



Audit of 2010 Safe Practices for Better Healthcare

TO: NQF Members
FR: NQF Staff
RE: Request for Comment: Audit of 2010 *Safe Practices for Better Healthcare*
DA: March 31, 2014

Overview

Purpose

The National Quality Forum (NQF) is committed to providing accurate, unbiased, evidence-based recommendations to improve the health and safety of patients. The *Safe Practices for Better Healthcare* reports (2003, 2006, 2009 and 2010) have served as important resources for more than a decade to help prevent adverse healthcare events, a leading cause of injury and death in the United States.

As NQF committed to in its February 27 report, [NQF Safe Practices and Related Processes](#), a comprehensive audit of the 2010 *Safe Practices for Better Healthcare* was conducted.

The purpose of the audit was twofold:

- to assess whether the 2010 report included reference to any commercial product or service, explicit or implicit;
- to assess the currency of the 2010 Safe Practices, in light of the four years that have passed since they were last updated.

Approach

The audit of the 2010 *Safe Practices for Better Healthcare* is an objective, systematic and critical analysis of the evidentiary base underlying each of the report's 34 safe practices. The audit was guided by explicit criteria to ensure consistency across internal and external reviewers. The audit relied heavily on recent systematic reviews and guidelines from the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Disease Control and Prevention (CDC). NQF convened eight nationally and internationally known health care safety experts, including key federal partners, as an [Expert Advisory Panel](#) to conduct the audit.

[Audit criteria](#) were developed to assess the benefit, specificity, evidence of effectiveness, generalizability, and readiness for use, as well as absence of implicit or explicit product or service endorsement of the 34 NQF-endorsed safe practices.

The three-part audit process included internal review by staff, external review by an Expert Advisory Panel, and member and public comment. The audit report is included as redlined recommendations, updated reference citations, and comments that have been inserted into the attached Table 1. As a result of this audit, the safe practices have been updated to reflect current evidence.

The audited practices are now submitted to NQF members and the public for review and comment. At the conclusion of this audit process, NQF will consider what are the most appropriate next steps to take to continue providing the US healthcare community with *Safe Practices for Better Healthcare*.

Action Requested

NQF members and the public are asked to review and comment on the audited Table 1 during the 15-day period from April 1 through April 15, 2014 at 6 p.m. EDT. The comments will become part of the information that informs next steps for the Safe Practices.

Comments must be submitted using the Safe Practices commenting tool at <http://www.qualityforum.org/commenting/publiccommentform.aspx?project=75958&form=87>

Please note that the comment period closes on April 15, 2014 at 6:00 pm EDT.



Audit of 2010 *Safe Practices for Better Healthcare*

The table below was taken from *Safe Practices for Better Healthcare – 2010 Update*. The 34 safe practices have undergone an audit based on the process and standards in Appendix A. The audit has resulted in suggested changes to continue to meet the 2010 criteria for inclusion in the set, to bring the practices up to date with current evidence and to assess whether the practices include implicit or explicit reference to commercial products or services.

Suggested changes (additions, deletions, modifications, updated reference citations) are made in **red** and are based on current evidence. Summary notes from the auditors have been added at the end of each practice (in **blue**). Auditors were not asked to review “Applicable Clinical Care Settings.” However, they noted that the care settings should be carefully reviewed for appropriateness and where specific suggestions regarding care settings were made, those are included.

The audited safe practices and specifications, with suggested changes, are submitted for NQF member and public comment. The comments will be used to help guide NQF leadership to its next steps in evolving the *Safe Practices for Better Healthcare*.

Table 1: Safe Practices, Care Settings, and Specifications

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 1: Leadership Structures and Systems 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. Applicable Clinical Care	Awareness Structures and Systems: 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.¹ ▪ 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.² ▪ 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. ▪ 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.³ ▪ 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. 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. Accountability Structures and Systems: Structures and systems should be established to ensure that there is direct accountability of the governance board,⁴ senior administrative management, midlevel management, physician leaders (independent and employed by the organization), and front-line caregivers to close certain performance gaps and to adopt certain patient safety practices.⁵

¹ Botwinick L, Bisognano M, Haraden C. Leadership Guide to Patient Safety. Cambridge, MA: Institute for Healthcare Improvement; 2006. Available at www.IHI.org. Last accessed February 2014.

² IHI. *Set Direction: Alignment and Coordination*. IHI Improvement Map. Cambridge, MA: IHI: 2006. Available at <http://www.ihi.org/imap/tool/#Process=096a9494-93e3-4708-b575-de26d77b3eb6>. Last accessed February 2014.

³ IHI. *Will: Patients & Families*. IHI Improvement Map. Cambridge, MA: IHI; 2009. Available at <http://www.ihi.org/imap/tool/#Process=13ffd8f7-9e9b-4ad0-b2af-dfe192ec66c9>. Last accessed February 2014.

⁴ Jiang HJ, Lockee C, Bass K, et al. Board engagement in quality: findings of a survey of hospital and system leaders. *J Healthc Manag*. 2008;53(2):121-134.

⁵ Botwinick L, Bisognano M, Haraden C. Leadership Guide to Patient Safety. Cambridge, MA: Institute for Healthcare Improvement; 2006. (Available at www.IHI.org) Last accessed February 2014

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Settings This practice is applicable to Centers for Medicare & Medicaid Services 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.	▪ Patient Safety Program: An integrated patient safety program should be implemented throughout the healthcare organization.⁶ This program should provide oversight, ensure the alignment of patient safety activities, and provide opportunities for all individuals who work in the organization to be educated and participate in safety and quality initiatives. Leaders should create an environment in which safety and quality issues are openly discussed. A just culture should be fostered in which front-line personnel feel comfortable disclosing errors – including their own – while maintaining professional accountability. ▪ Patient Safety Officer: The organization should appoint or employ a Patient Safety Officer who is the primary point of contact for questions about patient safety and who coordinates patient safety for education and the deployment of system changes. Governance boards and senior administrative leaders should support leaders in patient safety to ensure that there is compliance with the specifications of this safe practice. ▪ Direct Organization-Wide Leadership Accountability: Governance and senior management should have direct accountability for safety in the organization, including setting patient safety goals, ensuring that resources are provided to address those goals, and monitoring progress toward their achievement.⁷ ▪ The Patient Safety Officer should have direct and regular communication with governance leaders and senior administrative management. Senior administrative leaders and leaders of clinical service lines and units should be held accountable for closing patient safety performance gaps. Performance should be documented using methods such as performance reviews and/or compensation incentives. ▪ Interdisciplinary Patient Safety Committee: Leaders should establish and support an interdisciplinary patient safety improvement committee(s) or equivalent structure(s)⁸ that is (are) responsible for creating, implementing, and administering mechanisms to oversee root cause analyses of every appropriate incident and provide feedback to front-line workers about lessons learned, disclose the organization’s progress toward implementing safe practices, and provide professional training and practice in teamwork techniques (e.g., anesthesia crisis management, aviation-style crew resource management, medical team management). See the <i>Identification and Mitigation of Risks and Hazards</i> and <i>Teamwork Training and Skill Building</i> safe practices for detailed specifications. ▪ External Reporting Activities: Organizations should report adverse events to the appropriate external mandatory programs and voluntary programs as well as encourage voluntary practitioner reporting. Organizations should publicly disclose compliance with all National Quality Forum-endorsed® safe practices for public reporting that are applicable to the facility.

⁶ [The Joint Commission Comprehensive Accreditation Manual for Hospitals. Standard LD 04.04.05 Chicago \(IL\); 2013.](#)

⁷ IHI. *Set Direction: Alignment and Coordination. IHI Improvement Map*. Cambridge, MA: IHI; 2009. Available at <http://app.ihl.org/imap/tool/#Process=096a9494-93e3-4708-b575-de26d77b3eb6> . Last accessed February 2014.

⁸ [The Joint Commission Comprehensive Accreditation Manual for Hospitals. Standard LD03.03.01. Chicago \(IL\); 2013](#)

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	Structures- and Systems-Driving Ability: Capacity, resources, and competency are critical to the ability of organizations to implement changes in their culture and in patient safety performance. Systematic and regular assessment of resource allocations to key systems should be undertaken to ensure performance in patient safety. On a regular, periodic basis determined by the organization, governance boards and senior administrative leaders should assess each of the following areas for the adequacy of funding and should document the actions taken to adjust resource allocations to ensure that patient safety is adequately funded: ▪ Patient Safety Budgets: Specific budget allocations for initiatives that drive patient safety should be evaluated by governance boards and senior administrative leaders. Such evaluations should include the detailed context of information from the activities defined in the <i>Identification and Mitigation of Risks and Hazards</i> safe practice. Designating a Patient Safety Officer or someone in charge of patient safety without providing the appropriate staffing infrastructure or budget is an example of inadequate resource allocation. ▪ People Systems: Human resource issues should be addressed with direct input from the activities included in the <i>Identification and Mitigation of Risks and Hazards</i> safe practice, as well as those included in Safe Practices 9 and 10 relating to nurse staffing and direct caregiver staffing levels, competency, and training/orientation.⁹ ▪ Quality Systems: Quality systems and structures such as performance improvement programs and quality departments should be adequately funded, actively managed, and regularly evaluated for effectiveness and resource needs. ▪ Technology Systems: Budgets for technologies that can enable safe practices should be regularly evaluated to ensure that patient safety impact can be optimized. Action Structures and Systems: Structures and systems should be put in place to ensure that leaders take direct and specific actions, including those defined below. ▪ Performance Improvement Programs: Leaders should document the actions taken to verify that the remedial activities that are identified through the analysis of reported patient safety events are implemented, are effective, and do not cause unintended adverse consequences. Leaders should establish patient safety priorities for performance improvement. The direct participation of governance board members and senior administrative leaders should be documented, as specified in the <i>Identification and Mitigation of Risks and Hazards</i> safe practice, to satisfy this requirement.¹⁰

⁹ IHI. *Foundation: Build Capability for Execution & Improvement. IHI Improvement Map*. Cambridge, MA: IHI; 2009. Available at <http://app.ihi.org/imap/tool/#Process=eeec4d58-0c9d-48f8-ba37-9588f5140362> . Last accessed February 2014.

¹⁰ IHI. *Will: Measure, Oversee, & Communicate Transparency. IHI Improvement Map*. Cambridge, MA: IHI; 2009. Available at <http://app.ihi.org/imap/tool/#Process=77b22769-0a57-4c53-82b0-55c6ce7a85a1> . Last accessed February 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	▪ Regular Actions of Governance: • Confirmation of Values: Governance leaders should regularly confirm that senior administrative leadership is continuously ensuring that the values of the organization are mirrored by the behaviors of the staff and caregivers and that those values drive safety and performance improvement in the organization. At least annually<u>On a regular basis</u>, the board should document that it has confirmed that the behaviors of the organization related to quality and safety mirror its values with respect to patient safety.^{11,12} • Basic Teamwork Training and Interventions Briefings: Governance board members should receive a dedicated period of basic training in teamwork, communication, and patient safety per board member per year as determined by the board and as documented by agendas and attendance records. • Governance Board Competency in Patient Safety: The governance board should take a systematic approach to ensuring that board members' command of patient safety knowledge is adequate to support the organization. At least annually<u>On a regular basis</u>, the board should discuss its own competency and document its strategy for ensuring that all existing and new board members are well versed in patient safety.¹³ ▪ Regular Actions of Senior Administrative Leadership: The actions of the CEO and senior leaders have a critical impact on the safety of every organization. Such actions should be informed, monitored, and directed by an engaged governance leadership on a regular basis.¹⁴ • Time Commitment to Patient Safety: The CEO and senior administrative leaders should systematically designate a certain amount of time for patient safety activities (e.g., weekly walk-rounds and regular patient safety-related sessions at executive staff and governance meetings). Leaders should establish structures and systems to ensure that they are personally reinforcing the principles of patient safety regularly and continuously to staff at all levels of the organization. They should provide feedback to front-line healthcare providers about lessons learned about patient safety from outside sources and from within the organization. • Culture Measurement, Feedback, and Interventions: The CEO and senior administrative leaders should be directly involved in the application of the knowledge that is generated by the measurement of culture as defined in the specifications of the Culture Measurement, Feedback, and Intervention safe practice.

¹¹ IHI. *Foundation: Governance & Improvement. IHI Improvement Map*. Cambridge, MA:IHI; 2009. Available at <http://app.ihl.org/imap/tool/#Process=a3e67c0e-cdc9-423b-8be1-c2d390de773c> . Last accessed February 2014.

¹² IHI. *Foundation: Operating Values. IHI Improvement Map*. Cambridge, MA:IHI; 2009. Available at <http://app.ihl.org/imap/tool/#Process=12462e64-8045-42cb-a679-2418b10e706c> . Last accessed February 2014.

¹³ IHI. *5 Million Lives Campaign. Getting Started Kit: Governance Leadership "Boards on Board" How-to Guide*. Cambridge, MA: IHI; 2008. Available at <http://www.ihl.org/resources/Pages/Tools/HowtoGuideGovernanceLeadership.aspx>. Last accessed February 2014.

¹⁴ IHI. *5 Million Lives Campaign. Getting Started Kit: Governance Leadership "Boards on Board" How-to Guide*. Cambridge, MA: IHI; 2008. Available at <http://www.ihl.org/resources/Pages/Tools/HowtoGuideGovernanceLeadership.aspx>. Last accessed February 2014.

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	• Basic Teamwork Training and Team Interventions: The CEO and senior administrative leaders should be directly involved in ensuring that the organization implements the activities detailed in the specifications of the Teamwork Training and Skill Building safe practice. This includes participating in the defined basic training program. • Identification and Mitigation of Risks and Hazards: The CEO and senior administrative leaders should be continuously engaged in the activities addressed in the specifications of the Identification and Mitigation of Risks and Hazards safe practice. The actions taken to mitigate risks and hazards must be championed by senior administrative leaders with the support of the governance board. Such actions are vital to creating and sustaining a culture of patient safety. ▪ Regular Actions of Unit, Service Line, Departmental, and Midlevel Management Leaders: The entire leadership structure of an organization should be fully engaged in the patient safety activities addressed in Safe Practice 1: Leadership Structures and Systems. Leaders at all levels and in all clinical areas, including employed clinicians, should be continuously and actively engaged in the pursuit of patient safety. The CEO and senior administrative management should ensure that all leaders have the opportunity to lead and support patient safety activities.¹⁵ ▪ Regular Actions with Respect to Independent Medical Leaders: Governance and senior administrative leaders should establish the systems and structures needed to ensure that medical leaders in independent practice as well as those employed by the organization have regular and frequent opportunities to provide direct input to patient safety programs.¹⁶ Auditor Notes: Safe Practice <u>1</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice. The recent Agency for Healthcare Research and Quality (AHRQ) report, <i>Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices</i> is commended as a useful resource when considering the four patient safety culture practices as well as a number of other practices at the next update of the safe practices.

¹⁵ Botwinick L, Bisognano M, Haraden C. *Leadership Guide to Patient Safety*. Cambridge, MA: Institute for Healthcare Improvement; 2006. Available at www.IHI.org. Last accessed February 2014.

¹⁶ Botwinick L, Bisognano M, Haraden C. *Leadership Guide to Patient Safety*. Cambridge, MA: Institute for Healthcare Improvement; 2006. Available at www.IHI.org. Last accessed February 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 2: Culture Measurement, Feedback, and Intervention Healthcare organizations must measure their culture, provide feedback to the leadership and staff, and undertake interventions that will reduce patient safety risk. Applicable Clinical Care Settings This practice is applicable to Centers	▪ At least annuallyAt least biennially,¹⁷ leaders should assess the organization's <u>patient</u> safety and quality culture <u>as part of any safety practice implementation</u>. Survey tools <u>used for this purpose should be</u> 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.¹⁸ • Survey a census of units or service areas that in aggregate deliver care to more than 50 percent of the patients receiving care. • Measure service lines or units where there is a high patient safety risk. • Identify and prioritize culture PI targets; provide adequate resources to address performance gaps over a specified period of time. • Survey a valid sample to allow unit-level analysis and facilitate improvement. ▪ 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.^{19,20} ▪ The results of the culture survey process should be documented and disseminated widely across the enterprise in a systematic and frequent manner.^{21,22} 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.²³ ▪ The organization should document that the results of the survey process, as defined in the Leadership Structures and

¹⁷ Agency for Healthcare Research and Quality (AHRQ). 2014 *User Comparative Report: Hospital Survey on Patient Safety Culture*. AHRQ Publication No. 14-0019-EF. Rockville, MD: AHRQ. 2014. Available at <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/2014/index.html>. Last accessed March 2014.

¹⁸ AHRQ. *Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria*. AHRQ Publication No. 11-0006-EF. Rockville, MD: AHRQ. 2010. Available at <http://www.ahrq.gov/research/findings/final-reports/context-sensitive/index.html>. Last accessed February 2014.

¹⁹ Donnelly LF, Dickerson JM, Goodfriend MA, et al. Improving patient safety: effects of a safety program on performance and culture in a department of radiology. *AJR. Am J Roentgenol*. 2009;193(1):165-171.

²⁰ Kaafarani, HM, Itani KM, Rosen AK, et al. How does patient safety culture in the operating room and post-anesthesia care unit compare to the rest of the hospital? *Am J Surg*. 2009;198(1):70-75.

²¹ Audet AM, Raju R, Jacobs CM, et al.. Transparency as a pillar of a quality and safety culture: the experience of the New York City Health and Hospitals Corporation. *Jt Comm J Qual Patient Saf*. 2008;34(12):707-712.

²² Hutchinson A, Young TA, Cooper KL, et al. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System. *Qual Saf Health Care*. 2009;18(1):5-10.

²³ Sexton JB, Helmreich RL, Neilands TB, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. *BMC Health Serv Res*. 2006;6:44.

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for Medicare & Medicaid Services 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.	Systems safe practice and by the activities defined in the <i>Teamwork Training and Skill Building and the Identification and Mitigation of Risks and Hazards</i> safe practices, have been provided to governance and senior medical leaders. Auditor Notes: Safe Practice <u>2</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice. At the next update of the safe practices, appropriate reference to culture surveys that have been validated for use in areas such as medical office, nursing home, ambulatory surgery and provision of culture survey data to comparative databases should be addressed.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 3: Teamwork Training and Skill Building 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. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care	Effective Team Leadership: Training programs should systematically address and apply the principles of effective team leadership and team formation.²⁴ Leadership at all levels of an organization should be fostered. Effective Teamwork Training: Every organization <u>Organizations</u> should provide teamwork and communication training through basic and detailed programs.²⁵ - Basic Teamwork Training: Basic training should be provided <u>annually on a regular basis</u> 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. - Detailed Teamwork Training: 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.^{26,27} 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 regarding 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. - Effective Teamwork Skill Building: To develop the characteristics of “team-ness,” 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.²⁸ A specified number of care units or service line areas and length of training should be set and documented by organization leadership <u>each year on a regular basis</u> with

²⁴ Salas E, DiazGranados D, Weaver SJ, et al. Does team training work? Principles for health care. *Acad Emerg Med*. 2008;15(11):1002-100-9. Epub 2008 Oct 1.

²⁵ Salas E, DiazGranados D, Weaver SJ, et al. Does team training work? Principles for health care. *Acad Emerg Med*. 2008;15(11):1002-100-9. Epub 2008 Oct 1.

²⁶ Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. *Health Serv Res*. 2006 ;41(4 Pt 2):1690-1709.

²⁷ McKeon LM, Cunningham PD, Oswaks JS. Improving patient safety: patient-focused, high-reliability team training. *J Nurs Care Qual* 2009 Jan-Mar;24(1):76-82.

²⁸ Manser T. Teamwork and patient safety in dynamic domains of healthcare: a review of the literature. *Acta Anaesthesiol Scand*. 2009;53(2):143-151.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
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.	initiatives for building and measuring teamwork skills. Effective Team-Centered Interventions: 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 On a regular basis, 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. ▪ Specific Team Performance Improvement Projects: 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. ▪ Rapid Response Assessment: Annually On a regular basis, organizations should formally evaluate the opportunity for using rapid response systems to address the issues of deteriorating patients across the organization.^{29,30} ▪ Internal and External Reporting: 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. Minimum Requirements of Safe Practice 3: 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.³¹

²⁹ Kaplan LJ, Maerz LL, Schuster K, et al. Uncovering system errors using a rapid response team: cross-coverage caught in the crossfire. *J Trauma*. 2009;67(1):173-178.

³⁰ Bellomo, 2003: Bellomo R, Goldsmith D, Uchino S, et al. A prospective before-and-after trial of a medical emergency team. *Med J Aust*. 2003;179(6):283-287.

³¹ [Public domain team training resources and support opportunities that support teamwork interventions can be found online at http://www.ahrq.gov/professionals/quality-patient-safety/index.html.](http://www.ahrq.gov/professionals/quality-patient-safety/index.html)

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	Auditor Notes: Safe Practice <u>3</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Evidence supports the noted changes to the practice.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 4: Identification and Mitigation of Risks and Hazards 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. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings to include	Identification and Mitigation of Risks and Hazards ▪ Risk and Hazard Identification Activities: 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. 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.^{32, 33, 34} • 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 events³⁵; 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. <u>On a regular basis</u>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. 1. <i>Serious Reportable Events</i>. Processes for identifying, managing, and analyzing events should be defined and implemented to identify patterns and opportunities for improvement.^{36, 37} 2. <i>Sentinel Event Reporting</i>. Processes for identifying, managing, and analyzing events should be defined and implemented to identify patterns and opportunities for improvement. 3. <i>Adverse Event Reporting</i>. Processes for identifying, managing, and analyzing events should be defined and implemented to identify patterns and opportunities for improvement. 4. <i>Root Cause Analysis</i>. The root cause analysis process for identifying the causal factors for events, including sentinel events, should be undertaken. 5. <i>Closed Claims Analysis</i> This analysis should be undertaken.

³² Nuckols TK, Bell DS, Paddock SM, et al. Comparing process- and outcome-oriented approaches to voluntary incident reporting in two hospitals. *Jt Comm J Qual Patient Saf.* 2009 ;35(3):139-145.

³³ Pronovost PJ, Goeschel CA, Olsen KL, et al. Reducing health care hazards: lessons from the commercial aviation safety team. *Health Aff (Millwood)*. 2009;28(3):w479-w489. Epub 2009 Apr 7.

³⁴ Battles JB, Lilford RJ. Organizing patient safety research to identify risks and hazards. *Qual Saf Health Care.* 2003;12 (Suppl II):ii2-ii7.

³⁵ Nuckols TK, Bell DS, Paddock SM, et al. Comparing process- and outcome-oriented approaches to voluntary incident reporting in two hospitals. *Jt Comm J Qual Patient Saf.* 2009 ;35(3):139-145.

³⁶ Levinson D. Department of Health and Human Services. Office of Inspector General. *Adverse events in hospitals: state reporting systems*. Report No. OEI-06-07-00471. Washington, DC:HHS;2008. Available at <http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf>. Last accessed October 15, 2009.

³⁷ McDonald TB, Helmchen L, Smith KM, et al. Responding to patient safety incidents: the “seven pillars”. *Qual Saf Health Care.* 2010;19(6):e11.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	6. <i>Enterprise Systems Failures</i>. People systems, technology systems, and quality systems failures beyond those resulting in adverse outcomes should be evaluated. 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. 8. <i>Patient Safety Indicators</i>. Patient safety indicators should be used to generate hypotheses and guide deeper investigation. 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. 10. <i>External Reporting Source Input</i>. Such information should be an input to risk-assessment activities. • Real-Time and Near-Real-Time Identification: Real-Time and Near Real-Time Identification: Organizations should evaluate real-time or near real-time tools at least annually <u>on a regular basis</u> for their value in risk identification for the areas identified as high risk for the organization. A concise, thorough assessment of tools such as those noted below and others that become available to the organization should be documented. – Trigger tools, manually- or technology-enabled. – Observational tools, permitting direct observation of processes in high-risk areas. – Technology tools such as electronic health records. – Real-Time Risk Identification Behaviors. Organizations should support the front-line behaviors of real-time risk identification, including workflow design, that enable the early identification of patient risks and hazards and that inspire “stop-the-line” actions that can prevent patient harm. • Prospective Identification: A structured, proactive risk assessment should be undertaken by certain care units to identify risks and hazards in order to prevent harm and error. At least annually <u>On a regular basis</u>, an organization should evaluate the prospective or proactive tools and methods, such as the two listed below, in order to identify risks. At a minimum, the organization should perform one regular prospective analyses per year using the tool or method deemed appropriate by the organization. Specific steps should be taken to ensure that lessons learned are communicated across the organization and that they are applied in other care settings, where applicable.³⁸ – Failure Modes and Effects Analysis (FMEA).³⁹ – Probabilistic Risk Assessment (PRA).^{40, 41} • Integrated Organization-Wide Risk Assessment: The continuous, systematic integration of the information about risks

³⁸ Battles JB, Dixon NM, Borotkanics RJ, et al. Sensemaking of patient safety risks and hazards. *Health Serv Res*. 2006;41 (4 Pt 2):1555-1575.

³⁹ Chiozza ML, Ponzetti C. FMEA: a model for reducing medical errors. *Clin Chim Acta*. 2009;404(1):75-78.

⁴⁰ Alemi F. Probabilistic risk analysis is practical. *Qual Manag Health Care*. 2007;16(4):300-310.

⁴¹ Hovor C, O'Donnell LT. Probabilistic risk analysis of medication error. *Qual Manag Health Care*. 200;16(4):349-353.

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	and hazards across the organization should be undertaken to optimally prevent systems failures.⁴² Information about risks and hazards from multiple sources should be evaluated in an integrated way in order to identify patterns, systems failures, and contributing factors involving discrete service lines and units. The organization should integrate the information noted below, ensure that it is provided to those designing mitigation strategies and that it is documented and disseminated widely across the organization systematically and frequently, and ensure that the results of mitigation activities are made available to all who were involved in providing source information. Frequent progress reports should be generated on an ongoing basis, and a summary of such reports should be produced at least annually on a regular basis. – Risk management (claims management) services.⁴³ – Complaints and customer services participation. – Disclosure support system. (See the <i>Disclosure and Care of the Caregiver</i> safe practices included in this report.) – Culture measurement, feedback, and intervention. (See the <i>Culture Measurement, Feedback, and Intervention</i> safe practice.) – Retrospective, real-time and near real-time, and prospective information. – Anticipated risks for surge in capacity, for example, flu pandemic⁴⁴ and natural disaster emergency preparedness. 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. • 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.⁴⁵ • 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 Identification and Mitigation of Risks and Hazards safe practice. Such performance improvement programs should include education, skill building, measurement, reporting, and process improvement.

⁴² Chiozza ML, Ponzetti C. FMEA: a model for reducing medical errors. *Clin Chim Acta*. 2009 ;404(1):75-78.

⁴³ Boothman RC, Blackwell AC, Campbell DA Jr, et al. A better approach to medical malpractice claims? The University of Michigan experience. *J Health Life Sci Law*. 2009;2(2):125-159.

⁴⁴ Association for Professionals in Infection Control and Epidemiology (APIC). *Pandemics*. Washington, DC:APIC;2008. Available at http://apic.org/Resource/TinyMceFileManager/Practice_Guidance/Emergency_Preparedness/Document_1_HHS_Pandemic_Planning_Update_VI.pdf, Last accessed February 2014.

⁴⁵ Damiani G, Pinnarelli L, Scopelliti L, et al. A review on the impact of systematic safety processes for the control of error in medicine. *Med Sci Monit*. 2009;15(7):RA157-RA166.

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	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. 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. 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. 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.⁴⁶ 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. • Specific Risk Assessment and Mitigation Activities: The organization should <u>be able to</u> 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. 1. Falls: The organization should monitor the effectiveness of fall reduction programs, including risk reduction strategies, in-services, patient/family education, and environment of care redesign. 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. 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.

⁴⁶ Pronovost PJ, Goeschel CA, Olsen KL, et al. Reducing health care hazards: lessons from the commercial aviation safety team. *Health Aff (Millwood)*. 2009;28(3):w479-w89.

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	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. 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. Auditor Notes: Safe Practice <u>4</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Evidence supports the noted changes to the practice. While this practice meets the criteria for inclusion, it needs revision at the next update of the Safe Practices. The section on “Falls” in Specific Risk Assessment and Mitigation Activities has been eliminated in light of Safe Practice 33, Falls Prevention. The recent AHRQ report, <i>Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices</i> should prove useful for future updates.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 5: Informed Consent 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. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include	▪ At a minimum, patients should be able to explain, in their everyday words, 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. Decision aids such as illustrated pamphlets and video tools can improve knowledge and participation in decisionmaking.^{47,48,49,50} This safe practice includes all of the following elements: • Informed consent documents for use with the patient should be written at or below the 5th-grade level and in the preferred language of the patient. • 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. • A qualified medical interpreter or reader should be provided to assist patients with limited English proficiency, limited health literacy, and visual or hearing impairments.⁵¹ • The risk that is associated with high-risk elective cardiac procedures and high-risk procedures with the strongest volume-outcomes relationship should be conveyed. Auditor Notes: Safe Practice 5 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ___ Yes w/changes as noted <u> X </u> No ___ Comments: Updated evidence supports the noted changes to the practice. The practice meets criteria for inclusion; however, when the practices are updated next, suggest there be greater specificity with respect to “alternatives” to include an expectation that the level of detail approximate that of the primary

⁴⁷ Pizzi LT, Goldfarb NI, Nash DB. Role of the Patient: Procedures For Obtaining Informed Consent. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ);2001. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Section H, Ch. 48.

⁴⁸ Cordasco KM. Obtaining Informed Consent From Patients: Brief Update Review in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Rockville, MD: AHRQ; 2013. AHRQ Publication No. 13-E001-EF:p. 461-471. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html> . Last accessed February 2014.

⁴⁹ IHI. Shared Decision Making. IHI Improvement Map. Cambridge, MA: IHI; 2009. Available at <http://www.ihl.org/imap/tool/#Process=dd91f497-7eaa-433f-928c-838818fdf1f5>. Last accessed February 2014.

⁵⁰ The Joint Commission. *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals*. Oakbrook Terrace, IL: The Joint Commission; 2010. Available at <http://www.jointcommission.org/assets/1/6/a roadmap for hospitals final version 727.pdf>. Last accessed February 2014.

⁵¹ Divi C, Koss RG, Schmaltz SP, et al. Language proficiency and adverse events in U.S. hospitals: A pilot study. *Int J Qual Health Care*. 2007;19(2):60-67. Available at [http://www.commonwealthfund.org/usr_doc/1019_Divi_lang_proficiency_adverse_events_IntlJnlQualHltCare_04-2007_ITL\(web\).pdf](http://www.commonwealthfund.org/usr_doc/1019_Divi_lang_proficiency_adverse_events_IntlJnlQualHltCare_04-2007_ITL(web).pdf) Last accessed March 2014..

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	treatment/service/procedure recommendation. It is recommended that the specification regarding volume-outcomes be removed from this practice as it does not specifically address the issue of informed consent. This issue deserves further consideration in future safe practice reports.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 6: Life-Sustaining Treatment Ensure that written documentation of the patient's preferences for life-sustaining treatments is prominently displayed in his or her chart. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services 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.	Organization policies, consistent with applicable law and regulation, should be in place and address patient preferences for life-sustaining treatment and withholding resuscitation.⁵² Auditor Notes: Safe Practice <u>6</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u>X</u> Yes w/changes as noted ____ No ____ Comments: Updated evidence continues to support the existing specifications. As a practice specific to conforming to law, it is acceptable as written. When the practices are updated next, should examine the goal of the practice and whether that goal is met. Further, consider the need for practices when they reiterate law.

⁵² [Cerminara KL, Bogin SM. A paper about a piece of paper. Regulatory action as the most effective way to promote use of physician orders for life-sustaining treatment. J Leg Med.2008;29\(4\):479-503.](#)

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 7: Disclosure 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.⁵³ Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical	▪ The types of serious unanticipated outcomes addressed by this practice include, at a minimum: a) sentinel events; b) serious reportable events;⁵⁴ 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. ▪ 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. ▪ The governance and administrative leadership should ensure that <u>such event</u> information is systematically used for performance improvement by the organization. Policies and procedures should incorporate continuous quality improvement techniques and provide for <u>annual-periodic</u> reviews and updates. ▪ Adherence to the practice and participation with the support system is expected and may be considered as part of credentialing. ▪ Communication with patients, their families, and caregivers should include or be characterized by the following: • 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;⁵⁵ • empathic communication of the “facts,” a skill that should be developed and practiced in healthcare organizations; • an explicit and empathic expression of regret that the outcome was not as expected (e.g., “I am sorry that this has happened.”); • a commitment to investigate and, as much 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; • 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;⁵⁶ • “timeliness” – the initial conversation with the patient and/or family should occur within 24 hours, whenever

⁵³ Massachusetts Coalition for the Prevention of Medical Errors. *When Things Go Wrong: Responding to Adverse Events. A Consensus Statement of the Harvard Hospitals.* Burlington, MA: Massachusetts Coalition for the Prevention of Medical Errors; 2006. Available at <http://www.macoalition.org/documents/respondingToAdverseEvents.pdf>. Last accessed February 2014.

⁵⁴ http://www.qualityforum.org/Publications/2011/12/Serious_Reportable_Events_in_Healthcare_2011.aspx. Last accessed March 2014.

⁵⁵ Fein SP, Hilborne LH, Spiritus EM, et al. The many faces of error disclosure: a common set of elements and a definition. *J Gen Intern Med.* 2007;22(6):755-761.

⁵⁶ McDonald TB, Helmchen L, Smith KM, et al. Responding to patient safety incidents: the “seven pillars.” *Qual Saf Health Care.* 2010 ;19(6):e11.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	possible. Early and subsequent follow-up conversations should occur, both to maintain the relationship and to provide information as it becomes available; • 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; • emotional support for patients and their families by trained caregivers should be provided; and • a disclosure and improvement support system should be established and maintained to provide the following to caregivers and staff that includes: – 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, – education and skill building regarding 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,⁵⁷ – <u>24-hour timely</u> 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 – education of caregivers regarding <u>the organizational policies, care team disclosure processes, and available support from leaders, managers, providers when errors or adverse events happen.</u>^{58, 59} ■ 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 the healthcare organizations and/or the 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. ■ 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.^{60, 61}

⁵⁷ Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. *Health Serv Res.* 2006 Aug;41(4 Pt 2):1690-1709.

⁵⁸ Keller DR, Bell CL, Dottl SK. An effective curriculum for teaching third-year medical students about medical errors and disclosure. *WMJ.* 2009;108(1):27-29.

⁵⁹ Shannon SE, Foglia MB, Hardy M, et al. Disclosing errors to patients: perspectives of registered nurses. *Jt Comm J Qual Patient Saf.* 2009;35(1):5-12.

⁶⁰ Agency for Healthcare Research and Quality. Patient Safety Organizations. Legislation and Regulations: Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act): An Overview Web site. Available at <http://www.pso.ahrq.gov/regulations/regulations.htm>. Last accessed February 2014.

⁶¹ Public Law 109-41 - July 29, 2005. *Patient Safety and Quality Improvement Act of 2005*. Available at <http://www.pso.ahrq.gov/statute/pl109-41.pdf>. Last accessed February 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	▪ 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. Auditor Notes: Safe Practice <u>7</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice. 1) Absent specific time-based recommendations, it is recommended that the changes noted above be made. 2) A recent publication, <i>Safety is Personal: Partnering with Patients and Families for the Safest Care</i> (available at http://www.npsf.org/about-us/lucian-leape-institute-at-npsf/lli-reports-and-statements/safety-is-personal-partnering-with-patients-and-families-for-the-safest-care/) is commended as a resource that encompasses, and goes beyond, disclosure to patient engagement.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 8: Care of the Caregiver 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. Applicable Clinical Care	▪ Indications: • 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 Safe Practice 7: Disclosure.) • 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. ▪ 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: • 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.⁶² ^{63,64} 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. If, after an event investigation, the organization is contemplating a corrective action that could result in a serious loss of livelihood of an individual, 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. • 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

⁶² Frankel, A. *Decision Tree for Unsafe Acts Culpability*. Cambridge, MA: IHI;2011. Available at:

<http://www.ihl.org/resources/Pages/Tools/DecisionTreeforUnsafeActsCulpability.aspx>. Last accessed February 2014.

⁶³ Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. *Health Serv Res*. 2006;41(4 Pt 2):1690-1709.

⁶⁴ Wachter, RM, Pronovost, PJ. Balancing “no blame” with accountability in patient safety. *N Engl J Med*. 2009;361(14):1401-1406.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Settings This practice is applicable to Centers for Medicare & Medicaid Services 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.	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. (See Implementation Example Approaches.) • 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. • Supportive Care: Caregivers, staff, and administrators directly involved in serious unintentional harm as defined above must should be considered “patients requiring immediate and ongoing care.” <u>“to have sustained psychological trauma or injury that may require clinical care and thus would be considered “patients.”</u> 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 <u>“serious</u> near misses” that are reported to the organization. • 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.⁶⁵ ▪ 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.⁶⁶ ▪ 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

⁶⁵ McDonald TB, Helmchen L, Smith KM, et al. Responding to patient safety incidents: the “seven pillars.” *Qual Saf Health Care*.2010 ;19(6):e11.

⁶⁶ McDonald TB, Helmchen L, Smith KM, et al. Responding to patient safety incidents: the “seven pillars.” *Qual Saf Health Care*.2010 ;19(6):e11.

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	updates. ▪ 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.^{67 68} Auditor Notes: Safe Practice <u>8</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice.

⁶⁷ Agency for Healthcare Research and Quality. Patient Safety Organizations. Legislation and Regulations: Patient Safety and Quality Improvement Act of 2005 (the patient safety act): An Overview Web site. Available at <http://www.pso.ahrq.gov/regulations/regulations.htm>. Last accessed February 2014.

⁶⁸ Public Law 109-41. July 29, 2005. *Patient Safety and Quality Improvement Act of 2005*. Available at <http://www.pso.ahrq.gov/statute/pl109-41.pdf>. Last accessed February 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 9: Nursing Workforce Implement critical components of a well-designed nursing workforce that mutually reinforce patient safeguards, including the following:⁶⁹ ▪ 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;⁷⁰ ▪ Senior administrative nursing leaders, such as a Chief	<u>Action in support of a well-designed nursing workforce:</u>⁷¹ ▪ Implement explicit organizational policies and procedures, with input from nurses at the unit level, about effective staffing targets that specify the number, competency, and skill mix of nursing staff needed to provide safe, direct care services.⁷² ▪ Ensure that the governance board and senior, midlevel, and line managers are educated about the impact of nursing on patient safety. ▪ 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.⁷³ This assessment must be reviewed by senior administrative management and the governance board at least annually/periodically to ensure that resources are allocated and that performance improvement programs are implemented. ▪ 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. Such data should include, but not be limited to, nursing hours per patient day as defined in the National Quality Forum report, <u>Patient Safety – Complications Endorsement Maintenance: Phase II Final Report.</u>⁷⁴ ▪ 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. ▪ 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. ▪ Provide reports at least annually to the public through the appropriate organizations. ▪ 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

⁶⁹ Institute of Medicine(IOM). Keeping Patients Safe: Transforming the Work Environment of Nurses. Washington, DC: The National Academies Press; 2004. Available at http://www.nap.edu/catalog.php?record_id=10851. Last accessed February 2014.

⁷⁰ Tourangeau AE, Doran DM, Hall LM, et al. Impact of hospital nursing care on 30-day mortality for acute medical patients. *J Adv Nurs*;57(1): 32–44.

⁷¹ Institute of Medicine(IOM). Keeping Patients Safe: Transforming the Work Environment of Nurses. Washington, DC: The National Academies Press; 2004. Available at http://www.nap.edu/catalog.php?record_id=10851. Last accessed February 2014.

⁷² Aiken LH, Sloane DM, Bruyneel L, et al. Nurse staffing and education and hospital mortality in nine European countries: a retrospective observational study. *The Lancet*. Epub February 25, 2014.

⁷³ Needleman J, Buerhaus PI, Stewart M, et al. Nurse staffing in hospitals: is there a business case for quality? *Health Aff (Millwood)*. 2006;25(1):204-211.

⁷⁴ National Quality Forum (NQF). *Patient Safety - Complications Endorsement Maintenance: Phase II Final Report*. Washington, DC: NQF;2013.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Nursing Officer, as part of the hospital <u>organization's</u> senior management team; - 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; - Provision of budgetary resources to support nursing staff in the ongoing acquisition and maintenance of professional knowledge and skills. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include	organization, temporary staff, float pool nurses, contract staff, and temporarily assigned nurses. 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 population served. Auditor Notes: Safe Practice <u>9</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 10: Direct Caregivers 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. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services 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.	- Establish a staffing plan that is adequately resourced and actively managed, and the effectiveness of which is regularly evaluated with respect to patient safety. - 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. This assessment must be reviewed by senior administrative management and the governance board at least annually <u>periodically</u> to ensure that resources are allocated and performance improvement programs are implemented. - 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. - 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. - 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. Provide reports, at least annually, about the impact of non-nursing direct caregivers on patient safety to the governance board and senior administrative leaders. - 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, 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. Auditor Notes: Safe Practice <u>10</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Evidence supports the noted changes to the practice. Applicable care settings are too broad; some of these settings do not use non-nursing direct care staff.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 11: Intensive Care Unit Care 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”). Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include inpatient service/hospital.	▪ 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. ▪ 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. ▪ 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. ▪ If it is not possible to have a dedicated, critical care certified physician in the ICU, 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)⁷⁵ <u>with on-site “house staff, primary care physicians, and other on-site personnel (e.g. anesthesiologists) to respond physically to emergencies” and perform procedures.</u> Auditor Notes: Safe Practice <u>11</u> continues to meet the Criteria for Inclusion in the Safe Practices Set as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Evidence supports the noted changes to the practice. Present emphasis remains on having critical care certified physicians available “in-house,” rather than only in the ICU. It will be important to monitor evolving evidence in this area. There is a need for better evidence of the efficacy of ICU telemedicine (eICU); however, eICU coverage is not associated with increased harm and meets a well-defined need. Given the context of a national need for more intensivists, it is appropriate it be included as evidence continues to evolve.

⁷⁵ Rosenfeld BA, Dorman T, Breslow MJ, et al. Intensive care unit telemedicine: alternate paradigm for providing continuous intensivist care. *Crit Care Med*. 2000;28(12):3925-3931.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 12: Patient Care Information Ensure that care information is transmitted and appropriately documented in a timely manner and in a clearly understandable form to patients and appropriate family and caregivers, and to all of the patient's healthcare providers/professionals, within and between care settings, who need that information to provide continued care. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare &	- 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. - Implement a standardized process to ensure that critical results are communicated quickly to a licensed healthcare provider so that action can be taken.^{76, 77} 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.^{78, 79} - 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. Also, include a process of how to communicate critical test results that are completed after the patient has been discharged from the organization. - 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 <u>access to</u> patient care information when possible. Auditor Notes: Safe Practice 12 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Evidence supports the noted change to the practice. The specifications should be strengthened by clarifying the importance of direct communication between patient and provider. This should be addressed at the next safe practices update.

⁷⁶ Valenstein PN, Wagar EA, Stankovic AK, et al. Notification of critical results: a College of American Pathologists Q-Probes study of 121 institutions. *Arch Pathol Lab Med.* 2008;132(12):1862-1867.

⁷⁷ Rensburg MA, Nutt L, Zemlin AE, et al. An audit on the reporting of critical results in a tertiary institute. *Ann Clin Biochem.* 2009;46(Pt 2):162-164.

⁷⁸ Valenstein PN, Wagar EA, Stankovic AK, et al. Notification of critical results: a College of American Pathologists Q-Probes study of 121 institutions. *Arch Pathol Lab Med.* 2008;132(12):1862-1867.

⁷⁹ Huang EC, Kuo FC, Fletcher CD, et al. Critical diagnoses in surgical pathology: a retrospective single-institution study to monitor guidelines for communication of urgent results. *Am J Surg Pathol.* 2009;33(7):1098-1102.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Medicaid Service 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.	

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 13: Order Read-Back and Abbreviations Incorporate within your organization a safe, effective communication strategy, structures, and systems to include the following: - 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. - Standardize a list of “Do Not Use” abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization.	- 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. Explicit organizational policies and procedures on verbal and telephone orders should include, at a minimum: - strategies to minimize the use of verbal and telephone orders, and - the identification of items that cannot be ordered or reported verbally or by telephone. - The receiver of verbal information writes down the complete order or test result or enters it into a computer. - The receiver reads back the order or test result. - The receiver receives confirmation from the individual who gave the order or test result. - 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>. - 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. - Use the metric system to express all doses on prescription orders, except for therapies that use standard units, such as insulin and vitamins. - 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. Auditor Notes: Safe Practice <u>13</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u>X</u> Yes w/changes as noted ____ No ____ Comments: Evidence continues to support the existing specifications.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services 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.	

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 14: Ensure Accuracy of Study/Specimen Identification/Labeling of Diagnostic Studies 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. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency	- Label laboratory specimen containers at the time of use and in the presence of the patient <u>utilizing current and emerging technologies; (e.g., barcoding, radio frequency identification).</u>^{80, 81} - 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. - 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. - Label x-ray imaging studies with the correct patient information while in the darkroom or close to the imaging device. - Mark "left" or "right" on each radiographic image to prevent misinterpretation on the light box. - 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. Auditor Notes: Safe Practice 14 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u> X </u> Yes w/changes as noted <u> </u> No <u> </u> Comments: Updated evidence and changes in technology support the noted changes to the practice. The practice name has been changed for clarity of meaning.

⁸⁰ Poon EG, Keohane CA, Yoon CS, et al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Engl J Med 2010;362:1698-1707. Available at <http://www.nejm.org/doi/full/10.1056/NEJMsa0907115#t=articleTop> . Last accessed March 2014.

⁸¹ Morrison AP, Tanasijevic MJ, Goonan EM, et al. Reduction in specimen labeling errors after implementation of a positive patient identification system in phlebotomy. Am J Clin Pathol. 2010 Jun;133(6):870-7.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
room, dialysis facility, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	

Safe Practice 15: Discharge Systems 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.⁸²	▪ Discharge policies and procedures should be established and resourced <u>with explicit goals of bridging gaps in continuity of care and coordination of care across the health care continuum.</u>⁸³ They should address^{84,85} ▪ <u>multidisciplinary discharge planning teams with</u> explicit delineation of roles and responsibilities in the discharge process <u>including those of the pharmacist in medication management;</u> ▪ preparation for discharge occurring, with documentation, throughout the hospitalization; ▪ 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; ▪ completion of discharge plan and discharge summaries before discharge; ▪ patient or, as appropriate, family perception of coordination of discharge care; ▪ <u>post-discharge follow up;</u> and ▪ benchmarking, measurement, and continuous quality improvement of discharge processes. ▪ 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. At a minimum, the discharge plan must include the following:⁸⁶ • reason for hospitalization; • medications to be taken post-discharge, including, as appropriate, resumption of pre-admission medications, how to take them, and how to obtain them; • instructions for the patient on what to do if his or her condition changes; and • 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 discharge summary must be provided to the ambulatory clinical provider who accepts the patient’s care after hospital discharge. At a minimum, the discharge summary should include the following:^{87, 88} • reason for hospitalization;
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⁸² Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med.* 2009;150(3):178-187.

⁸³ Rennke S, Shoeb MH, Nguyen OK, et al. *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ.;2013. AHRQ Publication No. 13-E001-EF: 425-438. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html> . Last accessed February 2014.

⁸⁴ Coleman EA, Parry C, Chalmers S, et al. The care transitions intervention: results of a randomized controlled trial. *Arch Intern Med.* 2006;166(17):1822-1828.

⁸⁵ Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med.* 2009;150(3):178-187.

⁸⁶ Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med.* 2009;150(3):178-187.

Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services 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.	• significant findings; • procedures performed, and care, treatment, and services provided to the patient; • the patient's condition at discharge; • information provided to the patient and family; • a comprehensive and reconciled medication list; and • a list of acute medical issues, tests, and studies for which confirmed results are unavailable at the time of discharge and require follow-up. ▪ Original source documents (e.g., laboratory or radiology reports or medication administration records) should be in <u>reviewed by</u> the transcriber's immediate possession and should be visible when it is necessary to transcribe information from one document to another. ▪ 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. Auditor Notes: Safe Practice <u>15</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice.
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⁸⁷ Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med*. 2009;150(3):178-187.

⁸⁸ Forster A, Murff HJ, Peterson JF, et al. The incidence and severity of adverse events affecting patients after discharge from the hospital. *Ann Intern Med* 2003; 138:161-167. Available at <http://annals.org/article.aspx?articleid=716006>. Last accessed March 2, 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 16: Safe Adoption of Computerized Prescriber-Provider Order Entry 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.^{89,90,91} Applicable Clinical Care Settings	▪ 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: • 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. • Prospective re-engineering of care processes and workflow. • Readiness of integrated clinical information systems that include, at a minimum, the following information and management systems:⁹² – Admit Discharge and Transfer (ADT). – Laboratory with electronic microbiology output. – Pharmacy. – Orders. – Electronic Medication Administration Record (including patient, staff, and medication ID) (eMAR). – Clinical Data Repository with Clinical Decision Support Capability. – Scheduling. – Radiology. – Clinical Documentation. • Readiness of hospital governance, staff, and independent practitioners, including board governance, senior administrative management, front-line caregivers, and independent practitioners. • The following CPOE specifications, which: – facilitate the medication reconciliation process; – 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

⁸⁹ Kaushal R, Bates DW. Computerized Physician Order Entry (CPOE) with Clinical Decision Support Systems (CDSSs). Making Health Care Safer: A Critical Analysis of Patient Safety Practices. AHRQ Publication 01-E058. Rockville, MD: Agency for Healthcare Research and Quality. 2001 Jul: 67-76. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/er43/ptsafety/index.html> . Last accessed February 16, 2014.

⁹⁰ [Shamliyan TA, Duval S, Kane RL. Just What the Doctor Ordered. Review of the Evidence of the Impact of Computerized Physician Order Entry System on Medication Errors. Health Serv Res. 2008;43\(1 Pt 1\):32-53.](#)

⁹¹ [Wolfstadt JL, Gurwitz JH, Field TS, et al. The Effect of Computerized Physician Order Entry with Clinical Decision Support on the Rates of Adverse Drug Events: A Systematic Review. J Gen Intern Med. 2008;23\(4\):451-458.](#)

⁹² [Computerized Provider Order Entry \(CPOE\) Resources. American Society of Health-System Pharmacists. Available at http://www.ashp.org/Import/MEMBERCENTER/Sections/SectionofPharmacyInformaticsandTechnology/Resources/CPOE.aspx. Last accessed February 19, 2014.](#)

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include inpatient service/hospital.	(including medication administration record), and laboratory systems, to facilitate review of all orders by all providers; – are linked to prescribing error-prevention software with effective clinical decision support capability; – require prescribers to document the reasons for any override of an error prevention notice; – 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; – 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; – 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 – 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. ⁹³ Auditor Notes: Safe Practice <u>16</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u> X </u> No ____ Comments: Updated evidence supports the noted changes to the practice, including the more appropriate reference to “provider” order entry.

⁹³ Kuperman GJ, Bobb A, Payne TH, et al. Medication-related clinical decision support in computerized provider order entry systems: a review. *J Am Med Inform Assoc.* 2007;14(1):e29-e40.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 17: Medication Reconciliation The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care. ^{94,95} Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital,	▪ Educate clinicians upon hire on the importance of medication reconciliation, including how to take an accurate medication history and assess medication adherence; frequency of ongoing education is based on the risk of noncompliance and adverse drug events as determined by the organization. ▪ 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. ▪ 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: • prescription medications; • sample medications; • vitamins; • nutraceuticals; • over-the-counter drugs; • complementary and alternative medications; • radioactive medications; • respiratory therapy-related medications; • parenteral nutrition; • blood derivatives; • intravenous solutions (plain or with additives); • investigational agents; and • any product designated by the Food and Drug Administration (FDA) as a drug. ▪ 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. ⁹⁶ ▪ 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 finalized "home medications" list should be maintained unchanged

⁹⁴ [IHI. Medical Reconciliation at all Transitions. IHI Improvement Map. Cambridge, MA:IHI;2013. Available at http://www.ihl.org/imap/tool/#Process=7ce51016-b4f0-423c-9f8b-5e1ea8d7b810. Last accessed February 2014.](http://www.ihl.org/imap/tool/#Process=7ce51016-b4f0-423c-9f8b-5e1ea8d7b810)

⁹⁵ [The Joint Commission Comprehensive Accreditation Manual for Hospitals. National Patient Safety Goal 03.06.01. Chicago ,IL;:The Joint Commission;2013.](#)

⁹⁶ [Varkey P, Cunningham J, Bisping DS. Improving medication reconciliation in the outpatient setting. Jt Comm J Qual Patient Saf .2007;33\(5\):286-292.](#)

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
outpatient hospital, and skilled nursing facility.	(unless new information about home medications becomes available) 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. ▪ Any discrepancies (i.e., omissions, duplications, adjustments, deletions, additions) are reconciled and documented while the patient is under the care of the organization. ▪ 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. ▪ 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. ▪ 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. ▪ 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.^{97,98} ▪ In settings where medications are used minimally, or are prescribed for a short duration, modified medication reconciliation processes are performed: • 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. • 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. • In these settings, there is a complete, documented medication reconciliation process when: – Any new long-term (chronic) medications are prescribed. – There is a prescription change for any of the patient's current known long-term medications.

⁹⁷ Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med.* 2009;150(3):178-187.

⁹⁸ Schnipper JL, Kirwin JL, Cotugna MC, et al. Role of Pharmacist Counseling in Preventing Adverse Drug Events After Hospitalization. *Arch Intern Med.* 2006;166(5):565-571.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	– The patient is required to be subsequently admitted to an organization from these settings for ongoing care. • 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. Auditor Notes: Safe Practice 17 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u> X </u> Yes w/changes as noted <u> </u> No <u> </u> Comments: Updated evidence continues to support the existing specifications. AHRQ’s Evidence Report/Technology Assessment Number 211 <i>Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices</i> chapter related to medication reconciliation will prove a valuable resource in helping focus and guide the next update for this safe practice.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 18: Pharmacist Leadership Structures and Systems 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. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare &	Leadership and Culture of Safety 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. Pharmacists should actively participate in medication management processes, structures, and systems, by, at a minimum: - 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).^{99, 100, 101, 102} - 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. - 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. - 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. - Systematically identifying and mitigating medication safety risks and hazards to reduce preventable patient harm.¹⁰³ - Working with the interdisciplinary team to ensure evidence-based medication regimens for all patients.^{104,105} - 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. - Performing medication safety walk-rounds to evaluate medication processes and front-line staff input about medication

⁹⁹ Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care: anticoagulation control, patient outcomes, and health care costs. *Arch Intern Med.* 1998;158(15):1641-1647.

¹⁰⁰ Dudas V, Bookwalter T, Kerr KM, et al. The impact of follow-up telephone calls to patients after hospitalization. *Am J Med.* 2001;111(9B):26S-30S.

¹⁰¹ Schnipper JL, Kirwin JL, Cotugno MC, et al. Role of pharmacist counseling in preventing adverse drug events after hospitalization. *Arch Intern Med.* 2006;166(5):565-571.

¹⁰² Koshman SL, Charrois TL, Simpson SH, et al. Pharmacist care of patients with heart failure: a systematic review of randomized trials. *Arch Intern Med.* 2008;168(7):687-694.

¹⁰³ [Nickerson A, MacKinnon NJ, Roberts N, et al. Drug-therapy problems, inconsistencies and omissions identified during a medication reconciliation and seamless care service. *Healthc Q.* 2005;8 Spec No: 65-68.](#)

¹⁰⁴ Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA.* 1999;282(3):267-270.

¹⁰⁵ Kucukarslan SN, Peters M, Mlynarek M, et al. Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. *Arch Intern Med.* 2003;163(17):2014-2018.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Medicaid Services 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.	safe practices. - Ensuring that pharmacy staff engages in teamwork and communication, leadership, and safety culture training, at least annually. - 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.¹⁰⁶ - Engaging in public health initiatives on behalf of the pharmacy community, including best practice immunization and vaccination initiatives, smoking cessation, and emergency preparedness.¹⁰⁷ Selection and Procurement - 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. - Medication selection should be informed by the best scientific evidence and clinical guidelines for a given therapeutic area, and individualized for the patient. 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. - Pharmacists are actively involved in the development and implementation of evidence-based drug therapy protocols and/or order sets. Storage - 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. - Ensure that the written medication storage policy is implemented. The policy includes safe storage, safe handling, security, and disposition of these medications. - 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.

¹⁰⁶ ¹⁰⁶ McGregor JC, Weekes E, Forrest GN, et al. Impact of a computerized clinical decision support system on reducing inappropriate antimicrobial use: a randomized controlled trial. *J Am Med Inform Assoc.* 2006;13(4):378-384.

¹⁰⁷ Dent LA, Harris KJ, Noonan CW. Randomized trial assessing the effectiveness of a pharmacist-delivered program for smoking cessation. *Ann Pharmacother.* 2009;43(2):194-201.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	Ordering and Transcribing - Ensure with the healthcare team that only the medications needed to treat the patient’s condition are ordered, provided, and administered. Preparing and Dispensing - 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.¹⁰⁸ - Pharmacists should oversee the preparation of medications, including sterile products, and ensure that they are safely prepared. - Medications should be labeled in a standardized manner according to hospital policy, applicable law and regulation, and standards of practice.^{109,110} - 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. - When a full-time pharmacist is not available onsite, a pharmacist is available by telephone or accessible at another location that has 24-hour pharmacy services. Medication Administration - Organizations should prepare for 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.^{111,112,113,114}

¹⁰⁸ Westerlund T, Marklund B. Assessment of the clinical and economic outcomes of pharmacy interventions in drug-related problems. *J Clin Pharm Ther.* 2009;34(3):319-327.

¹⁰⁹ Shrank WH, Agnew-Blais J, Choudhry NK, et al. The variability and quality of medication container labels. *Arch Intern Med.* 2007;167(16):1760-1765.

¹¹⁰ [The Joint Commission Comprehensive Accreditation Manual for Hospitals. National Patient Safety Goal 03.04.01. Chicago \(IL\); 2013.](#)

¹¹¹ Larsen GY, Parker HB, Cash J, et al. Standard drug concentrations and smart-pump technology reduce continuous-medication-infusion errors in pediatric patients. *Pediatrics.* 2005;116(1):e21-e25.

¹¹² Rothschild JM, Keohane CA, Cook EF, et al. A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. *Crit Care Med* 2005;33(3):533-540.

¹¹³ Poon EG, Cina JL, Churchill W, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. *Ann Intern Med.* 2006;145(6):426-434.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	▪ 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. Monitoring ▪ 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.^{115,116} ▪ 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. ▪ 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. ▪ Proactive risk mitigation strategies should be demonstrated to prevent errors in the organization. Example: On an ongoing basis*, utilize external sources for review (such as ISMP, FDA) of reported near-miss/medication errors. *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. High-Alert Medications ▪ Identify high-alert medications within the organization. ▪ Implement institutional processes for procuring, storing, ordering, transcribing, preparing, dispensing, administering, and

¹¹⁴ Paoletti RD, Suess TM, Lesko MG, et al. Using bar-code technology and medication observation methodology for safer medication administration. *Am J Health Syst Pharm.* 2007;64(5):536-543.

¹¹⁵ Bond CA, Raehl CL. Clinical pharmacy services, pharmacy staffing, and adverse drug reactions in United States hospitals. *Pharmacotherapy.* 2006;26(6):735-747.

¹¹⁶ Gleason KM, Groszek JM, Sullivan C, et al. [Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. Am J Health Syst Pharm. 2004;61\(16\):1689-1695.](#)

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	monitoring high-alert medications. Evaluation - Perform medication safety self-assessments to identify organizational structure, system, and communication opportunities to proactively target harm reduction and risk mitigation strategies. - 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.^{117, 118} Auditor Notes: Safe Practice 18 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u> X </u> Yes w/changes as noted <u> </u> No <u> </u> Comments: Though the practice was not changed, the panel raised concerns about the level of evidence to support the existing practice. AHRQ's Evidence Report/Technology Assessment Number 211 <i>Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices</i> chapters related to pharmacist's role in preventing ADEs and medication reconciliation will prove valuable resources in helping focus and guide the next update for this safe practice.

¹¹⁷ Davis TC, Wolf MS, Bass PF 3rd, et al. Literacy and misunderstanding prescription drug labels. *Ann Intern Med*. 2006;145(12):887-894.

¹¹⁸ Davis TC, Wolf MS, Bass PF 3rd, et al. Low literacy impairs comprehension of prescription drug warning labels. *J Gen Intern Med*. 2006;21(8):847-851.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 19: Hand Hygiene Comply with current Centers for Disease Control and Prevention (CDC) Hand Hygiene Guidelines and/or World Health Organization (WHO) Guidelines on Hand Hygiene in Health Care.¹¹⁹ Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency,	At a minimum, this practice should include all of the following elements <u>of CDC and WHO guidelines</u>.^{120,121} ▪ Implement all Centers for Disease Control and Prevention guidelines with category IA, IB, or IC evidence and/or WHO Guidelines on Hand Hygiene in Health Care. ▪ Encourage compliance with CDC guidelines with category II evidence. ▪ Ensure that all staff know what is expected of them with regard to hand hygiene, and ensure <u>compliance/adherence</u>. Auditor Notes: Safe Practice <u>19</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Evidence supports the noted changes to the practice. CDC identifies the relevant healthcare settings to which this practice should apply as including, but not limited to, acute-care hospitals; long-term care facilities, such as nursing homes and skilled nursing facilities; physicians' offices; urgent-care centers, outpatient clinics; home healthcare; dialysis centers; and specific sites within non-healthcare settings (e.g., schools, prisons) where care is routinely delivered (e.g. a medical clinic embedded within a workplace or school).

¹¹⁹ The Joint Commission. *Comprehensive Accreditation Manual for Hospitals*. National Patient Safety Goal 07.01.01. Chicago, IL: The Joint Commission; 2013.

¹²⁰ Boyce JM, Pittet D. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR Recomm Rep*. 2002;51(RR-16):1-45

¹²¹ World Health Organization. *Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge. Clean Care is Safer Care*. Geneva, Switzerland: WHO; 2009. Available at http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf. Last accessed February 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 20: Influenza Prevention Comply with current Centers for Disease Control and Prevention (CDC) Recommendations for influenza vaccinations for healthcare professionals and the annual recommendations of the CDC Advisory Committee on Immunization Practices for individual influenza prevention and control. 122,123,124 Applicable Clinical Care Settings This practice is	- Healthcare workers-personnel (HCP) 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 defined as all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. <i>HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients</i>. All HCP should be offered vaccine annually unless they have a medical contraindication to influenza vaccination. - Patients who should be immunized are specified by current CDC recommendations¹²⁵ - Explicit organizational policies and procedures, as well as a robust voluntary healthcare professional and patient influenza immunization program, should be in place. - Document the immunization status of all employees, subject to collective bargaining, labor law, and privacy law. - At a minimum, this practice should include all of the following implement all the CDC Recommendations of the Advisory Committee on Immunization Practices (ACIP) Immunizations of Healthcare Personnel:¹²⁶ - Educate HCP regarding 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 nonvaccine infection control strategies, in accordance with their level of responsibility in preventing health-care--associated influenza - Offer influenza vaccine annually to all eligible HCP to protect staff, patients, and family members and to decrease HCP

¹²² CDC. Immunization of healthcare personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2011;60(RR-7):1-45.

¹²³ CDC. Prevention and control of seasonal influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, 2013-2014. *MMWR Recomm Rep*. 2013; 62(RR07):1-43.

¹²⁴ Ahmed F, Lindley MC, Allred N, et al. Effect of influenza vaccination of health care personnel on morbidity and mortality among patients: systematic review and grading of evidence. *Clin Infect Dis*. 2014 58(1):50-57.

¹²⁵ CDC. Immunization of healthcare personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2011;60(RR-7):1-45.

¹²⁶ Pearson M, Bridges C, Harper S. Influenza vaccination of health-care personnel: recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2006;55(RR-2):1-16.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
applicable to Centers for Medicare & Medicaid Services 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>absenteeism. Use of either available vaccine (inactivated and 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.</u> ▪ <u>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.</u> ▪ <u>Obtain a signed declination from HCP who decline influenza vaccination for reasons other than medical contraindications.</u> ▪ <u>Monitor HCP influenza vaccination coverage and declination at regular intervals during influenza season and provide feedback of ward-, unit-, and specialty-specific rates to staff and administration.</u> ▪ <u>Use the level of HCP influenza vaccination coverage as one measure of a patient safety quality program.</u> ■ ● Implement the CDC Advisory Committee on Immunization Practices annual recommendations for influenza prevention and control. ● Implement all CDC guidelines with category IA, IB, or IC evidence. — Educate healthcare professionals 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). — Offer influenza vaccine annually to all eligible healthcare professionals to protect staff, patients, and family members, and to decrease healthcare professional 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 healthcare professionals (category IA). — Provide influenza vaccination to healthcare professionals 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). — Monitor healthcare professional influenza vaccination coverage and declination at regular intervals during influenza season and provide feedback of ward-, unit-, and specialty-specific rates to staff and administration (category IB). ● Encourage compliance with CDC guidelines with category II evidence.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	- Use the level of healthcare professional influenza vaccination coverage as one measure of a patient safety quality program (category II). Auditor Notes: Safe Practice <u>20</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention Take actions to prevent central line-associated bloodstream infection by implementing evidence-based intervention practices.¹²⁷ Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include	<u>At a minimum, this practice should include the following elements of CDC guidelines^{128,129}</u> Before insertion: ▪ Educate healthcare personnel involved in the <u>indications for</u>, insertion, care, and maintenance of central venous catheters (CVCs) about central line-associated bloodstream infection (CLABSI) prevention. ▪ <u>Periodically reassess knowledge and adherence to guidelines for personnel involved in insertion and maintenance of catheters.</u> ▪ <u>Designate only personnel who demonstrate competence for insertion and maintenance of CVCs</u> ▪ <u>Ensure appropriate nursing staff levels in ICUs.</u> At insertion: ▪ Use a catheter checklist to ensure adherence with infection prevention practices at the time of CVC insertion.¹³⁰ ▪ Perform hand hygiene prior to catheter insertion or manipulation.¹³¹ ▪ Avoid using the femoral vein for central venous access in adult patients. (Subclavian or internal jugular are the preferred sites, unless contraindicated.)¹³² ▪ 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 <u>full-body</u> drape during catheter insertion.¹³³ ▪ Use <u>>0.5% chlorhexidine preparation with alcohol</u> as skin antiseptic preparation in patients over two months of age and allow appropriate drying time per product guidelines.¹³⁴

¹²⁷ The Joint Commission. *Comprehensive Accreditation Manual for Hospitals. National Patient Safety Goal NPSG 07.04.01*. Chicago, IL: The Joint Commission; 2013.

¹²⁸ O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011. Atlanta, GA: Centers for Disease Control and Prevention (CDC); 2011. Available at www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf, Last accessed March 2014.

¹²⁹ Chopra V, Krein SL, Olmsted RN, et al. *Prevention of Central Line-Associated Bloodstream Infections: Brief Update Review in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ. 2013. AHRQ Publication No. 13-E001-EF:88-109. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html>. Last accessed February 2014.

¹³⁰ Berenholtz SM, Pronovost PF, Lipsett PA, et al. Eliminating catheter-related bloodstream infections in the intensive care unit. *Crit Care Med*. 2004;32(10):2014-2020.

¹³¹ O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011. Atlanta, GA: Centers for Disease Control and Prevention (CDC); 2011. Available at www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf, Last accessed March 2014.

¹³² O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011. Atlanta, GA: Centers for Disease Control and Prevention (CDC); 2011. Available at www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf, Last accessed March 2014.

¹³³ O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011. Atlanta, GA: Centers for Disease Control and Prevention (CDC); 2011. Available at www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf, Last accessed March 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	- Make available and easily accessible for use a catheter cart or kit that contains all necessary components for aseptic catheter insertion.¹³⁵ After insertion: - Use a standardized protocol, <u>consistent with CDC guidance</u>, to disinfect catheter hubs, needleless connectors, and injection ports before accessing the ports. - Remove nonessential catheters.¹³⁶ - Use a standardized protocol for non-tunneled CVCs in adults and adolescents for dressing care, <u>consistent with CDC guidance</u>. - 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. Pediatric Specificity: - Chlorhexidine may be contraindicated for use in very low birth-weight (VLBW) infants. Optimal catheter site selection is specific to the size and condition of the infant or child and accessibility factors.¹³⁷ Auditor Notes: Safe Practice 21 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice.

¹³⁴ O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011. Atlanta, GA: Centers for Disease Control and Prevention (CDC); 2011. Available at www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf, Last accessed March 2014.

¹³⁵ Berenholtz SM, Pronovost PF, Lipsett PA, et al. Eliminating catheter-related bloodstream infections in the intensive care unit. *Crit Care Med*. 2004;32(10):2014-2020.

¹³⁶ O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011. Atlanta, GA: Centers for Disease Control and Prevention (CDC); 2011. Available at www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf, Last accessed March 2014.

¹³⁷ Chopra V, Krein SL, Olmsted RN, et al. *Prevention of Central Line-Associated Bloodstream Infections: Brief Update Review in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ. 2013. AHRQ Publication No. 13-E001-EF:88-109. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html> . Last accessed February 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 22: Surgical-Site Infection Prevention Take actions to prevent surgical-site infections by implementing evidence-based intervention practices.¹³⁸ Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory surgical center and inpatient service/hospital.	▪ 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)¹³⁹ including: ▪ 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-regularly thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities. ▪ Prior to all surgical procedures, educate the patient and his or her family as appropriate about SSI prevention. ▪ 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). ▪ 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. ▪ 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. ▪ Provide SSI rate data and prevention outcome measures to key stakeholders, including senior leadership, licensed independent practitioners, nursing staff, and other clinicians. ▪ Administer antimicrobial agents for prophylaxis with a particular procedure or disease according to evidence-based standards and guidelines for best practices. • Administer intravenous antimicrobial prophylaxis within one hour before incision to maximize tissue concentration (two hours are allowed for the administration of vancomycin and fluoroquinolones).¹⁴⁰ • Discontinue the prophylactic antimicrobial agent within 24 hours after surgery (within 48 hours is allowable for cardiothoracic procedures). ▪ When hair removal is necessary, use clippers or depilatories. Note: Shaving is an inappropriate hair removal method. ▪ Maintain normothermia (temperature >36.0°C) immediately following colorectal surgery. ▪ Control blood glucose during the immediate postoperative period for cardiac surgery patients. ▪ Preoperatively, use solutions that contain isopropyl alcohol as skin antiseptic preparation until other alternatives have been proven as safe and effective, and allow appropriate drying time per product guidelines.

¹³⁸ [The Joint Commission. Comprehensive Accreditation Manual for Hospitals. National Patient Safety Goal 07.05.01. Chicago, IL: The Joint Commission; 2013.](#)

¹³⁹ Anderson DJ, Kaye KS, Classen D, et al. Strategies to prevent surgical site infections in acute care hospitals. *Infect Control Hosp Epidemiol.* 2008;29 (Suppl 1):S51-S61.

¹⁴⁰ [Bratzler DW, Dellinger EP, Olsen KM, et al. Clinical practice guidelines for antimicrobial prophylaxis in surgery. Am J Health Syst Pharm..2013;70\(3\):195-283.](#)

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	Auditor Notes: Safe Practice <u>22</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Evidence supports the noted changes to the practice. However, the practice should be reevaluated as soon as revised guidelines from both SHEA and CDC become available. Significant revisions that will affect the specifications of this practice are anticipated.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 23: Care of the Ventilated Patient Take actions to prevent complications associated with ventilated patients: specifically, ventilator-associated pneumonia, venous thromboembolism, peptic ulcer disease, dental complications, and pressure ulcers. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include emergency room, home	▪ 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.¹⁴¹ ▪ 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)^{142,143} with emphasis on: ▪ For adult patients, institute a ventilated patient checklist and a standardized protocol for the following prevention measures: • Adherence to hand hygiene guidelines. • Subglottic suctioning • Regular antiseptic oral care, <u>preferably using chlorhexidine</u>, according to product guidelines. ▪ Maintain patients in semi-recumbent position: 30° -45° elevation of head of bed (unless medically contraindicated).¹⁴⁴ • Protocol-guided daily assessment of readiness to wean and <u>daily</u> sedation interruption. • Use weaning protocols. ▪ PUD prophylaxis based on patient risk assessment. (PUD prophylaxis data remain controversial. Clinical judgment should be used based on individual patient needs.) ▪ VTE prophylaxis (unless contraindicated) (refer to Safe Practice 28). ▪ Pressure ulcer prevention program based on patient risk assessment (refer to Safe Practice 27). ▪ For pediatric patients (less than 18 years of age), institute a ventilated patient checklist and a standardized protocol for the following prevention measures: • Elevate airway opening between 15°-30° for neonates and 30°-45° for infants through pediatric ages, unless clinically inappropriate for the patient.

¹⁴¹ Coffin SE, Klompas M, Classen D, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals. *Infect Control Hosp Epidemiol*. 2008; 29(Suppl 1):S31-S40.

¹⁴² Coffin SE, Klompas M, Classen D, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals. *Infect Control Hosp Epidemiol*. 2008; 29(Suppl 1):S31-S40.

¹⁴³ Winters BD, Berenholtz SM. *Ventilator-Associated Pneumonia: Brief Update Review in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ;2013. AHRQ Publication No. 13-E001-EF:110-116. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuftp.html> Last accessed February 2014.

¹⁴⁴ Alexiou VG, Ierodiakonou V, Dimopoulos G, et al. Impact of patient position on the incidence of ventilator-associated pneumonia: a meta-analysis of randomized controlled trials. *J Crit Care*. 2009;24(4):515-522.

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care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	● Assess readiness to extubate daily. ■ Implement policies and practices to: ■ Conduct active surveillance for VAP ventilator-associated events 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. ■ Provide ventilated patient data on VAP, VAP- ventilator-associated events and related process measures, and general care process measures to key stakeholders, including senior leadership, LIPS, nursing staff, and other clinicians. ■ Educate patients, as appropriate, and their families about prevention measures involved in the care of ventilated patients. ¹⁴⁵ Auditor Notes: Safe Practice 23 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice. There is insufficient data at present to determine the impact of head of bed elevation on duration of mechanical ventilation or mortality; however, most groups continue to classify this as a basic practice until further data are available.

¹⁴⁵ Coffin SE, Klompas M, Classen D, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals. *Infect Control Hosp Epidemiol.* 2008; 29(Suppl 1):S31-S40.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 24: Multidrug-Resistant Organism Prevention Implement a systematic multidrug-resistant organism (MDRO) <u>eradication-prevention</u> 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. <u>(NPSG.07.03.01 Implement evidence-</u>	▪ 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. ▪ Conduct a risk assessment for MDRO acquisition and transmission. ▪ Upon hire and <u>annually-periodically</u> thereafter <u>(in compliance with regulatory and accrediting bodies)</u>, educate staff and licensed independent practitioners about MDROs, including risk factors, routes of transmission, outcomes associated with infection, prevention measures, and local epidemiology. ▪ 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. ▪ Implement a surveillance program for MDROs based on risk assessment. ▪ Measure and monitor MDRO prevention processes and outcomes, including: • Infection rates using evidence-based metrics. • Compliance with evidence-based guidelines or best practices.¹⁴⁶ • Evaluation of the education program provided to staff and licensed independent practitioners. ▪ Provide MDRO surveillance data, prevention processes, and outcome measures to key stakeholders, including senior hospital leadership, physicians, nursing staff, and other clinicians.¹⁴⁷ ▪ Implement a laboratory-based alert system to provide immediate notification to infection control and clinical personnel about newly diagnosed MDRO-colonized or -infected patients.¹⁴⁸ ▪ Implement an alert system that identifies readmitted or transferred MRSA-colonized or -infected patients.¹⁴⁹ ▪ Promote compliance with hand hygiene recommendations.^{150, 151} <u>(NPSG.07.01.01 Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.),</u>

¹⁴⁶ Calfee DP, Salgado CD, Classen D, et al. Strategies to prevent transmission of methicillin-resistant *Staphylococcus aureus* in acute care hospitals. *Infect Control Hosp Epidemiol.* 2008;29(Suppl 1):S62-S80.

¹⁴⁷ Calfee DP, Salgado CD, Classen D, et al. Strategies to prevent transmission of methicillin-resistant *Staphylococcus aureus* in acute care hospitals. *Infect Control Hosp Epidemiol.* 2008;29(Suppl 1):S62-S80.

¹⁴⁸ Dubberke ER, Gerding DN, Classen D. Strategies to Prevent *Clostridium difficile* Infections. *Infect Control and Hosp Epidemiol.* 2008; 29(Suppl 1): S81-S92.

¹⁴⁹ Dubberke ER, Gerding DN, Classen D. Strategies to Prevent *Clostridium difficile* Infections. *Infect Control and Hosp Epidemiol.* 2008; 29(Suppl 1): S81-S92.

¹⁵⁰ Johnson PD, Martin R, Burrell LJ, et al. Efficacy of an alcohol/chlorhexidine hand hygiene program in a hospital with high rates of nosocomial methicillin-resistant *Staphylococcus aureus* (MRSA) infection. *Med J Aust.* 2005;183(10):509-514.

¹⁵¹ D'Agata EM, Webb GF, Horn MA, et al. Modeling the invasion of community-acquired methicillin-resistant *Staphylococcus aureus* into hospitals. *Clin Infect Dis.* 2009;48(3):274-284.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
<u>based practices to prevent health care–associated infections due to multidrug-resistant organisms in acute care hospitals.)</u> Note: This practice applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant <i>Staphylococcus aureus</i>, vancomycin-resistant enterococci, 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	▪ Use contact precautions for MDRO-colonized or -infected patients.¹⁵² ▪ Ensure cleaning and disinfection of equipment and environment. Auditor Notes: Safe Practice <u>24</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice.

¹⁵² Siegel JD, Rhinehart E, Jackson M, et al.; the Healthcare Infection Control Practices Advisory Committee. *Management of Multidrug-Resistant Organisms in Healthcare Settings*, Atlanta, GA: CDC;2006. Available at <http://www.cdc.gov/hicpac/pdf/MDRO/MDROGuideline2006.pdf>, Last accessed March 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
organizational risk assessments. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services 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.	

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 25: Catheter-Associated Urinary Tract Infection Prevention Take actions to prevent catheter-associated urinary tract infection by implementing evidence-based intervention practices.¹⁵³ Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory,	- 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).^{154,155,156} Evidence-based practices include, but are not limited to, the following: - Insert urinary catheters <u>only when necessary</u> for appropriate indications <u>(such as provided by CDC guidelines)</u>, and leave them in place only as long as indications remain. - Provide and document the education of healthcare personnel involved in the insertion, care, and maintenance of urinary catheters about CAUTI prevention, including alternatives to indwelling catheters and procedures for catheter insertion, management, and removal. Education should occur upon hire and <u>periodically (e.g. annually)</u> thereafter, and when involvement in these procedures is added to an individual's job responsibilities. - Prior to insertion of a urinary catheter, educate the patient, and his or her family, as appropriate, about CAUTI prevention.¹⁵⁷ - Identify the patient groups or units on which surveillance should be conducted, using risk assessments that consider frequency of catheter use and potential risk. - Perform hand hygiene immediately before and after catheter insertion and any manipulation of the catheter site or apparatus. - Ensure that the supplies necessary for aseptic technique for catheter insertion are readily available. - Insert catheters following an aseptic technique and using sterile equipment. - Obtain a urine culture before initiating antimicrobial therapy for <u>presumed</u> urinary tract infection in a patient with a urinary catheter.¹⁵⁸ - Measure compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention

¹⁵³ The Joint Commission. *Comprehensive Accreditation Manual for Hospitals. National Patient Safety Goal 07.06.01*. Chicago, IL: The Joint Commission; 2013.

¹⁵⁴ Meddings J, Krein SL, Fakih MG, et al. *Reducing Unnecessary Urinary Catheter Use and Other Strategies to Prevent Catheter-Associated Urinary Tract Infections: Brief Update Review in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ; 2013. AHRQ Publication No. 13-E001-EF:73-87. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html> Last accessed February 2014.

¹⁵⁵ Gould CV, Umscheid CA, Agarwal RK, et al. Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for prevention of catheter-associated urinary tract infections 2009. *Infect Control Hosp Epidemiol*. 2010;31(4):319-326.

¹⁵⁶ Lo E, Nicolle L, Classen D, et al. Strategies to prevent catheter-associated urinary tract infections in acute care hospitals. *Infect Control Hosp Epidemiol*. 2008;29(Suppl 1):S41-S50.

¹⁵⁷ Pratt RJ, Pellowe CM, Wilson JA, et al. epic2: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. *J Hosp Infect*. 2007; 65(Suppl 1):S1-S64.

¹⁵⁸ Hooton TM, Bradley SF, Cardenas DD, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America. *Clin Infect Dis*. 2010; 50(5):625-663.

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ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	efforts for internal performance improvement. SHEA 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. Auditor Notes: Safe Practice <u>25</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice. The recent Meddings meta-analysis shows potential benefit of catheter removal reminders or stop orders. The CDC Guideline mentions these as options as part of quality improvement. Suggest consideration be given to such a specification when the safe practices are next updated.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 26: Wrong-Site, Wrong-Procedure, Wrong-Person Surgery Prevention Implement the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ for all invasive procedures. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory surgical center, emergency room, inpatient service/hospital, and outpatient hospital.	<u>Universal Protocol requirements:</u> ¹⁵⁹ ■ Create and use a preoperative verification process to ensure that relevant preoperative tasks are completed and that information is available and correct. ¹⁶⁰ <u>The World Health Organization Surgical Safety Checklist is a prominent example.</u> ¹⁶¹ ■ Mark the surgical <u>or non-surgical invasive procedure</u> site and involve the patient in the marking process <u>when possible</u>, at a minimum, for cases involving right/left distinction, multiple structures (e.g., fingers, toes), or multiple levels (e.g., spinal procedures). ■ Immediately before the start of any invasive procedure, conduct a “time out” to confirm the correct patient, procedure, site, <u>that consent has been given</u>, and <u>availability of</u> any required <u>items such as blood products</u>, implants, <u>devices</u>, or special equipment. Auditor Notes: Safe Practice <u>26</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change___ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice.

¹⁵⁹ The Joint Commission. Comprehensive Accreditation Manual for Hospitals. National Patient Safety Goals UP 01.01.01, 01.02.01, 01.03.01. Chicago, IL: The Joint Commission; 2013.

¹⁶⁰ Treadwell JR, Lucas S. Preoperative and Anesthesia Checklists in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Rockville, MD: AHRQ; 2013. AHRQ Publication No. 13-E001-EF :122-139. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html> . Last accessed February 2014.

¹⁶¹ World Health Organization (WHO). WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives. Geneva, Switzerland: WHO; 2009. Available at http://whqlibdoc.who.int/publications/2009/9789241598552_eng.pdf . Last accessed February 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 27: Pressure Ulcer Prevention Take actions to prevent pressure ulcers by implementing evidence-based intervention practices.¹⁶² Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include home care, home health services/agency, hospice, inpatient	▪ Explicit organizational policies and procedures should be in place about the prevention of pressure ulcers.^{163,164} ▪ Plans are in place for the <u>skin assessment</u>, risk assessment, prevention, and early treatment of pressure ulcers, which address the following:¹⁶⁵ • During <u>At the time of</u> patient admission, identify individuals at risk of requiring pressure ulcer prevention using a pressure ulcer risk-assessment plan/guide, including a comprehensive skin assessment, to identify the specific risks.^{166,167} • Document <u>existence of any pressure ulcers present on admission</u>, the pressure ulcer risk assessment and <u>a</u> prevention plan as indicated in the patient's record. • Assess and periodically reassess each patient's skin and risk for developing a pressure ulcer, and take action to address any identified risks. • Maintain and improve tissue tolerance to pressure, <u>including through nutrition</u>, in order to prevent injury. • Protect against the adverse effects of external mechanical forces. • Reduce the incidence of pressure ulcers through staff educational programs. • 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: – education about the pertinent pressure ulcer frequency and severity; – skill building in the use of pressure ulcer prevention interventions; – implementation of process improvement interventions; – measurement of process or outcomes indicators; and

¹⁶² The Joint Commission. *Long Term Care (Medicare/Medicaid) National Patient Safety Goals. Goal 14.01.01*. Chicago (IL); The Joint Commission; 2013. Available at http://www.jointcommission.org/lt2_2014_npsgs/. Last accessed March 2014.

¹⁶³ Sullivan BA. *Preventing In-Facility Pressure Ulcers in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ; 2013. AHRQ Publication No. 13-E001-EF; 212-232. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html>. Last accessed March 2014.

¹⁶⁴ IHI. *IHI Improvement Map. Pressure Ulcer Prevention*. Cambridge, MA:IHI; 2009.Available at <http://app.ihi.org/imap/tool/> <http://www.ihi.org/imap/tool/>. Last accessed September 2009.

¹⁶⁵ European Pressure Ulcer Advisory Panel, National Pressure Ulcer Advisory Panel. *Pressure Ulcer Prevention: Quick Reference Guide, Pressure Ulcer Treatment: Quick Reference Guide*. Washington DC: National Pressure Ulcer Advisory Panel; 2009. Available at http://www.npuap.org/wp-content/uploads/2012/02/Final_Quick_Prevention_for_web_2010.pdf and http://www.epuap.org/guidelines/Final_Quick_Treatment.pdf. Last accessed March 2014.

¹⁶⁶ Braden B, Bergstrom N. *Braden Scale for Predicting Pressure Sore Risk*. Available at <http://www.bradenscale.com/braden.pdf>. Last accessed February 2014.

¹⁶⁷ Merck and Co., Inc. The Norton Scale for Predicting Pressure Sore Risk Web site. Available at <http://www.merck.com/mmpe/sec10/ch126/ch126a.html>. Last accessed February 2014.

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service/ hospital, outpatient hospital, and skilled nursing facility.	– internal reporting of performance outcomes. Auditor Notes: Safe Practice <u>27</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted changes to the practice. This should be reassessed at the next safe practices update. Specificity around what constitutes process improvement interventions should be specifically addressed.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 28: Venous Thromboembolism Prevention Evaluate each patient upon admission, and regularly thereafter, for the risk of developing venous thromboembolism. Utilize clinically appropriate, evidence-based methods of thromboprophylaxis. ¹⁶⁸ Applicable Clinical Care Settings	▪ Ensure that multidisciplinary teams develop institutions' protocols and/or "adopt" established, evidence-based protocols.^{169,170,171,172} ▪ 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).¹⁷³ ○ 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. ▪ Include provision for risk assessment/stratification, prophylaxis, diagnosis, and treatment.¹⁷⁴ ▪ 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. ▪ 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).^{175,176} ▪ Document in the patient's health record that VTE risk assessment/stratification was completed. ▪ 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

¹⁶⁸ Haut ER, Lau B. *Prevention of Venous Thromboembolism: Brief Update Review in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ; 2013. AHRQ Publication No. 13-E001-EF: 303-309. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html>. Last accessed February 2014.

¹⁶⁹ Falck-Ytter Y, Francis CW, Johanson NA, et al. Prevention of VTE in orthopedic surgery patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012;141(2 Suppl):e278S-e325S.

¹⁷⁰ Kahn SR, Lim W, Dunn AS, et al. Prevention of VTE in nonsurgical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;14(2 Suppl)1:e195S-e226S.

¹⁷¹ Gould MK, Garcia DA, Wren SM, et al. Prevention of VTE in nonorthopedic surgical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141(2 Suppl):e227S-e277S.

¹⁷² National Quality Forum (NQF). *National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Policy, Preferred Practices, and Initial Performance Measures: A Consensus Report*. Washington, DC:NQF; 2006.

¹⁷³ Lau BD, Haut ER. Practices to prevent venous thromboembolism: a brief review. *BMJ Qual Saf*. 2014;23(3):187-195.

¹⁷⁴ Hairon N. New risk assessment tool aims to help nurses prevent VTE. *Nurs Times*. 2008;104(39):23-25.

¹⁷⁵ Caprini JA. Implications of thromboprophylaxis registry data on clinical practice. *Am J Med Sci*. 2009;338(1):58-63.

¹⁷⁶ Patel J, Reade H, Sultanzadeh J, et al. Reminders: a simple measure to ensure the mandatory venous thromboembolism risk assessment of hospitalised patients. *Int J Clin Pract*. 2009;63(1):173-174.

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This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	issues related to that patient. Auditor Notes: Safe Practice <u>28</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u>X</u> Yes w/changes as noted ____ No ____ Comments: Updated evidence continues to support the existing specifications. Applicable clinical settings should be updated to align with the focus and application of the practice specifications.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 29: Anticoagulation Therapy Organizations should implement practices to prevent patient harm due to anticoagulant therapy.^{177,178} Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory,	▪ The organization implements a defined anticoagulation management program to individualize the care provided to each patient receiving anticoagulant therapy <u>including enhancing patient education to assist patients to manage their anticoagulation therapy,</u>¹⁷⁹ and documenting the patient's medication plan in the medication record.^{180,181} ▪ Clinical pharmacy medication review is conducted to ensure safe anticoagulant selection and avoidance of drug-drug interactions. ▪ 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.¹⁸² ▪ 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.¹⁸³ ▪ 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.¹⁸⁴ ▪ 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. ▪ When heparin is administered intravenously and continuously, the hospital uses programmable infusion pumps in order to provide consistent and accurate dosing.^{185,186} ▪ The organization has a written policy that addresses baseline and ongoing laboratory tests that are required for heparin

¹⁷⁷ The Joint Commission. *Comprehensive Accreditation Manual for Hospitals. National Patient Safety Goal 03.05.01*. Chicago, IL: The Joint Commission; 2013.

¹⁷⁸ Guyatt GH, Eikelboom JW, Gould MK, et al. Approach to outcome measurement in the prevention of thrombosis in surgical and medical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141(2 Suppl):185S – 194S.

¹⁷⁹ The Joint Commission. Sentinel Event Alert: Preventing errors relating to commonly used anticoagulants. Chicago, IL: The Joint Commission; 2008(Issue 41). Available at http://www.jointcommission.org/assets/1/18/SEA_41.PDF. Last accessed March 2014.

¹⁸⁰ Robert-Ebadi H, Le Gal G, Righini M. Use of anticoagulants in elderly patients: practical recommendations. *Clin Interv Aging*. 2009;4:165-177.

¹⁸¹ Holbrook A, Schulman S, Witt DM, et al. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012; 141(2 Suppl): e152S – e184S.

¹⁸² Shekelle PG, Wachter RM, Pronovost PJ, et al. Making health care safer II: an updated critical analysis of the evidence for patient safety practices. 2013. Evid Rep Technol Assess (Full Rep);211: p.24.

¹⁸³ Schumock GT, Blackburn JC, Nutescu EA, et al. Impact of prescribing guidelines for inpatient anticoagulation. *Ann Pharmacother*. 2004;38(10): 1570-1575.

¹⁸⁴ Merli GJ, Tzanis G. Warfarin: what are the clinical implications of an out-of-range-therapeutic international normalized ratio? *J Thromb Thrombolysis*. 2009;27(3):293-299.

¹⁸⁵ Prusch AE, Suess TM, Paoletti RD, et al. Integrating technology to improve medication administration. *Am J Health Syst Pharm*. 2011; 68(9):835-842.

¹⁸⁶ Fanikos J, Fiumara K, Baroletti S, et al. Impact of smart infusion technology on administration of anticoagulants (unfractionated Heparin, Argatroban, Lepirudin, and Bivalirudin). *Am J Cardiol*. 2007; 99(7):1002-1005.

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ambulatory surgery center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient service/hospital, outpatient hospital, and skilled nursing facility.	and low molecular weight heparin therapies. ▪ The organization provides education on anticoagulation therapy to prescribers, staff, patients, and families.¹⁸⁷ ▪ 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.^{188,189} Auditor Notes: Safe Practice <u>29</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change___ Yes w/changes as noted <u>X</u> No ____ Comments: Updated evidence supports the noted change to the practice.

¹⁸⁷ Holbrook A, Schulman S, Witt DM, et al. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012; 141(2 Suppl): e152S – e184S.

¹⁸⁸ Zhan C, Smith SR, Keyes MA, et al. How useful are voluntary medication error reports? The case of warfarin-related medication errors. *Jt Comm J Qual Patient Saf.* 2008;34(1):36-45.

¹⁸⁹ Institute for Healthcare Improvement. High-Alert Medication Safety Web site. www.ihi.org/explore/HighAlertMedicationSafety/Pages/default.aspx. Last accessed February 2014.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 30: Contrast Media-Induced Renal Failure Prevention 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. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory surgical center, inpatient service/hospital, and outpatient hospital.	▪ 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). ▪ Monitor and document the use of evidence-based protocols (include variance and rationale for departing from protocol). ▪ Document provider education that encompasses all aspects of contrast media-induced nephropathy prevention and care. ▪ 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. ▪ 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). ▪ Ensure that there is documentation by a licensed clinician placed in the patient's health record that risk assessment/stratification was completed. Auditor Notes: Safe Practice <u>30</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u> X </u> Yes w/changes as noted <u> </u> No <u> </u> Comments: Evidence continues to support the existing specifications. Recently published work refocuses the importance of this adverse event. The specifications amount to a primer on quality assurance around a medical staff set of protocols. The practice should be carefully reviewed for refinement in light of continuing research.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 31: Organ Donation 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 specifying the roles and desired outcomes for every stage of the donation process. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include inpatient service/hospital.	Key organ donation effective practice strategies are: ▪ 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 who are in need of transplantation. ▪ 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. ▪ 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. ▪ 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. ▪ 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. ▪ Hospital-specific organ donation performance outcomes are published by the Scientific Registry of Transplant Recipients at http://www.srtr.org/. ▪ 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: • Donor identification and referral are implemented using processes jointly developed by hospital and OPO experts. • 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. • Organ function optimization protocols are developed and jointly implemented by hospital and OPO experts and are evidence-based. • The donation process is documented by the hospital, beginning with donor identification and concluding with the operative procedure to retrieve donated organs. • 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. Auditor Notes: Safe Practice 31 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u> X </u> Yes w/changes as noted ____ No ____ Comments: Evidence continues to support the existing specifications.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 32: Glycemic Control 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. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include inpatient	Essential elements of improving glycemic control: • 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.¹⁹⁰ • 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.^{191,192,193} • Patient medications are reconciled appropriately, including, upon discharge, restarting pre-hospital antiglycemic agents when appropriate. • Patients with newly diagnosed diabetes or educational deficits have at least the following educational components reflected in their plan of care:^{194,195,196} • Medication management, including how to administer insulin (when appropriate) and potential medication interactions. • Nutritional management, including the role of carbohydrate intake in blood glucose management. • Exercise <u>and sleep</u>. • <u>Tobacco avoidance</u>. • <u>Psychosocial coping</u> • Signs, symptoms, and treatment of hyperglycemia and hypoglycemia. • Importance of blood glucose monitoring. • Instruction <u>on obtaining and</u> use of a blood glucose meter <u>and other needed medical equipment</u> • Sick-day guidelines.

¹⁹⁰ Kansagara D. *Inpatient Intensive Glucose Control Strategies To Reduce Death and Infection in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ; 2013 AHRQ Publication No. 13-E001-EF:233-247. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html>. Last accessed February 2014.

¹⁹¹ American Diabetes Association. Standards of Medical Care in Diabetes-2014. *Diabetes Care*. 2014 ;37(Suppl 1):S14-S80.

¹⁹² Haas L, Maryniuk M, Beck J, et al. National standards for diabetes self-management education and support. *Diabetes Care*. 2014;37(Suppl 1): S144-S153.

¹⁹³ Handelsman Y, Mechanick JI, Blonde L, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. *Endocr Pract*. 2011;17(Suppl 2):1-53.

¹⁹⁴ American Diabetes Association. Standards of Medical Care in Diabetes-2014. *Diabetes Care*. 2014 ;37(Suppl 1):S14-S80.

¹⁹⁵ Haas L, Maryniuk M, Beck J, et al. National standards for diabetes self-management education and support. *Diabetes Care*. 2014;37(Suppl 1): S144-S153.

¹⁹⁶ Handelsman Y, Mechanick JI, Blonde L, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. *Endocr Pract*. 2011;17(Suppl 2):1-53.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
service/hospital.	• Information on whom to contact in case of emergency or for more information. • A plan for post-discharge education or self-management support. • 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. Auditor Notes: Safe Practice <u>32</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ____ Yes w/changes as noted <u> X </u> No ____ Comments: Updated evidence supports the noted changes to the practice

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 33: Falls Prevention Take actions to prevent patient falls and to reduce fall-related injuries by implementing evidence-based intervention practices.¹⁹⁷ Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, dialysis facility, home care, home health services/agency, hospice, inpatient	▪ The hospital or healthcare organization must establish a <u>multi-component</u> fall reduction program.¹⁹⁸ ▪ The fall reduction program includes an evaluation appropriate to the patient population, settings, and services provided. ▪ An organization may consider individual patient assessments for what the organization deems to be the high-risk groups in its patient population.¹⁹⁹ ▪ The fall reduction program includes interventions to reduce the patient's fall risk factors. ▪ Staff receives education and training about the fall reduction program. Education occurs upon hire and annually thereafter.²⁰⁰ ▪ The patient, and family as needed, is educated about the fall reduction program and any individualized fall reduction strategies. ▪ The organization evaluates the fall reduction program to determine its effectiveness. Auditor Notes: Safe Practice 33 continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change ___ Yes w/changes as noted <u>X</u> No ___ Comments: Updated evidence supports the noted changes to the practice.

¹⁹⁷ The Joint Commission. *Long Term Care (Medicare/Medicaid) National Patient Safety Goals. Goal 14.01.01*. Chicago (IL); The Joint Commission; 2013. Available at http://www.jointcommission.org/lt2_2014_npsgs/. Last accessed March 2014.

¹⁹⁸ Miake-Lye IM, Hempel S, Ganz DA. *Preventing In-Facility Falls in Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ;2013. AHRQ Publication No. 13-E001-EF 178-200. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html>. Last accessed February 2014.

¹⁹⁹ National Collaborating Centre for Nursing and Supportive Care. *Clinical Practice Guideline for the Assessment and Prevention of Falls in Older People*. London, UK: National Institute for Clinical Excellence (NICE); 2004. Available at <https://www.ncbi.nlm.nih.gov/books/NBK55844/> Last accessed March 2014.

²⁰⁰ Dempsey J. Nurses values, attitudes and behaviour related to falls prevention. *J Clin Nurs*. 2009;18(6):838-848.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
service/hospital, outpatient hospital, and skilled nursing facility.	

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
Safe Practice 34: Pediatric Imaging When CT imaging studies are undertaken on children, “child-size” techniques should be used to reduce unnecessary exposure to ionizing radiation. Applicable Clinical Care Settings This practice is applicable to Centers for Medicare & Medicaid Services care settings, to include ambulatory, ambulatory surgical center, emergency room, inpatient service/hospital, and outpatient hospital.	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: ▪ Scan only when necessary.²⁰¹ This provides an opportunity to discuss the benefit 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. ▪ 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.^{202, 203} Refer to the Image Gently™ website (www.imagegently.org), and view the protocols provided for children. 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. ▪ 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. ▪ 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.²⁰⁴

²⁰¹ American College of Radiology Pediatric Imaging Criteria Web site. Available at <http://www.acr.org/quality-safety/appropriateness-criteria/diagnostic/pediatric-imaging>. Last accessed March 2014.

²⁰² ICRP. Diagnostic Reference Levels in Medical Imaging: Review and Additional Advice Web site. Available at http://www.icrp.org/docs/DRL_for_web.pdf. Last accessed March 2014.

²⁰³ International Atomic Energy Agency (IAEA). Report of a consultation on justification of patient exposures in medical imaging. *Radiat Prot Dosimetry*. 2009;135(2):137-144.

²⁰⁴ ICRP, Khong PL, Ringertz H, et al. Radiological protection in paediatric diagnostic and interventional radiology. *Ann ICRP*. 2013; 42(2):1-63.

PRACTICE AND CARE SETTINGS	ADDITIONAL SPECIFICATIONS
	Auditor Notes: Safe Practice <u>34</u> continues to meet the <i>Criteria for Inclusion in the Safe Practices Set</i> as specified in the 2010 Update. Yes w/o change <u> X </u> Yes w/changes (references) as noted <u> </u> No <u> </u> Comments: Updated evidence supports the existing specifications.

NQF Safe Practices Audit Process and Standards

The audit of the *Safe Practices for Better Healthcare – 2010 Update* is designed to provide an objective, systematic and critical analysis of the evidentiary base underlying the safe practices. Explicit criteria will guide the audit to encourage consistency across internal and external reviewers. Ultimately, NQF leadership will use audit outcomes to make determinations about next steps for the safe practices.

The audit will assess the benefit, specificity, evidence of effectiveness, generalizability, and readiness for use (Item A) as well as any implicit or explicit references to commercial products or services in the 34 NQF-endorsed safe practices.

NQF leadership has chosen a three-part audit process consisting of:

- 1) Internal staff review
- 2) Expert panel review
- 3) NQF member and public comment

Internal Audit

- Staff will review the safe practice statements and specifications as follows:
 - a) Review each safe practice against the audit standards noted below;
 - b) Identify presence or absence of evidentiary support, as outlined in the “Evidence of Effectiveness” (from Item A);
 - c) Bring supporting evidence for the practices and specifications forward;
 - d) Provide comments and questions to be addressed by the expert advisory panel and
 - e) Integrate changes suggested by the expert advisory panel for consideration by NQF members and the public, and ultimately NQF leadership.

External Audit

- Expert panel review: Panel members will review the safe practice statements and specifications as well as staff comments/questions:
 - a) Review each safe practice against the audit standards noted below;
 - b) Recommend changes to the practices considering the audit standards;
 - d) Provide additional evidence in support of practices and both existing and any new recommended specifications where deemed needed;
 - e) Provide rationale for retention of practices or specifications for which the evidentiary base is weak;
 - f) Review the edited table of practices and specifications to ensure it captures the intended changes; and
 - g) Adjudicate NQF member and public comments and make recommendations for how they should be addressed.
- Member and Public Comment: The audited report will be put out for member and public comment. Commenters are expected to view the safe practices through the lens of their stakeholder experiences and provide comment from a practical application point of view.

Audit Standards	Summary Questions
Specificity	Is the practice a clearly and precisely defined process or manner of providing a healthcare service?
Benefit	If the practice were more widely utilized, would it save lives endangered by healthcare delivery, reduce harm, disability or other morbidity, or reduce the likelihood of a serious reportable event?
Evidence of Effectiveness	Consistent with 2010 criteria, is there clear evidence that the practice would be effective in reducing patient safety events?
	a. Is there evidence based on research studies showing a direct connection between improved clinical outcomes and the practice?
	b. Is there evidence based on experiential data showing the practice is "obviously beneficial" or self-evident?
	c. Is there evidence from research findings or experiential data from nonhealthcare industries that should be substantially transferable to healthcare?
Generalizability	Can the safe practice be utilized in multiple applicable clinical care settings?
Readiness	Would the necessary technology and appropriately skilled staff be available to most healthcare organizations?
Evidence of Endorsement of any Specific Product or Service	Is there any implicit or explicit reference to any specific commercial product or service?
	a. If yes, does the quality, quantity and consistency of evidence justify the inclusion?
	b. If yes, should there be qualifiers to provide for inclusion of related products or services should they become available?
Overall assessment	Based on the audit criteria, do you support the continued inclusion of the safe practice?
	Based on the audit criteria, do you support the recommended changes to the safe practice specifications?

Item A - Criteria for Inclusion in the Safe Practices Set (from Safe Practices 2010)
Specificity. The practice must be a clearly and precisely defined process or manner of providing a healthcare service. All candidate safe practices were screened according to this threshold criterion. Candidate safe practices that met the threshold criterion of specificity were then rated against four additional criteria relating to the likelihood of the practice improving patient safety.
Benefit. If the practice were more widely utilized, it would save lives endangered by healthcare delivery, reduce disability or other morbidity, or reduce the likelihood of a serious reportable event (e.g., an effective practice already in near universal use would lead to little new benefit to patients by being designated a safe practice).
Evidence of Effectiveness. There must be clear evidence that the practice would be effective in reducing patient safety events. Such evidence may take various forms, including the following: • research studies showing a direct connection between improved clinical outcomes (e.g., reduced mortality or morbidity) and the practice; • experiential data (including broad expert agreement, widespread opinion, or professional consensus) showing the practice is “obviously beneficial” or self-evident (i.e., the practice absolutely constrains a potential problem or forces an improvement to occur, reduces reliance on memory, standardizes equipment or process steps, or promotes teamwork); or • research findings or experiential data from nonhealthcare industries that should be substantially transferable to healthcare (e.g., repeat-back of verbal orders or standardizing abbreviations).
Generalizability. The safe practice must be able to be utilized in multiple applicable clinical care settings (e.g., a variety of inpatient and/or outpatient settings) and/or for multiple types of patients.
Readiness. The necessary technology and appropriately skilled staff must be available to most healthcare organizations.



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