), the current provider(s) inform(s) the receiving provider(s) about the up-to-date reconciled medication list and document(s) the communication.</li> <li>▪ The patient's most current reconciled medication list is communicated to the next provider of service, either within or outside the organization. The communication between providers is documented.</li> </ul> <div data-bbox="1464 1208 1850 1332" style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice                      Red Text = Deleted Text                      Blue Underlined Text = New Text</p> </div>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 17: Medication Reconciliation</b>                      The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care.  <i>(continued)</i></p>	<ul style="list-style-type: none"> <li>▪ At the time of transfer, the transferring organization informs the next provider of service of how to obtain clarification on the list of reconciled medications.</li> <li>▪ When the patient leaves the organization's care, the current list of reconciled medications is provided to the patient, and family, as needed, and is explained to the patient and/or family, and the interaction is documented. <a href="#">[Jack, 2009; Note 17-7]</a></li> <li>▪ In settings where medications are used minimally, or are prescribed for a short duration, modified medication reconciliation processes are performed:                             <ul style="list-style-type: none"> <li>• The organization obtains and documents an accurate list of the patient's current medications and known allergies in order to safely prescribe any setting-specific medications (e.g., IV contrast, local anesthesia, antibiotics) and to assess for potential allergic or adverse drug reactions.</li> <li>• If no changes are made to the patient's current medication list, or when only short-term medications (e.g., a pre-procedure medication or a short-term course of an antibiotic) will be prescribed, the patient, and family, as needed, are provided with a list containing the short-term medication additions that the patient will continue after leaving the organization.</li> <li>• In these settings, there is a complete, documented medication reconciliation process when:                                     <ul style="list-style-type: none"> <li>– Any new long-term (chronic) medications are prescribed.</li> <li>– There is a prescription change for any of the patient's current known long-term medications.</li> <li>– The patient is required to be subsequently admitted to an organization from these settings for ongoing care.</li> </ul> </li> <li>• When a complete, documented, medication reconciliation is required in any of these settings, the complete list of reconciled medications is provided to the patient and the patient's family, as needed, and to the patient's known primary care provider or original referring provider, or a known next provider of service.</li> </ul> </li> </ul>

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<p><b>Safe Practice 18: Pharmacist Leadership Structures and Systems</b></p> <p>Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization.</p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 18 from 2009 Consensus Report).</b></p>	<p><b>Leadership and Culture of Safety</b></p> <p>A structure should be established and maintained to ensure that pharmacy leaders engage in regular, direct communications with the administrative leaders and the board of directors about medication management systems performance. <a href="#">[NQF, 2006; ASHP, 2003]</a></p> <p>Pharmacists should actively participate in medication management processes, structures, and systems, by, at a minimum:</p> <ul style="list-style-type: none"> <li>▪ Working with the interdisciplinary team to ensure safe and effective medication use across the continuum of care as patients move from one setting to another (e.g., from ambulatory care to inpatient to home care). <a href="#">[Chiquette, 1998; Dudas, 2002; Schnipper, 2006; Koshman, 2008; Jack, 2009]</a></li> <li>▪ Establishing pharmacy leadership structures and systems to ensure organization awareness of medication safety gaps; that there is direct accountability of senior leadership for these gaps with adequate budget available for performance improvement; and that action is taken to ensure the safe medication use by every patient. <a href="#">[Manasse, 2000; Mark, 2007a; Mark, 2007b]</a></li> <li>▪ Supporting an organizational culture of safe medication use; measuring pharmacy staff safety culture; providing feedback to leadership and staff; and undertaking interventions that will reduce medication safety risks. <a href="#">[Connor, 2007; Clarke, 2007; ISMP, 2007; Ashcroft, 2009]</a></li> <li>▪ Establishing a proactive, systematic, and organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable patient harm. <a href="#">[Seghal, 2008; Clark, 2009]</a></li> <li>▪ Systematically identifying and mitigating medication safety risks and hazards to reduce preventable patient harm. <a href="#">[Benjamin, 2003; Rath, 2008]</a></li> <li>▪ Working with the interdisciplinary team to ensure evidence-based medication regimens for all patients. <a href="#">[Leape, 1999; Scarsi, 2002; Kucukarslan, 2003; Rodgers, 2007]</a></li> <li>▪ Establishing a medication safety committee to review medication errors, adverse drug events (ADEs), and medication near misses, and reporting data and prevention strategies to senior leadership, the Patient Safety Officer, and the interdisciplinary patient safety committee. <a href="#">[Piotrowski, 2002; Kowiatek, 2004; Odwazny, 2005; Denham, 2007; Abramson, 2009]</a></li> <li>▪ Performing medication safety walk-rounds to evaluate medication processes and front-line staff input about medication safe practices. <a href="#">[Frankel, 2005; Thomas, 2005]</a></li> <li>▪ Ensuring that pharmacy staff engage in teamwork and communication, leadership, and safety culture training, at least annually. <a href="#">[Seghal, 2008; Clark, 2009]</a></li> <li>▪ Establishing a central role in readiness planning for the implementation of CPOE, medication and patient bar-coding, and other health information technologies that have an impact on medication management systems and medication use. <a href="#">[McGregor, 2006; Kilbridge, 2006; ASHP, 2003]</a></li> <li>▪ Engaging in public health initiatives on behalf of the pharmacy community, including best practice immunization and vaccination initiatives, smoking cessation, and emergency preparedness. <a href="#">[ASHP, 2003; Hoque, 2006; Terriff, 2008; Dent, 2009]</a></li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice  Red Text = Deleted Text  Blue Underlined Text = New Text</p> </div>

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<p><b>Safe Practice 18: Pharmacist Leadership Structures and Systems</b></p> <p>Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization.</p> <p><i>(continued)</i></p>	<p><b>Selection and Procurement</b></p> <ul style="list-style-type: none"> <li>▪ Pharmacists work with physicians and other health professionals to select and maintain a formulary of medications chosen for safety, effectiveness, and cost, as well as medication-associated products or devices, medication use policies, important ancillary drug information, decision support tools, and organizational guidelines. The formulary system should have a process for which the medical staff has oversight and approval of the formulary. <a href="#">[Pedersen, 2001; Pedersen, 2008]</a></li> <li>▪ Medication selection should be informed by the best scientific evidence and clinical guidelines for a given therapeutic area, and individualized for the patient. <a href="#">[NQF, 2006]</a> The prescriber should document the specific reason, clinical indications, and/or patient preferences, and why a patient is not receiving a recommended medication, based on readily available, current guidelines. <a href="#">[Meyer, 2000]</a></li> <li>▪ Pharmacists are actively involved in the development and implementation of evidence-based drug therapy protocols and/or order sets. <a href="#">[ASHP, 2003; Magee, 2007]</a></li> </ul> <p><b>Storage</b></p> <ul style="list-style-type: none"> <li>▪ Identify and, at least annually, review a list of look-alike/sound-alike drugs used in the organization, and take action to prevent errors involving the interchange of these drugs. <a href="#">[AHA, 2005; McCoy, 2005; TJC, 2009a]</a></li> <li>▪ Ensure that the written medication storage policy is implemented. The policy includes safe storage, safe handling, security, and disposition of these medications. <a href="#">[Rich, 2004; TJC, 2009a]</a></li> <li>▪ Ensure that all medications, including pediatric doses, parenteral, and those used during emergencies, are available in unit-dose (single unit), age- and/or weight-appropriate, and ready-to administer forms, whenever possible. <a href="#">[Rich, 2004; TJC, 2009b]</a></li> </ul> <p><b>Ordering and Transcribing</b></p> <ul style="list-style-type: none"> <li>▪ Ensure with the healthcare team that only the medications needed to treat the patient's condition are ordered, provided, and administered. <a href="#">[TJC, 2005; Gardner, 2009]</a></li> </ul>

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<p><b>Safe Practice 18: Pharmacist Leadership Structures and Systems</b></p> <p>Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization. <i>(continued)</i></p>	<p><b>Preparing and Dispensing</b></p> <ul style="list-style-type: none"> <li>▪ Pharmacists should review all medication orders and the patient medication profile for appropriateness and completeness, address any problems and ensure needed change, and document actions taken before medications are dispensed or made available for administration, except in those instances when review would cause a medically unacceptable delay or when a licensed independent practitioner controls the ordering, preparation, and administration of the medication. <a href="#">[TJC, 2009b; Westerlund, 2009]</a></li> <li>▪ Pharmacists should oversee the preparation of medications, including sterile products, and ensure that they are safely prepared. <a href="#">[Kastango, 2005; TJC, 2009b]</a></li> <li>▪ Medications should be labeled in a standardized manner according to hospital policy, applicable law and regulation, and standards of practice. <a href="#">[ISMP, 2008b; Jennings, 2007; Shrank, 2007; Momtahan, 2008; TJC, 2009a]</a></li> <li>▪ Every unit-dose package label should contain a machine-readable code identifying the product name, strength, and manufacturer. Machine-readable coding should be considered in compounding, stocking, and dispensing procedures to facilitate accuracy. <a href="#">[VHA, 2006; ASHP, 2009]</a></li> <li>▪ When a full-time pharmacist is not available onsite, a pharmacist should be available by telephone or accessible at another location that has 24-hour pharmacy services. <a href="#">[Woodall, 2004; Pedersen, 2008; TJC, 2009a]</a></li> </ul> <p><b>Medication Administration</b></p> <ul style="list-style-type: none"> <li>▪ Organizations should <b>consider</b> <a href="#">prepare for</a> the use of medication administration technologies such as barcode-enabled medication administration (BCMA) and “Smart Pump” infusion devices as part of their medication safety strategy. . <a href="#">[Johnson, 2002; Wilson, 2004; Larsen, 2005; Rothschild, 2005; Poon, 2006; Cohen, 2007b; Fanikos, 2007; Paoletti, 2007]</a></li> <li>▪ The five rights for medication administration (right patient, right medication, right dose, right time and frequency, and right route of administration) have historically been a guideline for nurses and caregivers; however, this framework is not all inclusive of domains relating to medication adverse events. It does not address all pertinent organizational systems, human factors performance, and human-technology interface issues. The practitioner’s duty is to follow the procedural rules designed by the organization to produce optimal outcomes. If system issues negatively affect the adherence to procedural rules and their intended impact, the practitioner also has the duty to report the hindrance so that it can be remedied. <a href="#">[Bechtel, 1993; ISMP, 2007]</a></li> </ul> <div data-bbox="1464 1208 1850 1332" style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice  Red Text = Deleted Text  Blue Underlined Text = New Text</p> </div>

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<p><b>Safe Practice 18: Pharmacist Leadership Structures and Systems</b></p> <p>Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization. <i>(continued)</i></p>	<p><b>Monitoring</b></p> <ul style="list-style-type: none"> <li>▪ Pharmacists should monitor patient medication therapy regularly, based on patient needs and best evidence, for effectiveness, adherence, persistence, and avoidance of adverse events. Monitoring information should be communicated to providers, caregivers, and patients. <a href="#">[Bond, 2006; Bond, 2007]</a></li> <li>▪ Medication errors and near-miss internal reports should be shared with organizational safety, risk, and senior leadership through the pharmacy leader. A performance improvement and risk mitigation plan should be created, integrated into the organization's improvement strategy, implemented, and documented annually. This plan should be updated as frequently as necessary based on internal data. <a href="#">[Cohen, 2000; Lehmann, 2007; Montesi, 2009]</a></li> <li>▪ Medication error and near-miss information is reported through external sources such as Patient Safety Organizations, the Food and Drug Administration (FDA), the United States Pharmacopeia, or the Institute for Safe Medicine Practices (ISMP), as appropriate, in an effort to trend data to prevent future patient harm. <a href="#">[Cohen, 2000; MCPME, 2006]</a></li> <li>▪ Proactive risk mitigation strategies should be demonstrated to prevent errors in the organization. Example: <b>At least annually</b> <a href="#">On an ongoing basis*</a>, utilize external sources for review (such as ISMP, FDA) of reported near-miss/medication errors. <a href="#">[ISMP, 2009]</a></li> </ul> <p><u><a href="#">*The NQF Maintenance Committee recommends quarterly review of published literature and internal organizational data to identify potential harm to patients and implementation of risk mitigation strategies.</a></u></p> <p><b>High-Alert Medications</b></p> <ul style="list-style-type: none"> <li>▪ Identify high-alert medications within the organization. <a href="#">[ISMP, 2008b]</a></li> <li>▪ Implement institutional processes for procuring, storing, ordering, transcribing, preparing, dispensing, administering, and monitoring high-alert medications. <a href="#">[Runy, 2004; Cohen, 2007a; Federico, 2007; TJC, 2009b]</a></li> </ul> <p><b>Evaluation</b></p> <ul style="list-style-type: none"> <li>▪ Perform <b>a</b> medication safety self-assessments to identify organizational structure, system, and communication opportunities to proactively target harm reduction and risk mitigation strategies. <a href="#">[ISMP, N.D.a ; Smetzer, 2003; TJC, 2009b]</a></li> <li>▪ Evaluate the ability of the patient to understand and adhere to medication regimens when in the community setting. Consider patient health literacy, feasible dosing schedules, and affordability, as well as cultural, physical, and environmental barriers. <a href="#">[NQF, 2006; Davis, 2006a; Davis, 2006b]</a></li> </ul> <div data-bbox="1464 1208 1850 1332" style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice  Red Text = Deleted Text  Blue Underlined Text = New Text</p> </div>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 19: Hand Hygiene</b>            Comply with current Centers for Disease Control and Prevention Hand Hygiene Guidelines <u>and/or World Health Organization (WHO) Guidelines on Hand Hygiene in Health Care</u>. [CDC, 2002; <u>WHO, 2009</u>; Note 19-3]</p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility. [<u>Aiello, 2008</u>]</p> <p><b>Note: No material change to this practice (SP 19 from 2009 Consensus Report).</b></p>	<p>At a minimum, this practice should include all of the following elements:</p> <ul style="list-style-type: none"> <li>▪ Implement all Centers for Disease Control and Prevention (CDC) guidelines with category IA, IB, or IC evidence <u>and/or WHO Guidelines on Hand Hygiene in Health Care</u>. [CDC, 2002; <u>Braun, 2009; Stevenson, 2009; WHO, 2009</u>]</li> <li>▪ Encourage compliance with CDC guidelines with category II evidence.</li> <li>▪ Ensure that all staff know what is expected of them with regard to hand hygiene, and ensure compliance. [<u>Boyce, 2008; Creedon, 2008; Kohli, 2009; McGuckin, 2009</u>; Note 19-3]</li> </ul>

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<p><b>Safe Practice 20: Influenza Prevention</b>                      Comply with current Centers for Disease Control and Prevention (CDC) recommendations for influenza vaccinations for healthcare personnel and the annual recommendations of the CDC Advisory Committee on Immunization Practices for individual influenza prevention and control.                      [Pearson, 2006; Fiore, 2008; <u>Note 20-2</u>; <u>Note 20-3</u>; <u>Note 20-4</u>]</p> <p><b>Applicable Clinical Care Settings</b>                      This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 20 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ <i>Healthcare workers</i> are individuals currently employed in a healthcare occupation or in a healthcare- industry setting who come in direct contact with patients. Healthcare workers with contraindications to immunization or who refuse immunization are exempted.</li> <li>▪ Patients who should be immunized are specified by current CDC recommendations.</li> <li>▪ Explicit organizational policies and procedures, as well as a robust voluntary healthcare worker and patient influenza immunization program, should be in place. <u>[Note 20-5]</u></li> <li>▪ Document the immunization status of all employees, subject to collective bargaining, labor law, and privacy law.</li> <li>▪ At a minimum, this practice should include all of the following elements: [Pearson, 2006; Fiore, 2008; <u>Fiore, 2009</u>]:</li> <li>▪ Implement the CDC Advisory Committee on Immunization Practices annual recommendations for influenza prevention and control.                             <ul style="list-style-type: none"> <li>• Implement all CDC guidelines with category IA, IB, or IC evidence.                                     <ul style="list-style-type: none"> <li>– Educate healthcare personnel (HCP) on the benefits of influenza vaccination and the potential health consequences of influenza illness for themselves and their patients, the epidemiology and modes of transmission, diagnosis, treatment, and non-vaccine infection control strategies, in accordance with their level of responsibility in preventing healthcare-associated influenza (category IB).</li> <li>– Offer influenza vaccine annually to all eligible HCP to protect staff, patients, and family members, and to decrease HCP absenteeism. Use of either available vaccine (inactivated or live, attenuated influenza vaccine [LAIV]) is recommended for eligible persons. During periods when inactivated vaccine is in short supply, use of LAIV is especially encouraged, when feasible, for eligible HCP (category IA).</li> <li>– Provide influenza vaccination to HCP at the work site and at no cost as one component of employee health programs. Use strategies that have been demonstrated to increase influenza vaccine acceptance, including vaccination clinics, mobile carts, vaccination access during all work shifts, and modeling and support by institutional leaders (category IB).</li> <li>– Monitor HCP influenza vaccination coverage and declination at regular intervals during the influenza season and provide feedback of ward-, unit-, and specialty-specific rates to staff and administration (category IB).</li> </ul> </li> <li>• Encourage compliance with CDC guidelines with category II evidence.                                     <ul style="list-style-type: none"> <li>– Use the level of HCP influenza vaccination coverage as one measure of a patient safety quality program (category II).</li> </ul> </li> </ul> </li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention</b></p> <p>Take actions to prevent central line-associated bloodstream infection by implementing evidence-based intervention practices. [CDC MMWR, 2002; <a href="#">Marschall, 2008a</a>; <a href="#">Mermel, 2009</a>; <a href="#">Note 21-1</a>; <a href="#">Note 21-2</a>]</p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 21 from 2009 Consensus Report).</b></p>	<p><b>Before insertion:</b></p> <ul style="list-style-type: none"> <li>Educate healthcare personnel involved in the insertion, care, and maintenance of central venous catheters (CVCs) about central line-associated bloodstream infection (CLABSI) prevention. [Sherertz, 2000; Eggimann, 2000; Coopersmith, 2002; Warren, 2003; Warren, 2004; <a href="#">Marschall, 2008a</a>; <a href="#">Note 21-3</a>; <a href="#">Note 21-4</a>]</li> </ul> <p><b>At insertion:</b></p> <ul style="list-style-type: none"> <li>Use a catheter checklist to ensure adherence with infection prevention practices at the time of CVC insertion. [Berenholtz, 2004; Tsuchida, 2007; <a href="#">Note 21-5</a>]</li> <li>Perform hand hygiene prior to catheter insertion or manipulation. [Boyce, 2002; Rosenthal, 2005; Yilmaz, 2007; <a href="#">Smith, 2008</a>; OSHA, N.D.]</li> <li>Avoid using the femoral vein for central venous access in adult patients. [Goetz, 1998; Merrer, 2001] (Subclavian or internal jugular are the preferred sites, unless contraindicated.)</li> <li>Make available and easily accessible for use a catheter cart or kit that contains all necessary components for aseptic catheter insertion. [Berenholtz, 2004]</li> <li>Use maximal sterile barrier precautions during CVC insertion to include a mask, cap, sterile gown, and sterile gloves worn by all healthcare personnel involved in the procedure. The patient is to be covered with a large sterile drape during catheter insertion. [Mermel, 1991; Raad, 1994; Hu, 2004; Young, 2006; <a href="#">Smith, 2008</a>]</li> <li>Use chlorhexidine-based <a href="#">gluconate 2% and isopropyl alcohol solution</a> as skin antiseptic preparation in patients over two months of age <a href="#">and allow appropriate drying time per product organization guidelines</a>. [Maki, 1991; Garland, 1995; Humar, 2000; Chaiyakunapruk, 2002; <a href="#">CDC MMWR, 2002</a>; <a href="#">Darouiche, 2008</a>; <a href="#">Pronovost, 2008</a>]</li> </ul> <p><b>After insertion:</b></p> <ul style="list-style-type: none"> <li>Use a standardized protocol to disinfect catheter hubs, needleless connectors, and injection ports before accessing the ports. [Salzman, 1993; Luebke, 1998; Casey, 2003; <a href="#">Shapey, 2009</a>]</li> <li>Remove nonessential catheters. [Lederle, 1992; Parenti, 1994; <a href="#">Garnacho-Montero, 2008</a>]</li> <li>Use a standardized protocol for non-tunneled CVCs in adults and adolescents for dressing care, such as changing transparent dressings and performing site care with a chlorhexidine-based antiseptic every five to seven days, or earlier if the dressing is soiled, loose, or damp; change gauze dressings every two days, or earlier if the dressing is soiled, loose, or damp. [Maki, 1994; Rasero, 2000; <a href="#">Ruschulte, 2009</a>]</li> <li>Perform surveillance for CLABSI and report the data on a regular basis to the units, physician and nursing leadership, and hospital administrators overseeing the units. [<a href="#">Marschall, 2008a</a>; <a href="#">Marschall, 2008b</a>; <a href="#">Rosenthal, 2008a</a>]</li> </ul> <p><b>*Pediatric Specificity:</b> Chlorhexidine may be contraindicated for use in very low birthweight (VLBW) infants. Optimal catheter site selection is specific to the size and condition of the infant or child and accessibility factors.</p> <div data-bbox="1464 1208 1850 1332" style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice  Red Text = Deleted Text  Blue Underlined Text = New Text</p> </div>

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<p><b>Safe Practice 22: Surgical-Site Infection Prevention</b>            Take actions to prevent surgical-site infections by implementing evidence-based intervention practices. [Mangram, 1999; Anderson, 2008; WHO, 2008; <a href="#">Note 22-1</a>; <a href="#">Note 22-2</a>; <a href="#">Note 22-3</a>]</p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory surgical center and inpatient service/hospital.</p> <p><b>Note: No material change to this practice (SP 22 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Document the education of healthcare professionals, including nurses and physicians, involved in surgical procedures about healthcare-acquired infections, surgical-site infections (SSIs), and the importance of prevention. Education occurs upon hire and annually thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities. [Bratzler, 2004; Bratzler, 2006; <a href="#">Chatzizacharias, 2009</a>; <a href="#">Rosenthal, 2009</a>; Note 22-4]</li> <li>▪ Prior to all surgical procedures, educate the patient and his or her family as appropriate about SSI prevention. [Torpy, 2005; Schweon, 2006]</li> <li>▪ Implement policies and practices that are aimed at reducing the risk of SSI that meet regulatory requirements, and that are aligned with evidence-based standards (e.g., CDC and/or professional organization guidelines). [Mangram, 1999; Dellinger, 2005; Bratzler, 2006; Anderson, 2008; <a href="#">WHO 2009</a>]</li> <li>▪ Conduct periodic risk assessments for SSI, select SSI measures using best practices or evidence-based guidelines, monitor compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention efforts. [Bratzler, 2006]</li> <li>▪ Ensure that measurement strategies follow evidence-based guidelines, and that SSI rates are measured for the first 30 days following procedures that do not involve the insertion of implantable devices, and for the first year following procedures that involve the insertion of implantable devices. [Horan, 1992; <a href="#">Biscione, 2009</a>]</li> <li>▪ Provide SSI rate data and prevention outcome measures to key stakeholders, including senior leadership, licensed independent practitioners, nursing staff, and other clinicians. [Mangram, 1999]</li> <li>▪ Administer antimicrobial agents for prophylaxis with a particular procedure or disease according to evidence-based standards and guidelines for best practices. [ASHP, 1999; Mangram, 1999; Antimicrobial, 2001; <a href="#">Note 22-5</a>]               <ul style="list-style-type: none"> <li>• Administer intravenous antimicrobial prophylaxis within one hour before incision to maximize tissue concentration (two hours are allowed for the administration of vancomycin and fluoroquinolones). [Bratzler, 2004; Bratzler, 2006]</li> <li>• Discontinue the prophylactic antimicrobial agent within 24 hours after surgery (within 48 hours is allowable for cardiothoracic procedures). [Bratzler, 2004; Bratzler, 2006]</li> </ul> </li> <li>▪ When hair removal is necessary, use clippers or depilatories.                Note: Shaving is an inappropriate hair removal method. [Mangram, 1999]</li> <li>▪ <a href="#">Preoperatively use chlorhexidine gluconate 2% and isopropyl alcohol solution as skin antiseptic preparation, and allow appropriate drying time per product organization guidelines. [Darouiche, 2008]</a></li> <li>▪ Maintain normothermia (temperature &gt;36.0°C) immediately following colorectal surgery. [Kurz, 1996]</li> <li>▪ Control blood glucose during the immediate postoperative period for cardiac surgery patients. [Bratzler, 2006; Dronge, 2006]</li> </ul>

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<p><b>Safe Practice 23: Care of the Ventilated Patient</b>            Take actions to prevent complications associated with ventilated patients: specifically, ventilator-associated pneumonia, venous thromboembolism, peptic ulcer disease, dental complications, and pressure ulcers. <a href="#">[Coffin, 2008; Note 23-3]</a></p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include emergency room, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 23 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Educate healthcare workers about the daily care of ventilated patients and the necessity for the prevention of associated complications such as ventilator-associated pneumonia (VAP), venous thromboembolism (VTE), peptic ulcer disease (PUD), dental complications, and pressure ulcers. <a href="#">[Bloos, 2009; Note 23-4]</a></li> <li>▪ Implement policies and practices for disinfection, sterilization, and maintenance of respiratory equipment that are aligned with evidence-based standards (e.g., CDC and professional organization guidelines). [Tablan, 2004; <a href="#">Brito, 2009; Note 23-5]</a></li> <li>▪ Conduct active surveillance for VAP and associated process measures in units that care for ventilated patients that are known or suspected to be at high risk for VAP based on risk assessment. [Erhart, 2004; Tablan, 2004; <a href="#">Hortal, 2009a; Hortal, 2009b]</a></li> <li>▪ Provide ventilated patient data on VAP, VAP-related process measures, and general care process measures to key stakeholders, including senior leadership, LIPs, nursing staff, and other clinicians.</li> <li>▪ Educate patients, as appropriate, and their families about prevention measures involved in the care of ventilated patients.</li> <li>▪ For adult patients, institute a ventilated patient checklist and a standardized protocol for the following prevention measures:               <ul style="list-style-type: none"> <li>• Adhere to hand hygiene guidelines. [Erhart, 2004; Tablan, 2004]</li> <li>• Perform regular antiseptic oral care according to product guidelines. <a href="#">[Panchabhai, 2009; Prendergast, 2009]</a></li> <li>• Maintain patients in semi-recumbent position: 30°-45° elevation of head of bed (unless medically contraindicated). [Torres, 1992; Kollef, 1993; Orozco-Levi, 1995; Drakulovic, 1999; Collard, 2003; Helman, 2003; Erhart, 2004; Tablan, 2004; Kollef, 2004; Dellinger, 2005; Resar, 2005]</li> <li>• Perform daily assessment of readiness to wean and sedation interruption. [ATS/ IDSA, 2005; Resar, 2005; Girard, 2008]</li> <li>• Use weaning protocols. [Thorens, 1995; Brook, 1999; Kress, 2000; Marelich, 2002; Needleman, 2002; Burns, 2003; Kollef, 2004; Dellinger, 2005; Girard, 2008; <a href="#">Burns, 2009]</a></li> <li>• Implement PUD prophylaxis based on patient risk assessment. (PUD prophylaxis data remain controversial. Clinical judgment should be used based on individual patient needs.) [Prod'hom, 1994; Bonten, 1997]</li> <li>• Provide VTE prophylaxis unless contraindicated (refer to Safe Practice 28).</li> <li>• Implement a pressure ulcer prevention program based on patient risk assessment (refer to Safe Practice 27).</li> </ul> </li> <li>▪ For pediatric patients (less than 18 years of age), institute a ventilated patient checklist and a standardized protocol for the following prevention measures:               <ul style="list-style-type: none"> <li>• Elevate airway opening between 15°-30° for neonates and 30°-45° for infants through pediatric ages, unless clinically inappropriate for the patient.</li> <li>• Assess readiness to extubate daily.</li> </ul> </li> </ul>

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<p><b>Safe Practice 24: Multidrug-Resistant Organism Prevention</b></p> <p>Implement a systematic multidrug-resistant organism (MDRO) eradication program built upon the fundamental elements of infection control, an evidence-based approach, assurance of the hospital staff and independent practitioner readiness, and a re-engineered identification and care process for those patients with or at risk for MDRO infections. <a href="#">[Siegel, 2006; Calfee 2008; Dubberke, 2008; Note 24-2]</a></p> <p>Note: This practice applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant <i>Staphylococcus aureus</i>, vancomycin-resistant <i>enterococci</i>, and <i>Clostridium difficile</i>. Multidrug-resistant gram-negative bacilli, such as <i>Enterobacter</i> species, <i>Klebsiella</i> species, <i>Pseudomonas</i> species, and <i>Escherichia coli</i>, and vancomycin-resistant <i>Staphylococcus aureus</i>, should be evaluated for inclusion on a local system level based on organizational risk assessments.</p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 24 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ The organization’s leadership has assigned responsibility for oversight and coordination of the development, testing, and implementation of a multidrug-resistant organism (MDRO) prevention program. <a href="#">[Note 24-3; Note 24-4]</a></li> <li>▪ Conduct a risk assessment for MDRO acquisition and transmission.</li> <li>▪ Upon hire and annually thereafter, educate staff and licensed independent practitioners about MDROs, including risk factors, routes of transmission, outcomes associated with infection, prevention measures, and local epidemiology. [Seto, 1995; Note 24-5]</li> <li>▪ Educate patients who are infected with methicillin-resistant <i>Staphylococcus aureus</i>, vancomycin-resistant <i>enterococci</i>, or <i>Clostridium difficile</i>, or who are colonized with MRSA, and their families, as needed, about healthcare-associated infections and infection prevention strategies. [Lewis, 1999]</li> <li>▪ Implement a surveillance program for MDROs based on risk assessment. <a href="#">[Note 24-6]</a></li> <li>▪ Measure and monitor MDRO prevention processes and outcomes, including:             <ul style="list-style-type: none"> <li>• Infection rates using evidence-based metrics.</li> <li>• Compliance with evidence-based guidelines or best practices. <a href="#">[Calfee, 2008]</a></li> <li>• Evaluation of the education program provided to staff and licensed independent practitioners.</li> </ul> </li> <li>▪ Provide MDRO surveillance data, prevention processes, and outcome measures to key stakeholders, including senior hospital leadership, physicians, nursing staff, and other clinicians. <a href="#">[Calfee, 2008]</a></li> <li>▪ Implement a laboratory-based alert system to provide immediate notification to infection control and clinical personnel about newly diagnosed MDRO-colonized or -infected patients.</li> <li>▪ Implement an alert system that identifies readmitted or transferred MRSA-colonized or -infected patients.</li> <li>▪ Promote compliance with hand hygiene recommendations. [Boyce, 2002; Gopal Rao, 2002; Johnson, 2005; <a href="#">D’Agata, 2009; Lederer, 2009</a>]</li> <li>▪ Use contact precautions for MDRO-colonized or -infected patients. [Siegel, 2006; CDC, 2007; Siegel, 2007; <a href="#">Salgado, 2009</a>]</li> <li>▪ Ensure cleaning and disinfection of equipment and environment. [Rampling, 2001; de Gialluly, 2006; Hardy, 2006; Huang, 2006; <a href="#">Salgado, 2009; Boyce, 2009; Note 24-7</a>]</li> </ul>

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<p><b>Safe Practice 25: Catheter-Associated Urinary Tract Infection Prevention</b></p> <p>Take actions to prevent catheter-associated urinary tract infection by implementing evidence-based intervention practices. [Gould, 2008; <a href="#">CDC, 2009</a>; <a href="#">Lo, 2008</a>]</p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 25 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Document the education of healthcare personnel involved in the insertion, care, and maintenance of urinary catheters about catheter-associated urinary tract infection (CAUTI) prevention, including alternatives to indwelling catheters and procedures for catheter insertion, management, and removal. <a href="#">[Willson, 2009]</a> Education should occur upon hire and annually thereafter, and when involvement in these procedures is added to an individual's job responsibilities. <a href="#">[Kanouff, 2009]</a></li> <li>▪ Prior to insertion of a urinary catheter, educate the patient, and his or her family, as appropriate, about CAUTI prevention.</li> <li>▪ Identify the patient groups or units on which surveillance should be conducted, using risk assessments that consider frequency of catheter use and potential risk.</li> <li>▪ Implement policies and practices that are aimed at reducing the risk of CAUTI, that meet regulatory requirements, and that are aligned with evidence-based standards (e.g., CDC and/or professional organization guidelines). [Smith, 2008] Evidence-based practices include, but are not limited to, the following: <a href="#">[Note 25-1; Note 25-2; Note 25-3]</a> <ul style="list-style-type: none"> <li>• Perform hand hygiene immediately before and after catheter insertion and any manipulation of the catheter site or apparatus. <a href="#">[Barford, 2009]</a></li> <li>• Ensure that the supplies necessary for aseptic technique for catheter insertion are readily available.</li> <li>• Insert catheters following an aseptic technique and using sterile equipment.</li> <li>• Insert urinary catheters only for appropriate indications, and leave them in place only as long as indications remain.</li> <li>• Obtain a urine culture before initiating antimicrobial therapy for urinary tract infection in a patient with a urinary catheter.</li> </ul> </li> <li>▪ Measure compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention efforts for internal performance improvement.</li> <li>▪ Provide CAUTI surveillance data, including process and outcome measures, to key stakeholders within the organization, including senior hospital leadership, physicians, nursing staff, and other clinicians.</li> </ul>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention</b></p> <p>Implement the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ for all invasive procedures. <a href="#">[Note 26-1; Note 26-2]</a></p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory surgical center, emergency room, inpatient service/hospital, and outpatient hospital.</p> <p><b>Note: No material change to this practice (SP 26 from 2009 Consensus Report).</b></p>	<p><b>Specifications of Universal Protocol:</b> <a href="#">[Angle, 2008; TJC, 2008b; Note 26-3]</a></p> <ul style="list-style-type: none"> <li>• Create and use a preoperative verification process to ensure that relevant preoperative tasks are completed and that information is available and correct. <a href="#">[Haynes, 2009; Henrickson, 2009; HPR, 2009; Note 26-4]</a></li> <li>• Mark the surgical site and involve the patient in the marking process, at a minimum, for cases involving right/left distinction, multiple structures (e.g., fingers, toes) or multiple levels (e.g., spinal procedures). <a href="#">[Robinson, 2009]</a></li> <li>• Immediately before the start of any invasive procedure, conduct a “time out” to confirm the correct patient, procedure, site, and any required implants or special equipment. <a href="#">[Dillon, 2008; Note 26-5]</a></li> </ul>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 27: Pressure Ulcer Prevention</b>            Take actions to prevent pressure ulcers by implementing evidence-based intervention practices. <a href="#">[NQF, 2009]</a></p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 27 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Explicit organizational policies and procedures should be in place about the prevention of pressure ulcers. [Note 27-1; <a href="#">IHI, 2009</a>; <a href="#">NPUAP, 2009</a>]</li> <li>▪ Plans are in place for the risk assessment, prevention, and early treatment of pressure ulcers, which address the following:               <ul style="list-style-type: none"> <li>• During patient admission, identify individuals at risk of requiring pressure ulcer prevention using a pressure ulcer risk assessment plan/guide, <a href="#">including a comprehensive skin assessment</a>, to identify the specific risks. [Note 27-1; Braden, N.D.; Norton, N.D.]</li> <li>• Document the pressure ulcer risk-assessment and prevention plan as indicated in the patient’s record.</li> <li>• Assess and periodically reassess each patient’s <a href="#">skin and</a> risk for developing a pressure ulcer, and take action to address any identified risks. <a href="#">[AHRQ, 2009a]</a>; Note 27-1]</li> <li>• Maintain and improve tissue tolerance to pressure in order to prevent injury.</li> <li>• Protect against the adverse effects of external mechanical forces.</li> <li>• Reduce the incidence of pressure ulcers through staff educational programs.</li> <li>• Perform quarterly prevalence studies to evaluate the effectiveness of the pressure ulcer prevention program, and implement a performance improvement initiative as indicated, including the following elements:                   <ul style="list-style-type: none"> <li>– education about the pertinent pressure ulcer frequency and severity;</li> <li>– skill building in the use of pressure ulcer prevention interventions;</li> <li>– implementation of process improvement interventions;</li> <li>– measurement of process or outcomes indicators; and</li> <li>– internal reporting of performance outcomes.</li> </ul> </li> </ul> </li> </ul>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 28: Venous Thromboembolism Prevention</b></p> <p>Evaluate each patient upon admission, and regularly thereafter, for the risk of developing venous thromboembolism. Utilize clinically appropriate, evidence-based methods of thromboprophylaxis.</p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory surgical center, emergency room, homecare, home health services/ agency, inpatient service/ hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 28 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Ensure that multidisciplinary teams develop institutions' protocols and/or "adopt" established, evidence-based protocols. [NQF, 2006; Geerts, 2008; <a href="#">Note 28-2</a>]</li> <li>▪ Have in place a system for ongoing quality improvement that demonstrates that evidence-based guidelines/practices are acted upon (rationale for departing from guidelines should be documented unless documentation itself is for some reason contraindicated).</li> <li>▪ Include provision for risk assessment/stratification, prophylaxis, diagnosis, and treatment. [<a href="#">Hairon, 2008</a>]</li> <li>▪ Include appropriate quality improvement activity/monitoring for all phases of care with periodic (as defined by institutional policy) assessment of compliance with policies and measures. [<a href="#">Note 28-3</a>; <a href="#">Note 28-4</a>]</li> <li>▪ Provide for a system of provider education that encompasses all aspects of venous thromboembolism (VTE) prevention and care, including primary and secondary prevention, risk assessment and stratification, prophylaxis, diagnosis, and treatment. [<a href="#">Note 28-5</a>]</li> <li>▪ Provide for the risk assessment of all patients based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/stratified). [<a href="#">Caprini, 2009</a>; <a href="#">Patel, 2009</a>; <a href="#">Note 28-6</a>]</li> <li>▪ Document in the patient's health record that VTE risk assessment/stratification was completed.</li> <li>▪ Provide and explain to VTE patients or their caregivers, at the patient-appropriate reading and health literacy level, written discharge instructions, or other educational material, addressing all of the following: 1) follow-up/monitoring; 2) compliance issues; 3) dietary restrictions; 4) potential for adverse drug reactions/ interactions; and 5) VTE prophylaxis issues related to that patient.</li> </ul>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 29: Anticoagulation Therapy</b> Organizations should implement practices to prevent patient harm due to anticoagulant therapy.</p> <p><b>Applicable Clinical Care Settings</b> This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/ agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 29 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ The organization implements a defined anticoagulation management program to individualize the care provided to each patient receiving anticoagulant therapy, and the patient’s medication plan is documented in the medication record. <a href="#">[Robert-Ebadi, 2009; Note 29-1; Note 29-2]</a></li> <li>▪ Clinical pharmacy medication review is conducted to ensure safe anticoagulant selection and avoidance of drug-drug interactions. [Note 29-3]</li> <li>▪ To reduce compounding and labeling errors, the organization uses only oral unit-dose products, prefilled syringes, or premixed infusion bags, when these types of products are available.</li> <li>▪ The organization uses approved, standardized protocols for the initiation and maintenance of anticoagulation therapy that is appropriate to the medication used, the condition being treated, and the potential for medication interactions. <a href="#">[Airee, 2009; Note 29-4]</a></li> <li>▪ For patients starting on warfarin, a baseline International Normalized Ratio (INR) is available, and for all patients receiving warfarin therapy, a current INR is available and is used to monitor and adjust therapy. <a href="#">[Merli, 2009]</a></li> <li>▪ When dietary services are provided by the hospital, the service is notified of all patients receiving warfarin and responds according to its established food/medication interaction program.</li> <li>▪ When heparin is administered intravenously and continuously, the hospital uses programmable infusion pumps in order to provide consistent and accurate dosing.</li> <li>▪ The organization has a written policy that addresses baseline and ongoing laboratory tests that are required for heparin and low molecular weight heparin therapies.</li> <li>▪ The organization provides education on anticoagulation therapy to prescribers, staff, patients, and families.</li> <li>▪ The organization evaluates its anticoagulation safety practices, takes appropriate action to improve its practices, and measures the effectiveness of those actions on a regular basis. <a href="#">[Zhan, 2008]</a></li> </ul>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 30: Contrast Media-Induced Renal Failure Prevention</b></p> <p>Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and gadolinium-associated nephrogenic systemic fibrosis, and utilize a clinically appropriate method for reducing the risk of adverse events based on the patient’s risk evaluations. <a href="#">[Ellis, 2009]</a></p> <p><b>Applicable Clinical Care Settings</b></p> <p>This practice is applicable to CMS care settings, to include ambulatory surgical center, inpatient service/hospital, and outpatient hospital.</p> <p><b>Note: No material change to this practice (SP 30 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ Use evidence-based protocols, developed by a multidisciplinary team that includes a pharmacist and that are approved by the medical staff, for the prevention of contrast media-induced nephropathy (ensure frequent updates based on the rapid evolution of contrast agents and forthcoming national guidelines). <a href="#">[Reddan, 2009; Note 30-1; Note 30-2]</a></li> <li>▪ Monitor and document the use of evidence-based protocols (include variance and rationale for departing from protocol).</li> <li>▪ Document provider education that encompasses all aspects of contrast media-induced nephropathy prevention and care.</li> <li>▪ Specify the qualifications for staff who are authorized to initiate protocols for imaging that include contrast media, and screen patients at risk for contrast media-induced nephropathy.</li> <li>▪ Perform risk assessments on all patients that are based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/stratified).</li> <li>▪ Ensure that there is documentation by a licensed clinician placed in the patient’s health record that risk assessment/stratification was completed.</li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 31: Organ Donation</b> Hospital policies that are consistent with applicable law and regulations should be in place and should address patient and family preferences for organ donation, as well as specify the roles and desired outcomes for every stage of the donation process. [DHHS, 2005]</p> <p><b>Applicable Clinical Care Settings</b> This practice is applicable to CMS care settings, to include inpatient service/hospital.</p> <p><b>Note: No material change to this practice (SP 31 from 2009 Consensus Report).</b></p>	<p><b>Key organ donation effective practice strategies:</b></p> <ul style="list-style-type: none"> <li>▪ Hospitals and organ procurement organizations (OPOs) maintain a focus on joint accountability and intent for implementing highly effective organ donation programs on behalf of donors, donor families, and patients with end-stage organ failure in need of transplantation. <a href="#">[Antommaria, 2009; Note 31-2]</a></li> <li>▪ Key hospital and OPO donation staff are linked rapidly and early to support and assist potential donor families and to implement donor evaluation, organ optimization, organ placement, and organ procurement procedures. <a href="#">[Rudow, 2009]</a></li> <li>▪ Hospitals and OPOs establish and manage an integrated donation process that clearly defines roles and responsibilities; focuses on the needs of donors, donor families, and transplant candidates; and provides feedback about results. <a href="#">[Note 31-3]</a></li> <li>▪ Hospitals and OPOs build and sustain a network of quick response and collaborative relationships among the donor family, the hospital staff, the OPO staff, medical examiners/coroners, transplant physicians and surgeons, and the transplant program staff. <a href="#">[Note 31-4]</a></li> <li>▪ Every organ donation opportunity is highly valued and is routinely evaluated through death record reviews, quick deployment, re-approaches, and organ optimization to ensure that every suitable organ can be transplanted and that the end-of-life intentions of the donor and donor family have been honored. <a href="#">[Iltis, 2009]</a></li> <li>▪ Hospital-specific organ donation performance outcomes are published by the Scientific Registry of Transplant Recipients at <a href="http://www.ustransplant.org">www.ustransplant.org</a>. [Scientific Registry, 2008]</li> <li>▪ The hospital addresses the wishes of the patient, or surrogate decision-maker, about donation by incorporating processes and staff education that focus on the following: <ul style="list-style-type: none"> <li>• Donor identification and referral are implemented using processes jointly developed by hospital and OPO experts. [Shafer, 2006]</li> <li>• Donation consent discussions are informed by previously registered donation intentions and conducted by experienced healthcare team members that are jointly identified by hospital and OPO representatives. [DHHS, 2005]</li> <li>• Organ function optimization protocols are developed and jointly implemented by hospital and OPO experts and are evidence-based. [Wood, 2004; DHHS, 2005]</li> <li>• The donation process is documented by the hospital, beginning with donor identification and concluding with the operative procedure to retrieve donated organs.</li> <li>• Continuous quality improvement methods are utilized to evaluate the effectiveness of donation protocols. Outcomes are benchmarked against national goals and those of other similar organizations. [IOM, 2006]</li> </ul> </li> </ul>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 32: Glycemic Control</b>            Take actions to improve glycemic control by implementing evidence- based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes.</p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include inpatient service/hospital. <b>especially those who are critically ill, have hyperglycemia and diabetes, or are elderly and frail.</b></p> <p><b>Note: No material change to this practice (SP 32 from 2009 Consensus Report).</b></p>	<p><b>Essential elements of improving glycemic control:</b> [ADA, 2008; <a href="#">Moghissi, 2009</a>; TJC, N.D.; <a href="#">Note 32-1</a>]</p> <ul style="list-style-type: none"> <li>▪ A multidisciplinary team is established that is empowered to develop and guide processes for improving glycemic control for patients. This team should be charged with assessing and monitoring the quality of glycemic management within the organization. Members of this team should include all key stakeholders.</li> <li>▪ Organizations systematically track glucose data and medication error or near-miss reports to assess the quality of care delivered and share this data with senior leadership and front-line clinicians. <a href="#">[Note 32-2]</a></li> <li>▪ Evidence-based protocols and order sets are developed to guide the management of hyperglycemia and hypoglycemia throughout the organization. Specifically, written protocols are developed for the management of patients on intravenous insulin infusions.</li> <li>▪ Patient medications are reconciled appropriately, including, upon discharge, restarting pre-hospital antiglycemic agents when appropriate.</li> <li>▪ Patients with newly diagnosed diabetes or educational deficits have at least the following educational components reflected in their plan of care: <a href="#">[Note 32-3]</a> <ul style="list-style-type: none"> <li>• Medication management, including how to administer insulin (when appropriate) and potential medication interactions.</li> <li>• Nutritional management, including the role of carbohydrate intake in blood glucose management.</li> <li>• Exercise.</li> <li>• Signs, symptoms, and treatment of hyperglycemia and hypoglycemia.</li> <li>• Importance of blood glucose monitoring and how to obtain a blood glucose meter.</li> <li>• Instruction on the use of a blood glucose meter if available.</li> <li>• Sick-day guidelines.</li> <li>• Information for whom to contact in case of emergency or for more information.</li> <li>• A plan for post-discharge education or self-management support.</li> </ul> </li> </ul>

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**Table 1: Safe Practices, Care Settings, and Specifications**

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 33: Falls Prevention</b>            Take actions to prevent patient falls and to reduce fall-related injuries by implementing evidence-based intervention practices.</p> <p><b>Applicable Clinical Care Settings</b>            This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.</p> <p><b>Note: No material change to this practice (SP 33 from 2009 Consensus Report).</b></p>	<ul style="list-style-type: none"> <li>▪ The hospital or healthcare organization must establish a fall reduction program. <a href="#">[Note 33-2]</a></li> <li>▪ The fall reduction program includes an evaluation appropriate to the patient population, settings, and services provided.</li> <li>▪ An organization may consider individual patient assessments for what the organization deems to be the high-risk groups in its patient population. <a href="#">[Note 33-3]</a></li> <li>▪ The fall reduction program includes interventions to reduce the patient’s fall risk factors. <a href="#">[Note 33-4]</a></li> <li>▪ Staff receive education and training about the fall reduction program. Education occurs upon hire and annually thereafter. <a href="#">[Dempsey, 2009]</a></li> <li>▪ The patient, and family as needed, is educated about the fall reduction program and any individualized fall reduction strategies.</li> <li>▪ The organization evaluates the fall reduction program to determine its effectiveness. <a href="#">[Note 33-5]</a></li> </ul>

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PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<p><b>Safe Practice 34: Pediatric Imaging</b> When CT imaging studies are undertaken on children, “child-size” techniques should be used to reduce unnecessary exposure to ionizing radiation.</p> <p><b>Applicable Clinical Care Settings</b> This practice is applicable to CMS care settings, to include ambulatory, ambulatory surgical center, emergency room, inpatient service/ hospital, and outpatient hospital.</p> <p><b>Note: No material change to this practice (SP 34 from 2009 Consensus Report).</b></p>	<p>Organizations should establish a systematic approach to regularly updating protocols for computed tomography (CT) imaging of children. Four simple steps should be undertaken by imaging team members to improve patient care in the everyday practice of radiology: <a href="#">[Goske, 2008]</a></p> <ul style="list-style-type: none"> <li>▪ Scan only when necessary. This provides an opportunity to discuss the benefits of the CT exam as well as the potential risks with the child’s pediatrician or other healthcare provider, who has unique medical knowledge critical to the care of the patient. Commit to making a change in daily practice by working as a team with technologists, medical physicists, referring doctors, and parents to decrease the radiation dose.</li> <li>▪ Reduce or “child-size” the amount of radiation used. This can be accomplished by contacting a medical physicist to determine the baseline radiation dose for an adult for CT equipment and comparing that dose with the maximum recommended by the American College of Radiology’s (ACR’s) CT Accreditation Program. If the doses are higher than those suggested, reduce the technique for adult patients. Use evidence-based protocols for children. Refer to the Image Gently™ website (www.imagegently.org), and view the protocols provided for children. <a href="#">[Strauss, 2009]</a> These protocols are independent of equipment manufacturer, age of machine, or number of detectors. Although an institution or site may wish to lower scan technique even more, these protocols provide a starting point for making this important change. Work with radiologic technologists to implement the protocols. These professionals control the critical “last step” before a scan is obtained. <a href="#">[Singh, 2009]</a></li> <li>▪ Scan only the indicated area required to obtain the necessary information. Protocols in children should be individualized. Be involved with patients. Ask the questions required to ensure that the scan is “child-sized.” Decisions about shielding those radiosensitive areas (such as reproductive organs) outside of the scan range or those within the scan field (in-plane shielding) should be based on discussion with a qualified physicist and should incorporate local and national standards of practice.</li> <li>▪ Scan once; single-phase scans are usually adequate in children. Pre- and post-contrast and delayed CT scans rarely add additional information in children, yet can double or triple the radiation dose to the child. Consider removing multiphase protocols from routine practice.</li> </ul> <div data-bbox="1464 1208 1850 1329" style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p style="text-align: center;"><b>Edit Legend:</b></p> <p>Black Text = Original 2009 Safe Practice that will remain in the updated practice  Red Text = Deleted Text  Blue Underlined Text = New Text</p> </div>