2014 Hospital Nursing Law Update – CMS and TJC Hot Problematic Standards

Thursday, January 16th, 2014

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Learning Objectives

1. Discuss some of the CMS and TJC top problematic standards for hospitals

2. List some of the key CMS changes in effect for 2014 that impact nurses

3. Discuss the role nurses play in preventing CMS and TJC deficiencies and in overall regulatory compliance
You Don’t Want One of These
The Conditions of Participation (CoPs)

- Regulations first published in 1986
  - Manual updated August 30, 2013 and 457 pages
  - Revised discharge planning standards published May 27, 2013 are now in manual

- First regulations are published in the Federal Register then CMS publishes the Interpretive Guidelines and some have survey procedures

- Hospitals should check this website once a month for changes

The Conditions of Participation (CoPs)

- The manual is known as the conditions of participation or the CoPs for short
- The CoP sections are called tag numbers
- They go from Tag 0001 to 1164
  - All the sections contain a tag number so it is easy to go back and look up that section if you want to read more about it
- There are currently 437 pages in the current manual
- There were changes in the Federal Register went into effect July 16, 2012 and IG issued March 15, 2013 and in June 7, 2013 manual
Location of CMS Hospital CoP Manuals

CMS Hospital CoP Manuals new address
State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents

(Rev. 89, 08-30-13)

Transmittals for Appendix A

Survey Protocol

Introduction
Task 1 - Off-Site Survey Preparation
Task 2 - Entrance Activities
Task 3 - Information Gathering/Investigation
Task 4 - Preliminary Decision Making and Analysis of Findings
Task 5 - Exit Conference
Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines
§482.2 Provision of Emergency Services by Nonparticipating Hospitals

Policy & Memos to States and Regions

CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Select From The Following Options:

- Show all items

- Show only (select one or more options):
  - Show only items whose [text input field]
  - Show only items whose Fiscal Year is [text input field]
  - Show only items containing the following word [text input field]

Click on policy & memos to states

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
<table>
<thead>
<tr>
<th>Title</th>
<th>Memo #</th>
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<td>Hospital Equipment Maintenance Requirements</td>
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<td>2013-12-20</td>
<td>2014</td>
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<td>14-08-Transplant Programs</td>
<td>2013-12-20</td>
<td>2014</td>
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<td>14-06-Hospitals /CAHs</td>
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<td>14-05-CLIA</td>
<td>2013-11-08</td>
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<td>2013-10-25</td>
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<td>Cardiopulmonary Resuscitation (CPR) in Nursing Homes</td>
<td>14-01-NH</td>
<td>2013-10-18</td>
<td>2014</td>
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Privacy & Confidentiality Memo 3-2-12

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Office of Clinical Standards and Quality/Survey & Certification Group

DATE: March 2, 2012
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Hospital Patient Privacy and Medical Record Confidentiality

Memorandum Summary

- **Hospital Patient Privacy and Medical Record Confidentiality**: Guidance concerning the protection of patient privacy and medical record information is clarified. This guidance is consistent with the standards under the Federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

- **Incidental Uses and Disclosures**: Guidance concerning permitted incidental uses and disclosures is clarified and includes reasonable safeguards that must be in place to ensure patient privacy.

- **Automated Survey Processing Environment (ASPEN) Changes**: Tags A-0441, A-0442 and A-0443 have been combined. It will take time for this guidance to be incorporated into a future ASPEN release. Prior to this conversion citations should be made only to Tag A-0441.

Patient Rights to Privacy and Medical Record Confidentiality

We are taking this opportunity to clarify our guidance for the hospital requirements governing patient privacy and medical record confidentiality at 42 CFR §482.13(c)(1), §482.13(d)(1) and §482.24(b)(3).
Privacy & Confidentiality Memo 3-2-12

- Discusses privacy & confidentiality consistent with HIPAA
- Changes not in manual yet
- Discusses incidental uses and disclosures
- Allows name on spine of chart
- Allows name on outside of patient room
- Allows signs such as fall risk or diabetic diet
- Changes to HIPAA privacy, security, HITECH, and Gina effective September 23, 2013
CMS Memo on Insulin Pens

- CMS issues memo on insulin pens on May 18, 2012
- Insulin pens are intended to be used on one patient only
- CMS notes that some healthcare providers are not aware of this
- Insulin pens were used on more than one patient which is like sharing needles
- Every patient must have their own insulin pen
- Insulin pens must be marked with the patient’s name
Insulin Pens May 18, 2012

Office of Clinical Standards and Quality/Survey & Certification Group

DATE: May 18, 2012
TO: State Survey Agency Directors
FROM: Director, Survey and Certification Group
SUBJECT: Use of Insulin Pens in Health Care Facilities

Memorandum Summary

Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. Insulin pens are meant for use by a single patient only. Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

Background

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more than one patient/resident. Reproduction of blood into the insulin reservoir after injection will

Regurgitation of blood into the insulin cartridge after injection can occur creating a risk if used on more than one patient.

Hospital needs to have a policy and procedure.

Staff should be educated regarding the safe use of insulin pens.

More than 2,000 patients were notified in 2011 because an insulin pen was used on more than one patient.

CDC issues reminder on same and has free flier.
CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person

Available for download Clinical Reminder: Insulin Pens [PDF - 182 KB]

Summary
The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must never be used on more than one person.

Background
Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin pens must never be used for more than one person.
Insulin Pen Safety – One Insulin Pen, One Person

The Safe Injection Practices Coalition created an insulin pen poster and brochure for healthcare providers as a reminder that insulin pens and other injectable medications are meant for one person and should never be shared. PDFs of these educational materials are linked below:

Specific Materials for Safe Use of Insulin Pens – for Clinicians and Patients

- Poster
- Brochure

Click here to order free copies of these materials from the Centers for Disease Control and Prevention (CDC) (publication numbers 22-1501 and 22-1503).

Additional Resources

- VA Patient Safety Alert: Multi-Dose Pen Injectors (Department of Veterans Affairs, January 2013)
CMS issues memo related to the relative humidity (RH)

AORN use to say temperature maintained between 68-73 degrees and humidity between 30-60% in OR, PACU, cath lab, endoscopy rooms and instrument processing areas

CMS says if no state law can write policy or procedure or process to implement the waiver

Waiver allows RH between 20-60%

In anesthetizing locations- see definition in memo
Humidity in Anesthetizing Areas

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland  21244-1800

Center for Clinical Standards and Quality/Survey & Certification Group

DATE:  April 19, 2013
TO:  State Survey Agency Directors
FROM:  Director
Survey and Certification Group
SUBJECT:  Relative Humidity (RH): Waiver of Life Safety Code (LSC) Anesthetizing Location Requirements; Discussion of Ambulatory Surgical Center (ASC) Operating Room Requirements

Memorandum Summary

• **RH of ≥20 Percent Permitted in Anesthetizing Locations:** The Centers for Medicare & Medicaid Services (CMS) is issuing a categorical LSC waiver permitting new and existing ventilation systems supplying hospital and critical access hospital (CAH) anesthetizing locations to operate with a RH of ≥20 percent, instead of ≥35 percent. We are also recommending that RH not exceed 60 percent in these locations.

• **This Waiver Does Not Apply:**
  - When more stringent RH control levels are required by State or local laws and regulations, or
  - Where reduction in RH would negatively affect ventilation system performance.

• **Hospitals & CAHs Must Elect to Use the Categorical Waiver:**
  - Individual waiver applications are not required, but facilities are expected to have written documentation that they have elected to use the waiver.
  - At the entrance conference for any survey assessing LSC compliance, a facility that has elected to use this waiver must notify the survey team.

• **Ongoing Requirements:**
  - Facilities must monitor RH in anesthetizing locations and take corrective actions when needed to ensure RH remains at or above 20 percent.

• **ASCs:** ASCs are not subject to all of the same LSC requirements as hospitals, but are required, consistent with 42 CFR 416.44(a)(1), to maintain RH in operating rooms in accordance with nationally accepted guidelines.

• **State Operations Manual (SOM) Appendices A, I, L & W are being updated accordingly.**
Luer Misconnections Memo

- CMS issues memo March 8, 2013
- This has been a patient safety issues for many years
- Staff can connect two things together that do not belong together because the ends match
- For example, a patient had the blood pressure cuff connected to the IV and died of an air embolism
- Luer connections easily link many medical components, accessories and delivery devices
Luer Misconnections Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1890

Center for Clinical Standards and Quality / Survey & Certification Group

DATE: March 8, 2013
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Luer Misconnection Adverse Events

Ref: S&C: 13-14-ALL

Memorandum Summary

- Luer Misconnections continue to result in adverse events and deaths – Luer
  connectors easily link many medical components, accessories, and delivery systems.
  Clinicians, in any type of provider or supplier setting, can mistakenly connect the wrong
  devices and deliver substances through the wrong route. Despite numerous alerts and
  warnings, a patient’s blood pressure tubing was recently misconnected to an
  intravenous (IV) line in an ambulatory surgery center (ASC) resulting in a patient death.

- Adverse Event Complaint Investigation: During a complaint investigation for an
  adverse event involving delivery of an incorrect substance or utilization of an incorrect
  delivery route, surveyors must be alert to whether the event involved misconnection of
  a Luer device. If so, surveyors must determine whether the facility has taken actions to
  ensure systems are in place to prevent recurrence of this type of adverse event.

- Facility Reporting to Food & Drug Administration (FDA): Surveyors should
  encourage health care facilities to report problems with Luer misconnections to the
  FDA, even if no adverse event occurred.
### Table. Tubing Misconnections Reported to the Pennsylvania Patient Safety Authority, January 2008 to September 2009

<table>
<thead>
<tr>
<th>MISCONNECTION</th>
<th>NUMBER OF REPORTS</th>
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<tbody>
<tr>
<td>Secondary intravenous (IV) infusion connected to lower “Y” port of primary IV tubing set</td>
<td>8</td>
</tr>
<tr>
<td>Hemodialysis arterial and venous tubing lines reversed</td>
<td>5</td>
</tr>
<tr>
<td>G-tube and J-tube lines reversed</td>
<td>3</td>
</tr>
<tr>
<td>Incorrect tubing connection (no further explanation provided in reports)</td>
<td>3</td>
</tr>
<tr>
<td>Epidural and patient-controlled analgesia (PCA) tubing sets reversed</td>
<td>2</td>
</tr>
<tr>
<td>Nonhemodialysis arterial and venous tubing lines reversed</td>
<td>2</td>
</tr>
<tr>
<td>Cell saver tubing connected to cell saver reservoir</td>
<td>1</td>
</tr>
<tr>
<td>Feeding tube set connected to Braviac®</td>
<td>1</td>
</tr>
<tr>
<td>Feeding tube set connected to peripherally inserted central catheter (PICC) line</td>
<td>1</td>
</tr>
<tr>
<td>Feeding tube set connected to suction port</td>
<td>1</td>
</tr>
<tr>
<td>Imaging contrast tubing set connected to tracheostomy cuff</td>
<td>1</td>
</tr>
<tr>
<td>IV tubing set connected to dialysis catheter</td>
<td>1</td>
</tr>
<tr>
<td>IV tubing set connected to PICC line</td>
<td>1</td>
</tr>
<tr>
<td>IV tubing set connected to tracheostomy cuff</td>
<td>1</td>
</tr>
<tr>
<td>Knee irrigation connected to peripheral IV tubing</td>
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</tr>
<tr>
<td>Miscommunication (arterial line noted in medical record as peripheral IV)</td>
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<td>Oral medication delivered through peripheral IV line</td>
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<tr>
<td>Suction line connected to water seal</td>
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<td>Suction and feeding tubing sets reversed</td>
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CMS Federal Law Changes for the Hospital CoP Manual
CMS Issues Final Regulation

- CMS publishes 165 page final regulations changing the CMS CoP, IG issued 3-15-2013 and effective June 7, 2013
  - Published in the May 16, 2012 Federal Register
- CMS publishes to reduce the regulatory burden on hospitals-more than two dozen changes
- States will save healthcare providers over 5 billion over five years
- Includes changes regarding plan of care, restraint and seclusion, drug orders, verbal orders, blood transfusions, IV medications, and standing orders
burdensome rules, and thereby increasing the ability of hospitals and CAHs to devote resources to providing high quality patient care.

B. Summary of the Major Provisions

Revisions To Allow Flexibility and Eliminate Burdensome Conditions of Participation (CoPs): We have reduced burden to providers and suppliers by modifying, removing, or streamlining current regulations that we have identified as excessively burdensome.

- Single governing body for multiple hospitals: We will allow one governing body to oversee multiple hospitals in a multi-hospital system and have added a requirement for a member, or members, of the hospital’s medical staff to be included on the governing body as a means of ensuring communication and coordination between a single governing body and the medical staffs of individual hospitals in the system.

- Reporting of Restraint-Related Deaths: We have replaced the requirement that hospitals must report deaths that occur while a patient is only in soft, 2-point wrist restraints with a requirement that hospitals must maintain a log (or other system) of all

- Nursing care plan: We have allowed hospitals the options of having a stand-alone nursing care plan or a single interdisciplinary care plan that addresses nursing and other disciplines.

- Administration of medications: We have allowed hospitals to have an optional program for patient(s)/support person(s) on self-administration of appropriate medications. The program must address the safe and accurate administration of specified medications; ensure a process for medication security; address self-administration training and supervision; and document medication self-administration.

- Administration of blood transfusions and intravenous medications: We have eliminated the requirement for non-physician personnel to have special training in administering blood transfusions and intravenous medications and have revised the requirement to clarify that those who administer blood transfusions and intravenous medications do so in accordance with State law and approved medical staff policies and procedures. We believe that this clarification will make the requirement consistent with current
Patient Safety Brief
Emergency Medicine Patient Safety Foundation

CMS Final Hospital CoP Changes
Sue Dill Calloway RN MSN JD CPHRM
July 16, 2012

There are important changes that hospitals should know about. These changes were published in the Federal Register on May 16, 2012 and become effective on July 16, 2012 and affect every hospital that receives Medicare or Medicaid reimbursement. They make over two dozen changes
CMS Hospital CoP Changes

- Hospitals in systems could have one board
- Eliminate IV medication and blood transfusion required training and include in your hospital P&P what training is required but still must be competent
- No requirement for the board to include one medical staff member
- Did **not** approve hospitals to have a shared medical staff
- Will not require nursing to have separate plan of care if participated in interdisciplinary plan of care
CMS Hospital CoP Changes

- Renewed section that sunset that allows any doctor on the case to sign off the verbal orders of any other physician on the case
- Verbal orders must still be signed off within the time frame set by the state law
- If no state law, CMS use to say that they had to be signed off within 48 hours and now no longer says this so state without a state law can a P&P and many adopted 30 day policy
- No longer need to keep an infection control log and deleted tag 750
CMS Hospital CoP Changes

- Discusses self administration of drugs and P&P requirements and added 2 new tags; 412 and 413
  - Must train patient who must be competent
  - Must document when given and ensure patient is competent
- CMS removed the duplicative requirement from the transplant center regulations to require the team to verify the blood type before organ recovery
- Hospital may grant privileges to physicians and non-physicians and need to go through the MS approval process within their scope of practice as allowed by state law (see tag 406)
History and Physicals

CMS and TJC Standards
History and Physicals

- CMS and TJC requirement

- If admitted for pneumonia must be done and on chart within 24 hours

- If elective surgery make sure H&P is not older than 30 days

- H&P must also be updated the day of surgery
  - Should say that H&P was reviewed, the patient examined, and that “no change” has occurred in the patient’s condition since the H&P was completed
History and Physicals

- Make sure on the chart before the patient goes to surgery unless an emergency
- Required for all surgeries and procedures requiring anesthesia
- Person doing H&P must be qualified
- Will allow surgeon to delegate to PA or NP if hospital and state allows
- Can be handwritten or transcribed or electronic
- CMS did clarification in the FR changes 2012
CMS H&P Clarification

- CMS publishes clarification in the 75 pages of proposed changes to the hospital CoPs
  - 17 pages if you use the three column PDF version
  - Contained in the Federal Register on October 24, 2011
    - Vol. 76, No. 205, Starts at page 65891
- Clarified H&P for hospitals and only located here
- CMS Tag numbers 358-359 and 458-461
- TJC PC.01.02.03, MS.03.01.01 and RC.02.01.03
Clarifying Changes  H&P

- History and Physicals is another hot spot with CMS
- CMS wants to clarify the intent of the rule where a H&P is done by a non-hospital practitioner or a practitioner with hospital privileges prior to the patient’s hospital visit
- The H&P must be no older than 30 days
- The H&P must be updated the day of surgery
- CMS thinks that some may think a full H&P is required when only an updated H&P for changes is required
Clarifying Changes  H&P

 CMS says a hospital may adopt a P&P allowing a H&P to be used by a practitioner who may not be a member of the hospital's MS or who does not have admitting privileges by that hospital, or by a QLP who does not practice at that hospital but is acting within his/her scope of practice under State law or regulation.

 The H&P can be updated for any changes.

 The exam must be conducted by a practitioner who is C&P to perform the H&P by the hospital MS.
Clarifying Changes  H&P

- The update note to the H&P must document the examine for any changes since the H&P was initially done.

- If the practitioner finds no change then the following can be documented:
  - The patient was examined and there is no change" has occurred in the patient's condition since the H&P was completed.

- The extent of the exam is not specified and CMS leaves it to the clinical judgment of the hospital staff.

- Includes patients undergoing surgery or anesthesia.
CMS Timing of Medications
Medication Timing Rule 405

- CMS issues 14 page memo on November 18, 2011 and final transmittal December 22, 2012
  - March 15, 2013 CMS moved section on standing orders to tag 457
- Updated Guidance on Medication Administration
  - Amends tag 405 which use to require that all medications be given within 30 minutes of the scheduled time
- ISMP did a study of 18,000 nurses and found that the 30 minute rule was a patient safety issue
- Nurses were doing work-arounds and other unsafe practices to adhere to the 30 minute time period
ISMP Acute Care Guidelines for Timely Administration of Scheduled Medications

Background

The Institute for Safe Medication Practices (ISMP) developed these Acute Care Guidelines for Timely Administration of Scheduled Medications after conducting an extensive survey in late 2010 involving almost 18,000 nurses regarding the requirement in the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation Interpretive Guidelines to administer medications within 30 minutes before or after the scheduled time. The nurses who responded to the survey made it clear that changes to drug delivery methods and gradual increases in the complexity of care, number of prescribed medications per patient, and number of patients assigned to each nurse have made the long-standing CMS “30-minute rule” error prone.

Many nurses reported feeling great pressure to take shortcuts to comply with the rule, which have led to errors, some harmful. While delays in administering certain time-sensitive medications can also result in harm, a one-size-fits-all, inflexible requirement to administer all scheduled medications within 30 minutes of the scheduled time is a precarious mandate given that relatively few medications truly require exact timing of doses.

CMS staff have requested a copy of the final guidelines, and based on our conversations with them, we are optimistic that positive changes will be made to the current “30-minute rule.” For now, hospitals will still be held accountable for the “30-minute rule” in the CMS Interpretive Guidelines. However, given widespread support for these more reasonable and clinically appropriate guidelines, we hope CMS surveyors will allow hospitals to justify their carefully considered policies and procedures regarding timely medication administration using these guidelines to anchor the process.

How to Use the Guidelines

These guidelines are applicable ONLY to scheduled medications (see definition below).

The guidelines are intended to be used as a resource when acute care organizations develop or revise policies and procedures related to timely administration of scheduled medications. The guidelines are not standards or evidence-based practices that have been proven by scientific studies, but they have been vetted by hundreds of medication and patient safety experts; hospital medication safety teams; professional nursing, pharmacy, and respiratory therapy organizations; The Joint Commission; hospital pharmacists; and frontline nurses who bear ultimate responsibility for administering medications in a timely manner.

An interdisciplinary team with adequate nursing representation needs to translate the guidelines into facility-specific policies and procedures. In general, the guidelines represent a safe, effective, and efficient approach to timely administration of scheduled medications. However, the details may differ from one organization to another based on differing patient populations and medication systems, including available technology.

Please keep in mind that the policies and procedures developed by acute care organizations using these guidelines will require flexibility of the goals for timely administration, as appropriate, to accommodate the additional time needed to learn to operate new medication-related technologies.

Advisory Group
Changes to 30 Minute Medication Rule

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Office of Clinical Standards and Quality / Survey & Certification Group

DATE: November 18, 2011
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

SUBJECT: Updated Guidance on Medication Administration, Hospital Appendix A of the State Operations Manual (SOM)

Memorandum Summary

• **Medication Administration Guidance Updated**: SOM Appendix A guidance concerning medication administration in hospitals is being updated to:
  - Reflect current standards of practice related to timeliness of medications. Hospitals are expected to establish policies and procedures for the timing of medication administration that appropriately balance patient safety with the need for flexibility in work processes.
  - Incorporate policy regarding standing orders from S&C-09-10.

• **ASPEN Changes**: Tags A-404 and A-405 have been combined. It will take time for this guidance to be incorporated into a future ASPEN release. Prior to this conversion citations should be made only to Tag A-404.

Background
SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for 42 CFR 482.23(c), concerning medication administration.

REVISED MATERIAL - EFFECTIVE DATE: December 22, 2011
IMPLEMENTATION DATE: December 22, 2011

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGE IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) — (Only One Per Row.)

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<thead>
<tr>
<th>R</th>
<th>CHAPTER/SECTION/SUBSECTION/TITLE</th>
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<tbody>
<tr>
<td></td>
<td>Appendix A/§482.23(c) Standard: Preparation and Administration of Drugs/A-0405</td>
</tr>
</tbody>
</table>

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their current operating budgets.

IV. ATTACHMENTS:

- Business Requirements
- Manual Instruction
- Confidential Requirements
- One-Time Notification
- Recurring Update Notification

A-0405

(Rev.77, Issued: 12-22-11, Effective/Implementation: 12-22-11)
Medication Timing Rule

- The policy establishes 3 different time frames for which medication must be administered
  
  - Timeframe one is that some medicines are time critical and must be given within 30 minutes of the schedule time which is a one hour window like fast acting insulin for lunch
  
  - Timeframe is one hour with two hour window for any medication given more than once a day so bid, tid, qid, every 6 hours etc.
  
  - Timeframe is two hours with four hour window for any medication more than once a day so includes once a week and once a month
Medication Timing Rule

- Hospital must adopt P&P based on acceptable standards of practice
- Gives hospitals flexibility for the timing of medication that takes into account the medicine and patient needs
  - Patient needs this antibiotic within one hour of the surgery
  - Patient needs insulin more timely with meal schedule
  - Patient who gets once a day Lanoxin has a four hour window of time
Medication Timing Rule

- The hospital policy needs to comply with the requirements of the CMS interpretive guidelines.
- The hospital policy must be based on standards of care.
- Nursing staff should be trained on this in orientation and periodically.
- Policy must be approved by MS with input from pharmacy and nursing.
- CMS has many requirements to be in the policy so confirm that all are present and do a gap analysis.
Verbal Orders
CMS and TJC Standards
Verbal Orders

- Common problematic standard with CMS and TJC
- Should not be a common practice
- Physician is not allowed to give if standing in nursing station absent an emergency
- May take if needed and physician at home, in office, or scrubbed in surgery
- Nurse needs to write it down and read it back
- Nurse needs to sign name, date and time
- Physician must sign name, date and time also
Verbal Orders  2013 Changes

- Physician must sign off the VO (including date and time) within time specified by state law
  - Most states say 24 or 48 hours
  - If state does not say then it use to say 48 hours and now what your P&P says so many picked 30 days if no state law
- CMS will allow PA or NP to sign off VO for the physician if state and hospital allows and within their scope of practice
- Any physician on the case can sign off the VO for any other doctor including ED doctors signing for each other when relieving them
Verbal Orders

- Have a P&P on who can accept VO in your facility
  - Must be qualified staff
  - Policy may allow pharmacist for pharmacy orders, dietician for dietary orders, nurses, etc.
- Include in P&P when will not take VO
  - Such as many hospitals do not take a VO for chemotherapy
    - CMS 407-408 and 454 and 457
    - TJC RC.02.03.07. PC.02.02.07 and PC.01.01.01
Patient Safety Brief  
Emergency Medicine Patient Safety Foundation

CMS Final Hospital CoP Changes  
Sue Dill Calloway RN MSN JD CPHRM  
July 16, 2012

There are important changes that hospital should know about. These changes were published in the Federal Register on May 16, 2012 and become effective on July 16, 2012 and affect every hospital that receives Medicare or Medicaid reimbursement. They make over two dozen changes to the hospital conditions of participation (CoPs). CMS will publish interpretive guidelines on these at a later date. Many of these standards have some impact on the emergency department.

CMS said these changes would modernize the CoPs. In fact, CMS states these are the most significant changes in over two decades. CMS published the changes to reduce the regulatory burden on hospital.
CMS Pharmacy Changes
Medication Errors, ADE, and Drug Incompatibilities
Pharmaceutical Services  Tag A-0508

- Standard: Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician.
  - If appropriate also to the PI program.
- Hospitals are required to make sure the attending doctor is immediately aware of the following:
  - Medication errors or drug errors
  - Adverse drug reactions (ADRs)
  - Incompatibilities
Background

The final FY 2011 Inpatient Prospective Payment System (IPPS) rule was published on August 18, 2010 (75 FR 49,504) and effective on October 1, 2010. The FY 2011 IPPS final rule contained revisions to the Hospital Conditions of Participation (CoPs) governing rehabilitation. The final rule, effective October 1, 2011, contained revisions to the Hospital Conditions of Participation (CoPs) governing rehabilitation and nursing services. The COI was revised to clarify the CoP's that support the implementation of the IPPS final rule revisions. The revisions to the CoP's were effective October 1, 2011. In the attached SOM Transmittal, the reference to 484.244 Transmittal 1416 was changed to 482.244 for Tag A-116.

Memorandum Summary

SOM Hospital Appendix A Updated

The final FY 2011 Inpatient Prospective Payment System (IPPS) rule was published on August 18, 2010 (75 FR 49,504) and effective on October 1, 2010. The FY 2011 IPPS final rule contained revisions to the Hospital Conditions of Participation (CoPs) governing rehabilitation. The final rule, effective October 1, 2011, contained revisions to the Hospital Conditions of Participation (CoPs) governing rehabilitation and nursing services. The COI was revised to clarify the CoP's that support the implementation of the IPPS final rule revisions. The revisions to the CoP's were effective October 1, 2011. In the attached SOM Transmittal, the reference to 484.244 Transmittal 1416 was changed to 482.244 for Tag A-116.

Subject:

State Operations Manual (SOM) Hospital Appendix A Update

Revisions have been made to reflect new regulations, changes governing orders for medications, clarifications have been made to provisions related to blood transfusions and intravenous medications, and other changes in the CoP's. The changes are highlighted in yellow color.
Drug Incompatibilities

- Any unexpected reaction that occurs between the IV medications must also be reported.

- CMS said hospitals can minimize risk by having resources available such as:
  - Up to date drug incompatibility (DI) chart
  - Online incompatibility references

- Incompatibility information must be readily available to staff:
  - Must be kept up-to-date as information is frequently updated by manufacturer.
Reporting to the Attending

- An immediate report must be made to the attending if medication error, ADE, or DI harmed or has the potential to harm the patient.

- If outcome of medication error is unknown then physician must be notified:
  - Be sure the incident report is filled out and document in the incident report that the attending physician was notified.
  - Document notification of the attending physician in the patient’s medical record.
Drug Administration Errors

- CMS says hospital staff are expected to use their best clinical judgment in determining whether immediate reporting is required
  - Based on patient’s presentation and assessment
  - This must be done in accordance with the hospital P&P
- PI program must track and report medication errors and near misses
  - Must also track suspected ADTs
  - To determine system errors and prevent future errors
Drug Interactions Checker

Drug Interactions Checker

Type in a drug name and select a result from the list. Repeat the process to add multiple drugs. When complete, save your list for future reference or check for interactions immediately.

Drug Name:

Your interactions list is empty. Type a drug name in the box above to get started.

www.drugs.com/drug_interactions.php
Incompatibility Charts

IVMedication Compatibility Charts

- IV Medication Compatibility Chart
- Low Vitamin D Symptoms
- Low Blood Pressure
- High Blood Pressure Medication
- IV Medication Compatibility Chart Privacy Policy
- Contact Us At IVMedication Compatibility Chart
- Site Map

AdChoices

Life Line Screening
Detect Stroke, AAA, and PAD Risk, Schedule a Screening

www.pharmedium.com

Pharmaceutical Admixtures
Quality IV & Epidural Preparations. View Our Selection Online Today!

www.TheRecoveryPlace.net/Tre
Effective Drug Treatment
Drug Treatment and Rehabilitation Programs. Call (888) 494-8536

www.PfizerPro.com/Lyrica
LYRICA® (pregabalin) CV
Get Prescribing Information And Other Resources At PfizerPro.com.

www.TransformationsTreatment.com
#1. Addiction Rehab Center
Adult, Addiction Rehab & Detox All Private Rooms.

www.ivmedicationcompatibilitychart.com/
Hospital Policies and Procedures (P&P)  508

- Hospital must establish P&P for the reporting of medication errors, ADRs, and incompatibilities
- Hospital must make sure staff are aware of the reporting requirements
  - Hospital should add this information to orientation for new employees
  - Hospital should consider periodic CNE
- Immediate reporting must be required in the P&P with timeframes for reporting that are based on the clinical effects of harm on the patient
Non-punitive Environment  A-0508

- Hospitals are encouraged by CMS to adopt a non-punitive environment
  - Non-punitive environment so staff will report
  - Many hospitals balance the non-punitive environment with Just Culture
- Should focus on system analysis theory and system issues and not individual staff
  - The majority of medication errors are made by long term employees with unblemished records
  - It is a system that allows the error to occur
Hospital Requirements    A-508

- The hospital cannot just rely on incident reports
- Additional steps must be taken besides
  - Encouraging reporting
  - Adopting a broad definition of medication error and
  - PI reporting
- Incident reports fail to identify most errors and ADEs
IHI Has Three Trigger Tools for ADEs

- **Trigger Tool for Measuring Adverse Drug Events (IHI Tool)**
  A method for using "triggers," or clues, in patient records to identify ADEs that may not have been reported through traditional mechanisms; developed by the Institute for Healthcare Improvement (Boston, Massachusetts, USA) and Premier, Inc. (San Diego, California, USA).

- **Paediatric Trigger Tool for Measuring Adverse Events (UK version)**
  This trigger tool is a structured case note review tool that measures the rate of harm (adverse events) in the organisation using paediatric-specific triggers to identify adverse events; developed by the Safer Care Team, NHS Institute for Innovation and Improvement (Coventry, England).

- **Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting**
  This Trigger Tool, developed for use with mental health inpatients, includes a list of known adverse drug event triggers in mental health settings and provides instructions for conducting a retrospective review of patient records using these triggers to identify possible ADEs; developed by the Institute for Healthcare Improvement (Cambridge, Massachusetts, USA).
Introduction to Trigger Tools for Identifying Adverse Events

The use of "triggers," or clues, to identify adverse events (AEs) is an effective method for measuring the overall level of harm from medical care in a health care organization. Traditional efforts to detect AEs have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm.

There are various Trigger Tools available on IHI.org, including:

- **IHI Global Trigger Tool for Measuring Adverse Events**
- **Trigger Tool for Measuring Adverse Drug Events**
- **Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting**
- **Trigger Tool for Measuring Adverse Drug Events in the Nursing Home**
- **Surgical Trigger Tool for Measuring Peri-operative Adverse Events**
- **Intensive Care Unit Adverse Event Trigger Tool**
- **Pediatric Trigger Toolkit: Measuring Adverse Drug Events in the Children's Hospital**
- **Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit**
- **Outpatient Adverse Event Trigger Tool**

These Trigger Tools provide an easy-to-use method for accurately identifying AEs (harm) and measuring the rate of AEs over time. Tracking AEs over time is a useful way to tell if changes being made are improving the safety of the care processes.

Choosing a Tool

There are two approaches to using the harm measures from the Trigger Tools:

1. To monitor an overall level of harm as a "dashboard" item
2. To track harm in a specific topic or area

The **IHI Global Trigger Tool** is designed specifically for the first approach. This is the tool to use for an organization-wide measure that can be reported to leadership. It is designed for use with the records of adult inpatients in acute care.
NIOSH Hazardous Drugs 2012 List

- Previous update was Dec 2010
- Updated in 2012 (FR June 27, 2012)
- NIOSH reviewed 70 new drugs that received FDA approval
- NIOSH reviewed 180 drug that received new special warnings (usually black box warnings)
- Found 26 of these that were added to the list
- Removed 15 drugs that are no longer available
NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012

The National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2004 (http://www.cdc.gov/niosh/docs/2004-165/). In Appendix A of the Alert, NIOSH identified a sample list of major hazardous drugs. The list was compiled from information provided by four institutions that have generated lists of hazardous drugs for their respective facilities and by the Pharmaceutical Research and Manufacturers of America (PhRMA) from the American Hospital Formulary Service Drug Information (AHFS DI) monographs.
CMS Visitation
Visitation

- Effective January 19, 2011 and final transmittal issued 12-2-2011
- Must rewrite policy on visitation including visiting hours in ICU
- Must inform each patient of their visitation rights
- Must include any restrictions on those rights
  - Can not restrict or deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity or disability
- For example same sex partner may present visitation advance directive
Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

DATE: May 13, 2011

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: State Operations Manual (SOM) Hospital Appendix A Update

*** In the attached SOM Transmittal, the reference to 484.24 is changed to 482.24 for Tag A-1164. The change is highlighted in yellow color***

Memorandum Summary

SOM Hospital Appendix A Updated

- Revisions have been made to reflect regulation changes governing orders for rehabilitation (42 CFR 482.56) and respiratory care services (42 CFR 482.57)
- Clarifications have been made for provisions related to:
  - Nursing requirements related to blood transfusions and intravenous medications (42 CFR 482.23(e)(3))
  - Immediate reporting of medication administration errors, adverse events, and incompatibilities (42 CFR 482.25(b)(6))
Visitation Transmittal 12-2-2011

CMS Manual System
Pub. 100-07 State Operations
Provider Certification
Transmittal 75

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Date: December 2, 2011

SUBJECT: Revised Appendix A, Interpretable Guidelines for Hospitals, and Appendix W, Interpretable Guidelines for Critical Access Hospitals (CAHs)

I. SUMMARY OF CHANGES: Clarification is provided for existing hospital regulations 42 CFR 482.13(a) and (b), and new 42 CFR 482.13(h), concerning hospital patients’ rights, including advance directives and visitation rights. Clarification is provided for existing CAH regulations at 42 CFR 485.608(a), concerning compliance with Federal laws and regulations, including regulations governing advance directives and required patient disclosures. Guidance is provided for new 42 CFR 485.635(f), concerning CAH patients’ visitation rights.

NEW/REVISED MATERIAL - EFFECTIVE DATE: December 2, 2011
IMPLEMENTATION December 2, 2011

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/ revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.) (R = REVISED, N = NEW, D = DELETED) - (Only One Per Row.)

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<td>N</td>
<td>Appendix A/§482.13(b) Standard: Patient Visitiation Rights/A-0217</td>
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Visitation

- This was a 34 page memo
- It included more than just visitation so all hospitals should read this closely
- It includes changes to plan of care, advance directives, and informed consent
- Need to revise your hospital policies and procedures
- Need to educate staff so be sure to include in orientation for new nurses
- Gives rights to patient advocate or support person
Patient Advocate or Support Person

- Must ask patient if they have one and suggest you get it in writing
- Patient advocate must be given a copy of the patient rights if present even if the patient is competent
- Patient advocate has a right to be informed in the plan of care
- Patient advocate is asked to sign the consent form if present even if patient is competent
- Patient advocate can stay with patient with certain restrictions
CMS Post Anesthesia Standard
CMS Anesthesia Standards

- CMS revised anesthesia standards for a fourth time and transmittal issued 12-2-2011
  - Tag 1000, 1003 (pre-anesthesia evaluations) and 1005 (post-anesthesia evaluations changed)

- Preanesthesia evaluation must be done within 48 hours and time is calculated from delivery of first dose for inducing anesthesia
  - They are some elements that may be collected for the assessment within 30 days
SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is being provided for various provisions of 42 CFR 482.52, concerning anesthesia services.

NEW/REVISED MATERIAL - EFFECTIVE DATE: December 2, 2011
IMPLEMENTATION DATE: December 2, 2011

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

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(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

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<td>R</td>
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<tr>
<td>R</td>
<td>§482.52(b)(3) Standard: Post-anesthesia Evaluation</td>
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III. FUNDING: No additional funding will be provided by CMS; contractor activities are...
CMS Anesthesia Standards

- Added elements for what to document during surgery
- List of policies and procedures required
- Discussed what must be documented in preanesthesia and post anesthesia assessment
- Changes make the post anesthesia evaluation less problematic
Post Anesthesia Evaluation 1005

- Post-anesthesia evaluation for proper anesthesia service for outpatients
  - Including CV status, LOC, any complications
  - Follow up care needed or patient instructions given
- In accordance with P&P
- Document in chart within **48 hours** for patients receiving anesthesia services (general, regional, MAC)
  - Included inpatients and outpatients now
  - May need to call outpatient at home if not seen by an anesthesia provider before they go home
Post Anesthesia Evaluation

- Has to be done only by 1 of 5 qualified anesthesia person (CRNA, AA, or anesthesiologist)
  - 48 hours starts at time patient moved into PACU or area patient is recovered
  - Evaluation can not generally be done at point of movement to the recovery area since patient not recovered from anesthesia
  - Patient must be sufficiently recovered form the acute administration of the anesthesia
  - No longer says that for outpatients, must be completed before discharge (48 hours)
Post-Anesthesia Assessment to Include

- Respiratory function with respiratory rate,
- Airway patency and oxygen saturation
- CV function including pulse rate and BP
- Mental status, temperature
- Pain
- Nausea and vomiting
- Post-operative hydration
CMS Restraint and Seclusion Standards
## Number of Patient Rights Violations 2013

<table>
<thead>
<tr>
<th>Right</th>
<th>Tag(s)</th>
<th>Count</th>
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<tr>
<td>Restraint and seclusion</td>
<td>Tag 133</td>
<td>362</td>
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<tr>
<td>Care in a safe setting</td>
<td>Tag 115</td>
<td>309</td>
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<td>Patient Rights</td>
<td>Tag 115</td>
<td>135</td>
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<td>Personal privacy</td>
<td>Tag 143</td>
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<td>Tag 119 and 120</td>
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<td>Tag 144)</td>
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<td>Confidentiality 28</td>
<td>Tag 146</td>
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<td>Admission status notification</td>
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<td>Tag 215-217</td>
<td>8</td>
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<tr>
<td><strong>Access to Medical Records</strong></td>
<td>Tag 148</td>
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<tr>
<td><strong>Exercise of Patient Rights</strong></td>
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<tr>
<td><strong>Total patient rights violations</strong></td>
<td></td>
<td><strong>950</strong></td>
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Patient Rights Restraint and Seclusion

- Currently there are about 50 pages of standards on restraint and seclusion (R&S)

- Currently CMS requires that every death that occurs if the patient is in restraint or within 24 hours of being in a restraint must be reported to CMS

- It also included reporting of any death that occurs within one week after R&S if the restraint is reasonable to assume contributed to or caused the death

- A report form had to be filled out and sent to the regional office
Restraint and Seclusion Patient Safety Briefing
Emergency Medicine Patient Safety Foundation

Written by: Sue Dill Calloway RN MSN JD CPHRM
Michael Gerardi, MD, FAAP, FACEP
John (Jack) Kelly DO, FACEP, FAAEM

March 2012
Revised July 16, 2012

Introduction
Restraint and seclusion is a very important patient safety issue. Appropriately applied restraints can protect patients from harming themselves or others. Paradoxically, improperly applied restraints can result in patient injury and death. It is also an important regulatory issue for accreditation organizations such as the Joint Commission. Likewise, any hospital accredited by DNV Healthcare or by the American Osteopathic Association (AOA) Healthcare Facility Accreditation Program must follow
Patient Rights Restraint and Seclusion

- This included the use of two points wrist restraints that were used in critical care settings to prevent patients from removing central lines, NG, or ET tubes.

- No research to show that this type of use ever caused a patient’s death.

- CMS has changed this in the interpretive guideline that we would **not** have to report and fill out the worksheet if a patient died in two-point wrist restraints and no use of seclusion was used.
The hospital would not need to report to the CMS regional office.

- Instead the hospital could just keep an internal log.
- The log would include the patient’s name, date of birth, date of death, attending physician, primary diagnosis, and medical record number.
- Name of practitioner responsible for patient could be used in lieu of attending if under care on non-physician practitioner.

CMS could request to review the log at anytime.

Would still require reporting of deaths within seven days.
Restraint Worksheet


- This is an official OMB form-new form in 2013

- Can not mandate hospital fill out but will save time on phone from them asking you the information
  - List of regional offices (to put in your P&P) at www.cms.hhs.gov/RegionalOffices/01_overview.asp

- Must still notify regional office by phone the next business day and document this in medical record

- Patient dies in restraint, within 24 hours of being in a restraint or 7 day rule if death caused by R&S
  - Except two soft wrist restraints as discussed previously
HOSPITAL RERAINT/SECLUSION DEATH REPORT WORKSHEET

A. Hospital Information:

Hospital Name: ____________________________ CCN: ____________________
Address: ____________________________ City: __________ State: _____ Zip Code: ______
Person Filing the Report: ____________________________ Filer’s Phone Number: __________

B. Patient Information:

Name: ____________________________ Date of Birth: ________________

Medical Record Number _____________ Primary Diagnosis(es): ________________

________________________________________________________

________________________________________________________

Date of Admission: ________________ Date of Death: ______________________

Cause of Death: ____________________________

C. Restraint Information (check only one):

_____ While in Restraint, Seclusion, or Both
C. Restraint Information (check only one):

_____ While in Restraint, Seclusion, or Both
_____ Within 24 Hours of Removal of Restraint, Seclusion, or Both
_____ Within 1 Week, Where Restraint, Seclusion or Both Contributed to the Patient’s Death

Type (check all that apply): Physical Restraint ______ Seclusion _________ Drug Used as a Restraint _______

If Physical Restraint(s), Type (check all that apply):

_____ 01 Side Rails
_____ 02 Two Point, Soft Wrist
_____ 03 Two Point, Hard Wrist
_____ 04 Four Point, Soft Restraints
_____ 05 Four Point, Hard Restraints
_____ 06 Forced Medication Holds
_____ 07 Therapeutic Holds
_____ 08 Take-downs
_____ 09 Other Physical Holds
_____ 10 Enclosed Beds
_____ 11 Vest Restraints
_____ 12 Elbow Immobilizers
_____ 13 Law Enforcement Restraints
_____ 14 Other

If Drug Used as Restraint: Drug Name______________________ Dosage__________________
Restraint and Seclusion

- Patient has a right to be free from unnecessary R&S
- Leadership has responsibility to create culture that supports right to be free from R&S
- Should not considered as part of routine part of fall prevention
- If use protocol you still need an order
- Know the CMS definition of restraint and seclusion
- Know if drug used as a restraint
Restraint and Seclusion

- CMS has 50 pages of restraints that start at tag number 154
- CMS calls it violent and or self destructive as opposed to TJC who calls it behavioral health
- CMS calls it non violent/non self destructive and TJC calls it non behavioral health patient
- TJC has similar standards for hospitals that use them for deemed status (DS)
  - Know what restraints do not include such as forensic restraints, orthopedically prescribed devices, holding for medical test, surgical dressings, or postural supports
Restraint and Seclusion

- Know what it does include such as freedom splints, and all 4 side rails if patient can not lower them
- Try or consider and document less restrictive interventions and alternatives
- Document the assessment
- Need order from physician or LIP
- If LIP gives order notify doctor ASAP
- Amend plan of care
- Consider debriefing although not required by CMS on V/SD patients
Restraint and Seclusion

- End at the earliest time
- Do PI, mitt is not a restraint unless like a boxing glove
- Use as directed
- If V/SD need one hour face to face
- Time limited orders for V/SD patients
- Need P&P on R&S
- Educate staff and document this
- Follow any stricter state law, and
- Report restraint deaths as required
CMS and TJC on Informed Consent
Informed Consent

- TJC has consent standard in RI chapter RI.01.03.01 and one RC standard
  - RC.02.01.01 EP 4 requires the medical record to contain evidence of informed consent

- CMS has 3 section on informed consent
  - Informed decisions (Tag A-131 Patient Rights)
  - Medical records with minimum requirements for consent form (Tag A-465)
  - Surgical services (Tag A-955)
There are 13 Elements of Performance but only 11 apply to hospitals:

- EP1 - The hospital has a written policy on informed consent
- EP2 - The policy identifies specific care and treatment that requires an informed consent and this must be consistent with law and regulations
- EP3 - Policy describes exceptions to the rule
  - Such as emergencies then document in chart
EP4 - Policy describes the process to be followed

EP5 - Describe in policy how to document consent in the medical record
   - On a form or in progress notes

EP6 - Policy describes when a surrogate decision maker can give the informed consent
   - See RI.01.02.01 EP6
   - If the patient is unable to make decisions about care, then it is made by surrogate decision maker
TJC Informed Consent RI.01.03.01

- EP7 - Consent process includes a discussion about the patient’s proposed care, treatment and services

- EP9 - Process includes a discussion about potential benefits, risks, and side effects, likelihood of achieving the patient’s goals and any potential problems that might occur during recuperation

- EP11 - Process includes a discussion of the reasonable alternatives to the patient’s proposed care, risks, benefits, and side effects of the alternatives
  - Includes the risks of not having the proposed treatment
EP12 - Informed consent process includes a discussion about any circumstance under which information about the patient must be disclosed or reported

- Examples: mandatory reporting requirements for HIV, TB, viral meningitis, and other diseases to CDC or state department of health

EP13 Must obtain consent in accordance with the hospital P&P and prior to surgery

- Except in an emergency
CMS Minimum (Mandatory) Elements

- Name of the hospital where the procedure or other type of medical treatment is to take place
- Name of the specific procedure, or other type of medical treatment for which consent is being given
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment
Minimum (Mandatory) Elements Required

- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative
- Same discussion of likelihood and severity
- Signature of patient or representative
- Date and time signed by patient
- Any applicable state law requirements
Hospitals can adopt optional elements

Therefore, physicians and others practicing in the hospital need to review the hospital’s policy to determine what other elements have been adopted

Also be aware of any informed consent requirements in the medical staff bylaws or rules and regulations
Optional Elements May Include:

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient’s representative
- Date, time, and signature of the person witnessing the patient or the patient’s legal representative signing the consent form
- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient’s representative
Optional Elements May Include:

- **Statement**, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
TJC 2013 and 2014 Changes to the Patient Flow Standard
TJC Patient Flow Standards

- TJC has revised their standards on patient flow effective January 1, 2013 and 2014
  - Not called JCAHO anymore
- LD.04.03.11 EP 6 goes into effect January 1, 2014 regarding setting a 4 hour window as the goal for boarding of patients in the ED before they get to their bed
- LD.04.03.11 EP 9 goes into effect January 1, 2014 regarding boarding of behavioral health patients in the ED
TJC Amends Patient Flow Standards

www.jointcommission.org/standards_information/prepublication_standards.aspx

Standards Revisions to Address Patient Flow Through the Emergency Department Hospital Accreditation Program

**Standard LD.04.03.11**
The hospital manages the flow of patients throughout the hospital.

**Element of Performance for LD.04.03.11**

1. The hospital has processes that support the flow of patients throughout the hospital.
2. The hospital plans for the care of admitted patients who are in temporary bed locations, such as the post anesthesia care unit or the emergency department.
3. The hospital plans for care to patients placed in overflow locations.
4. Criteria guide decisions to initiate ambulance diversion.
5. The hospital measures the following components of the patient flow process:
   - The available supply of patient beds
   - The efficiency of areas where patients receive care, treatment, and services
   - The safety of areas where patients receive care, treatment, and services
Patient Flow Revisions 2013

- Revisions include leadership use of data and measures to identify and mitigate and manage patient flow issues and management of ED throughput as a system wide issue

- Revisions include safety for boarded patients and leadership communication with behavioral health providers so care of boarded patients is coordinated

- TJC also revised PC.01.01.01 because of safety issues of boarding behavioral health patients especially in the ED
Infection Control Issues
A Major Focus Now
October 14, 2011 CMS issues a 137 page memo in the survey and certification section

Memo discusses surveyor worksheets for hospitals by CMS during a hospital survey

Addresses discharge planning, *infection control*, and QAPI and all nurses should review IC one

It was pilot tested in hospitals in 11 states and on May 18, 2012 CMS published a second revised edition
- Piloted test each of the 3 in every state over summer 2012

November 9, 2012 CMS issued the third revised worksheet which is now 88 pages
Infection Control Worksheet

- Has section on safe injection practices
- Section on preventing MDROs such as C-diff, MRSA, VRE, etc.
- Section on infection control training, cleaning of equipment and environmental services
- Has tracers on hand hygiene, standard precautions, urinary catheters, central venous catheters, respiratory therapy, spinal injection, point of care devices, isolation precautions, surgical procedure tracer, etc.
Third Revised Worksheets

DEPARTMENT OF HEALTH & HUMAN SERVICES
Center for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-14
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality / Survey & Certification Group

DATE: November 9, 2012
TO: State Survey Agency Directors
FROM: Director, Survey & Certification Group


Memorandum Summary

- **Patient Safety Initiative**: The Centers for Medicare & Medicaid Services (CMS) is continuing to test revised surveyor worksheets for assessing compliance with three hospital Conditions of Participation (CoPs): Quality Assessment and Performance Improvement (QAPI), Infection Control, and Discharge Planning. We are focusing on compliance with these CoPs as a means to reduce hospital-acquired conditions (HACs), including healthcare associated infections (HAIs), and preventable readmissions.

- **Draft Worksheets Made Public**: Via this memorandum we are making the revised draft worksheets publicly available. As was the case previously, there may be additional revisions to the worksheets at the end of FY 2013.

Patient Safety Initiative Pilot Phase

The Survey & Certification Group (SCG) Patient Safety Initiative is continuing to pilot test three revised surveyor worksheets designed to help surveyors assess compliance with the hospital CoPs for QAPI, infection control, and discharge planning. In S&C-12-01 released October 14, 2011 and in S&C-12-32 released May 18, 2012, we made available to the public copies of the initial and revised draft surveyor worksheets. These worksheets were used during the pre-test and pilot phases of the SCG initiative, from September 2011 through September 2012.
CMS Memo on Insulin Pens

- CMS issues memo on insulin pens on May 18, 2012
- Insulin pens are intended to be used on one patient only
- CMS notes that some healthcare providers are not aware of this
- Insulin pens were used on more than one patient which is like sharing needles
- Every patient must have their own insulin pen
- Insulin pens must be marked with the patient’s name
Insulin Pens May 18, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Office of Clinical Standards and Quality/Survey & Certification Group

DATE: May 18, 2012
TO: State Survey Agency Directors
FROM: Director Survey and Certification Group
SUBJECT: Use of Insulin Pens in Health Care Facilities

Ref: S&C: 12-30-ALL

Memorandum Summary

Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. Insulin pens are meant for use by a single patient only. Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

Background
Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more than one patient/resident. Penetration of blood into the insulin cartridge after injection will

Background
Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more than one patient/resident. Penetration of blood into the insulin cartridge after injection will
CMS Memo on Safe Injection Practices

- June 15, 2012 CMS issues a 7 page memo on safe injection practices
- Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
- Notes new exception which is important especially in medications shortages
- General rule is that single dose vial (SDV) can only be used on one patient
- Will allow SDV to be used on multiple patients if prepared by pharmacist under laminar hood following USP 797 guidelines
Single Dose June 15, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Office of Clinical Standards and Quality/Survey & Certification Group

DATE: June 15, 2012
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

Memorandum Summary

- Under certain conditions, it is permissible to repack single-dose vials or single use vials (collectively referred to in this memorandum as “SDVs”) into smaller doses, each intended for a single patient: The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, Pharmaceutical Compounding - Sterile Preparations (“USP <797>”). Under USP <797>, healthcare facilities may repack SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repacking under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.
  - Administering drugs from one SDV to multiple patients without adhering to USP <797>
CMS Memo on Safe Injection Practices

- All entries into a SDV for purposes of repackaging must be completed with 6 hours of the initial puncture in pharmacy following USP guidelines
- Only exception of when SDV can be used on multiple patients
- Otherwise using a single dose vial on multiple patients is a violation of CDC standards
- CMS will cite hospital under the hospital CoP infection control standards since must provide sanitary environment
  - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.
Infection Control

- Recent issues with immediate sterilization from CMS and TJC so be sure to follow the manufacturer’s instruction
  - CMS and TJC issues memos and instructions

- Cleaning of medical equipment is being scrutinized
  - Instruments should be cleansed of debris and wiped down then soaked in enzymatic solution and then sent to central supply for sterilizing so no bio burden left on the instrument

- Make sure all the scopes are cleaned properly for endoscopies
Flash Sterilization (Immediate Use)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-09-55

DATE: September 4, 2009
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

SUBJECT: Flash Sterilization Clarification - FY 2010 Ambulatory Surgical Center (ASC) Surveys

Memorandum Summary

Flash Sterilization Clarification: State survey agencies (SAs) using the new survey process in FY 2009, including completing the Infection Control Surveyor Worksheet, have experienced challenges in evaluating use of “flash sterilization” by ASCs. Attachment 1 clarifies what this term means, and how to distinguish appropriate from inappropriate use of flash sterilization.

Background

We are clarifying the issue of the Infection Control Surveyor Worksheet and flash sterilization. This is an area in which technological changes require changes in the way surveyors assess compliance of sterilization practices in ASCs. Attachment 1 is a set of bullets the Centers for Medicare & Medicaid Services (CMS) has developed with assistance from the Centers for Disease Control & Prevention and the Food and Drug Administration. They have been informally distributed to FY 2009 ASC-HAI volunteer SAs, and will be reviewed at the October 20-22 surveyor training.
UPDATE: The Joint Commission’s Position on Steam Sterilization

The Joint Commission has been in discussion with multiple professional and trade organizations in regards to the common and proper use of sterilization using steam in hospital, critical access hospital, ambulatory care, and office-based surgery settings. Recently, some decisions have been made which will have an impact on the interpretation of standards and the survey process, effective immediately. In reviewing this method of sterilization, several issues have emerged including nomenclature, indications, and process issues.

*Flash sterilization* is the most common term used to describe certain types of steam sterilization that do not utilize a full cycle (also known as a terminal cycle). Originally, *flash sterilization* meant sterilizing unwrapped instruments using steam for 3 minutes, at 270°F at 27 to 28 pounds of pressure. Over the last several decades, a number of improvements have been made to this process, such as longer exposure of the instruments to steam, the use of special trays and packs to hold and protect the instruments, and the routine use of biological indicators. To help sort out confusion about nomenclature, this discussion refers only to steam sterilization as defined (3 minutes at 270°F at 27 to 28 pounds of pressure).

Indication-related issues involve the selection of the sterilization cycle or method. Previously, the selection of a sterilization cycle or method was a primary focus during a survey.

### Three Critical Steps of Reprocessing

1. **Cleaning and decontamination.** All visible soil must be removed prior to sterilization because steam and other sterilants cannot penetrate soil, particularly organic matter. Manufacturers’ instructions are available for all instruments; these include directions for the cleaning and decontamination process. Some smooth metal instruments may be easily brushed clean, while complex products may require disassembly and special cleaning techniques. Many manufacturers specify that an enzymatic soak be used as well.

2. **Sterilization.** Most sterilization is accomplished via steam, but other methods are also available. Steam sterilization of all types, including flashing, must meet parameters (time, temperature and pressure) specified by both the manufacturer of the sterilizer, the maker of any wrapping or packaging, and the manufacturer of the surgical instrument. In addition to these instructions, parametric, chemical, and biological controls must be used as designed and directed by their manufacturers.
Infection Control

- Clean glucose meters between use
- Mandate that all direct care givers must watch the infection control video published by HHS
  - Part of Partnering to Heal
- Be aware of the CDC intravascular guidelines
  - Standards on how to prep the skin to insert a peripheral IV, PICC line, midline, central line or arterial line
  - How and time to change the dressing
  - Time period to change IVs and tubing
**Infection Control Video**

- HHS has published a training video that every nurse, physician, infection preventionist and healthcare staff should see.
  - This includes risk managers.
  - It is an interactive video.
  - Go to [http://www.hhs.gov/partneringtoheal](http://www.hhs.gov/partneringtoheal)
  - HHS wants to decrease HAI by 40% in 2013, want 1.8 million fewer injuries and can save 60,000 lives.
Partnering to Heal:
TEAMING UP AGAINST HEALTHCARE-ASSOCIATED INFECTIONS

Partnering to Heal is a computer-based, video-simulation training program on infection control practices for clinicians, health professional students, and patient advocates.

The training highlights effective communication about infection control practices and ideas for creating a "culture of safety" in healthcare institutions to keep patients from getting sicker. Users assume the identity of the following five main characters and make decisions about preventing healthcare-associated infections (HAIs):

A **Physician**, Nathan Green, Director of a Hospital Post-op Unit, ready to start new prevention efforts in the unit;

www.hhs.gov/ash/initiatives/hai/training/

A **Registered Nurse**, Dena Gray, working to learn effective communications skills that could make the difference for her patients;

An **Infection Preventionist**, Janice Upshaw, a new employee charged with using a team-based approach...


1National Institutes of Health, Bethesda, Maryland
2Infusion Nurses Society, Norwood, Massachusetts
3Greenwich Hospital, Greenwich, Connecticut
Infection Control

- One of three CMS revised worksheets is on Infection Control
  - Hospital infection preventionist and staff should be familiar with this worksheet and what is in it
  - Foley catheter tracer, central line tracer, hand hygiene, etc
- CMS is focusing on safe injection practices
  - One needle, one syringe every time
  - If they make it in a single vial then buy it
  - Multidose vials and try and use on only one patient if possible
### Section 2. B Injection Practices and Sharps Safety (Medications, Saline, Other Infusates)

<table>
<thead>
<tr>
<th>Elements to be assessed</th>
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<tr>
<td>Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:</td>
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<td>2. 8.1 Injections are prepared using aseptic technique in an area that has been cleaned and free of visible blood, body fluids, or contaminated equipment.</td>
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<td>2. 8.2 Needles are used for only one patient.</td>
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<td>2. 8.3 Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).</td>
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The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 99,000 deaths occur as a result. Infection prevention and control is an important issue in today’s healthcare environment. It is important to accreditation organizations like the Joint Commission (TJC). The Joint Commission has eight pages of standards in the chapter on Infection Prevention and Control (IC).
Injection Safety

- Recent issue where syringes were reused resulting in contamination to many patients in Nevada
- Never reuse a needle or syringe
- Include in orientation education
- Use single doses vials when possible
- Multidose vials for single patient
- CDC has list of 10 recommendation for injection safety at www.cdc.gov/ncidod/dhqp/injectionsafety.html
Infection Control

- There have been more than 35 outbreaks of viral hepatitis in the past 10 years because of unsafe injection practices.

- This has resulted in the exposure of over 100,000 individuals to HBV and 500 patients to HCV.

- This includes inappropriate care of maintenance of finger stick devices and glucometers.

- Includes syringe reuse, contaminations of vials or IV bags and failure of safe injection practices.

  - Source: APIC position paper: Safe injection, infusion, and medication vial practices in health care.
CDC Injection Safety Website

- The CDC has an injection safety website
- Contains information for providers
- Injection Safety FAQs
- Safe Injection Practices to Prevent Transmissions of Infections to Patients
- Section from Guidelines for the Isolation Precautions to Prevent Transmission and more
- www.cdc.gov/ncidod/dhqp/injectionsafety.html
Unsafe Injection Practices and Disease Transmission

Reuse of syringes combined with the use of single-dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.

1. A clean syringe and needle are used to draw the sedative from a new vial.
2. It is then administered to a patient who has been previously infected with hepatitis C virus (HCV). Backflow into the syringe contaminates the syringe with HCV.
3. The needle is replaced, but the syringe is reused to draw additional sedative from the same vial for the same patient, contaminating the vial with HCV.
4. A clean needle and syringe are used for a second patient, but the contaminated vial is reused. Subsequent patients are now at risk for infection.
What to Do?

- Use only single dose vials and not multidose vials when available
- This includes the use of saline single dose flushes
- Single use of a disposal needle and syringe for each injection
- Prevent contamination of injection equipment and medication
- Insulin pens are for one person use only
What to Do?

- Wear masks when inserting epidural or spinals
- Discard used syringe intact in appropriate sharps container
- Make sure sharps container in each patient room
- Do not administer medications from single dose vials to multiple patients or combine left over contents for later use
What to Do?

- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients
- Follow the CDC 10 recommendations
- Don’t spike IVs more than an hour in advance
- Maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination
  - CMS Hospital CoP requirement, tag 501
  - TJC MM.05.01.07
  - Clean top with Bleach wipe after each use
Injection practices among clinicians in United States health care settings

Gina Puigliese, RN, MS\textsuperscript{a}, \textsuperscript{b}, Cathie Gosnell, RN, MS, MBA, \textsuperscript{b} Judene M. Barley, MS, MPH, CIC\textsuperscript{c}, Scott Robinson, MA, MPH\textsuperscript{d}

Background

Improper use of syringes, needles, and medication vials has resulted in patient-to-patient transmission of bloodborne pathogens, including hepatitis C virus. This study examined the injection practices of health care providers to identify trends and target opportunities for education on safe practices.

Methods

An on-line survey was conducted in May and June 2010 of clinicians in US health care settings that prepare and/or administer parenteral medications.

Results

The majority of the 5446 eligible respondents reported injection practices consistent with current recommendations. However, the following unsafe practices were identified: 6.0% “sometimes or always” use single-dose/single-use vials for more than 1 patient; 0.9% “sometimes or always” reuse a syringe but change the needle for use on a second patient; 15.1% reuse a syringe to enter a multidose vial and then 6.5% save that vial for use on another patient (1.1% overall).

Conclusion

Unsafe injection practices represent an ongoing threat to patient safety. Ensuring safe injection practices in all health care settings will require a multifaceted approach that focuses on surveillance, oversight, enforcement, and continuing education.
Advancing ASC Quality

- ASC Quality Collaboration has ASC tool kits for infection prevention
- Includes one on hand hygiene and safe injection practices and point of care devices (glucose meters)
- Includes a basic and expanded version of the toolkit
- These are available at http://www.ascquality.org/advancing_asc_quality.cfm
Advancing ASC Quality

To support the ASC industry’s focus on high quality care, the ASC Quality Collaboration is assembling ASC Tools for Infection Prevention, or ASC TIPS. Our goal is to make infection prevention resources readily accessible to ASCs by bringing them together in one location.

The following ASC TIPS are now available:

- Hand Hygiene Toolkit
- Safe Injection Practices Toolkit
- Point of Care Devices Toolkit
- Environmental Infection Prevention Toolkit
- Single-Use Device Reprocessing Toolkit
- Endoscope Reprocessing Toolkit
- Sterilization and High-Level Disinfection Toolkit
CMS & Joint Commission Top Problematic
Reported in 2013
Hospital Top Problematic Standards

- These are also referred to as The Joint Commission (TJC) hot buttons (no longer called JCAHO)

- TJC releases data on top standard compliance issues

- Includes data for half or 2013 which is the most current data published in Perspectives and on e-edition website

  - TJC collects data on compliance with its standards, the NPSGs, Universal Protocol (UP) and accreditation participation requirements
Top Problematic Standards for Hospitals

- **RC.01.01.01** (60% in 2012, 66% in 2011, 65% 2010) The hospital maintains complete and accurate medical records.

  - Make sure there is a date and **TIME** on every entry in the medical record

  - MR must contain all necessary records such as H&P, consults, discharge summary, signed off VO, patient identification, information to support diagnosis, etc.
Top Problematic Standards for Hospitals

- **LS.02.01.20** (51% in 2012, 56% in 2011, 51% 2010) The hospital maintains the integrity of the means of egress.
  - Don’t clutter the hallway and corridors
  - Don’t block the exit doors
  - Anything in the hallway more than 30 minutes is storage
  - Crash carts, isolation carts or chemo carts are considered to be in use in hallways
- **LS.02.01.10** (47% in 2012, 52% in 2011, 49% 2010) Building and fire protection features are designed and maintained to minimize the effects of fire, smoke, and heat.
  - Make sure automatic fire doors close
  - Don’t prop open fire doors or keep them from closing
  - Be careful when pushing carts so don’t bang against crash bars and damage them
Top Problematic Standards for Hospitals

- **LS.02.01.30 (46% in 2011, 40% 2010)** The hospital provides and maintains building features to protect individuals from the hazards of fire and smoke.
  - People run computer and other cables through the walls and like to poke holes and then don’t seal them so penetration can let smoke through
  - The interior finished need to be controlled to minimize smoke and to prevent them from giving off toxic gases
  - Openings are necessary for heating, ventilation, air conditions, elevator shafts, and laundry chutes
  - These openings need to be designed to contain the fire to a compartment floor
Risk of Infections With Equipment

- **IC.02.02.01** (42% in 2012, 36% in 2011, 29% in 2010) The hospital reduces the risk of infections associated with medical equipment, devices, and supplies

- Also IC.02.01.01 had 12% in 2011 and 2010

- CMS has a 12 page infection control chapter and section under surgical services

- Make sure you clean those glucometer between cases, clean scopes well, use immediate use stream sterilization according to manufacturer instruction, and clean laryngoscopes
Hospital Top Problematic Standards

- **EC.02.03.05** (40% in 2012, 40% in 2011, 42% in 2010) The hospital maintains fire safety equipment and fire safety building features.
  - Make sure fire alarms, sprinklers, portable fire extinguishers, and hamper switches are inspected, tested and maintained.
  - If these types of equipment are in the hospital it is important to make sure they are maintained, tested and inspected.
  - Many organizations use outside vendors for these tasks.
  - Make sure the process to share results or outcomes of inspections and testing goes up the chain of command and repairs get made.
Top Problematic Standards for Hospitals

- **MM.03.01.01** (35% in 2012, 33% in 2011, 33% 2010) The hospital safely stores medications.
  - Follow manufacturers guidelines
  - Make sure secure area to prevent diversion
  - Make sure to get rid of all expired or damaged medications
  - Control between receipt and administration
Hospital Top Problematic Standards

- **RC.02.03.07 (32% in 2011, 33% 2010)**
  Qualified staff receive and record verbal orders
    - Make sure staff are aware of P&P and who is allowed to give and accept verbal orders
    - Only those authorized in the P&P can accept VO
    - Make sure staff write them down and read them back
    - Make sure they are signed off, dated, and timed within time frame specified by your state law

William A. Rutala, Ph.D., M.P.H.\textsuperscript{1,2}, David J. Weber, M.D., M.P.H.\textsuperscript{1,2}, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)\textsuperscript{3}

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University of North Carolina Health Care System
Chapel Hill, NC 27514

\textsuperscript{2}Division of Infectious Diseases
University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030

www.cdc.gov/hicpac/Disinfection_Sterilization/13_0Sterilization.html
Life Safety Code Compliance

Infection Control and CMS gets $50 million grant to enforce in 2011 and 2013 so this is important and HHS 1 billion and surveyors now more knowledgeable

Patient Rights especially R&S and grievances

EMTALA, hand hygiene,

Performance Improvement (CMS calls it QAPI)

Medication Management and security of medications

Dietary and cleanliness of dietary

Care plans
CMS Problematic Standards

- Verbal orders
- History and physicals
- Need order for respiratory and rehab (such as physical therapy)
- Need order for diet, medications, and radiology
- Anesthesia (updated four times)
- Standing orders and protocols
- Timing of medication (changed)
- Outpatient under one person (Tag 1078, changed)
Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data

- Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com

- This is the CMS 2567 deficiency data and lists the tag numbers

- Will update quarterly
  - Available under downloads on the hospital website at www.cms.gov
Access to Hospital Complaint Data

- There is a list that includes the hospital’s name and the different tag numbers that were found to be out of compliance
  - Many on restraints and seclusion, EMTALA, infection control, patient rights including consent, advance directives and grievances
- Two websites by private entities also publish the CMS nursing home survey data
  - The ProPublica website
  - The Association for Health Care Journalist (AHCJ) websites
Access to Hospital Complaint Data

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-10
Baltimore, Maryland • 21244-1001

Center for Clinical Standards and Quality/Survey & Certification Group

DATE: March 22, 2013
TO: State Survey Agency Directors
FROM: Director Survey and Certification Group


Ref: S&C: 13-21-ALL

Memorandum

Survey FindingsPosted on [CMS.gov]: In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (CMS-2567s) for skilled nursing facilities and nursing facilities on Nursing Home Compare. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaint investigations. This memorandum describes the contents and location of these files.

Other Web-based Tools Based on These Data: At least two additional websites, provided by private parties (ProPublica and the Association for Health Care Journalists), publish information based on the CMS-2567 data. These websites are independent of CMS. CMS does not endorse or sponsor any particular private party application.

Plans of Correction (POC): The posted CMS data do not contain any POC information. State Survey Agencies (SAs) and CMS Regional Offices (RO) may see an increase in requests for both the CMS-2567 and any associated POCs.

Question & Answers: We plan to issue an update to this memorandum that will include an attachment of frequently asked questions, in order to provide answers to other queries that may arise.

Background – Nursing Home Survey Findings

In July 2012, CMS began posting nursing home statements of deficiencies, derived from the Farm...
Medication Errors

- Medication errors are the most common type of medical errors
- Consider having a medication management committee
- Review medication policies
- Include all the required medication policy required by CMS in the hospital CoP and by the TJC medication management chapter
- Consider having a medication management champion on each unit
Chasing Zero

Watch this Video!!!!!

http://www.safetyleaders.org/home.jsp
Medication Errors

- Medication champion can prevent education to the department staff
- Number one cause of medical errors
- Be aware of recent and problematic issues
  - Tubing misconnections continue
  - Dosing errors of children (kg weights only)
  - Phenergan, neuromuscular blocker and Fentanyl patches
  - Know list of do not crush medications
  - Know list of high alert drugs and safety measures
  - CMS changes 30 minute rule to give medications
Medication Errors

- Consider having a medication management committee
- Consider a medication management champion in every unit
- MM champion does quarterly presentations for all staff in the department
- Keep abreast of current evidenced based literature
- Weights in children use kg only
- Consider education in orientation and periodically for all staff
Drug Interactions Checker

Type in a drug name and select a result from the list. Repeat the process to add multiple drugs. When complete, save your list for future reference or check for interactions immediately.

Your interactions list is empty. Type a drug name in the box above to get started.

Please sign in to view previously saved lists.

Disclaimer: Every effort has been made to ensure that the information provided by Multum is accurate, up-to-date, and complete, but no guarantee is made to that effect. In addition, the drug information contained herein may be time sensitive and should not be utilized as a reference resource beyond the date hereof. Multum's drug information does not endorse drugs, diagnose patients, or recommend therapy. Multum's drug information is a reference resource designed as supplement to, and not a substitute for, the expertise, skill, knowledge, and judgement of healthcare practitioners in patient care. The absence of a warning for a given drug or drug combination in no way should be construed to indicate that the drug of drug combination is safe, effective, or appropriate for any given patient. Multum Information Services, Inc. does not assume any responsibility for any aspect of healthcare administered with the aid of information Multum provides. Copyright 2000-2010 Multum Information Services, Inc. The information in contained herein is not intended to cover all possible uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the drugs you are taking, check with your doctor, nurse, or pharmacist.
TJC Record of Care Chapter
Documentation Considerations
TJC Record of Care (RC) Chapter

- This was a new chapter that was developed in 2009
- Also referred to as the documentation chapter
- Hospitals should pay attention to this chapter when revising assessment or other hospital forms
- This includes hospitals going toward an EMR in creating fields to meet the standards required by TJC
- Documentation important in establishing medical necessity and ensuring reimbursement
Joint Commission  RC Standards

- Has a Record of Care chapter which has 11 standards
  - Clinical Record Components (RC.01.01.01)
  - Authentication (RC.01.02.01)
  - Timeliness (RC.01.03.01)
  - Audit (RC.01.04.01)
  - Retention (RC.01.05.01)
  - Care and Treatment (RC.02.01.01-RC.02.01.07)
  - Verbal Orders (RC.02.03.07)
  - Discharge Information (RC.02.04.01)
TJC Standards Topics RC.02.01.01

- MR needs patient’s name, address, sex, DOB
- Reason for admission
- Initial diagnosis or condition
- Findings of assessment and reassessments
- Allergies to food and medications
- Conclusion drawn from H&P
- Consult reports
- Patient’s responses to care and treatments
TJC Standards Topics

- Emergency treatment given prior to arrival
- Progress notes
- Medications ordered or prescribed
- Plan of care and revisions
- Orders for tests and procedures
- Medication dispensed upon discharge
- Advance directives
- Informed consent
TJC Standards Topics

- Records of communication including telephone calls or emails
- Patient generated information
- ED patients records include
  - Time and means of arrival
  - If patient left AMA
- Conclusions reached at termination of care such as final disposition, conditions, discharge instructions
RC Chapter Topics

- Informed consent
- H&P
- Verbal orders
- Summary list by third outpatient visit
- Discharge information RC.02.04.01
- R&S documentation RC.02.01.05
- Operative or high risk procedures and use of moderate sedation under RC.02.01.03
- Unanticipated outcomes and disclosure
TJC Patient Centered Communication
Patient-Centered Communication standards were previously called patient provider standards.

Surveyors evaluate compliance with the standards now.

It is essential that healthcare providers and their staff be able to communicate effectively with one another to provide quality patient-centered healthcare.

Use qualified language interpreters (attended 40 hour course) and hearing impaired interpreters must be certified.
TJC Patient-Centered Communication

- Joint Commission has standards in the following four chapters with two in the Patient Rights chapter;
  - Human Resources
    - HR.01.02.01
  - Provision of Care
    - PC.02.01.21
  - Patient Rights
    - RI.01.01.01 and RI.01.01.03
  - Record of Care
    - RC.02.01.01
Introduction

- Studies show that failure to communicate is the major root cause of medical errors
- Ineffective communication leads to misdiagnosis and inappropriate treatment
- It leads to unnecessary readmissions
  - October 2012 hospitals with a higher rate of readmission were financially penalized
  - 307 hospitals will receive maximum penalty of 1% and only 34% will not receive a penalty
  - Hospitals will forfeit 280 million dollars
The hospital must define staff qualifications

Interpreters must be qualified

- Staff is not qualified just because they speak the language
- Someone who is fluent in Spanish and has attended a minimum 40 hour education class is qualified to be an interpreter
- If deaf interpreter must be certified

Two organizations were formed that certify interpreters for professional competence that meet national standards of knowledge, skill, and performance for healthcare interpreters.
There are now two organizations that provide certification of professional competence in Spanish:

- First one in September 2009
  - Certification Commission for Healthcare Interpreters (CCHI)

- Second one effective January of 2011
  - It is an oral and written exam from National Board of Certification
  - So now this person is qualified and certified
  - Offered only in Spanish but other languages forthcoming
Certification  CHI AHI CMI QMI SMI

- National Council on Interpreting in Health Care and CCHI or the Certification Commission for Healthcare Interpreters (CCHI Associate Healthcare Interpreter credential and has two credentials)
  - CHI stands for Certified Healthcare Interpreter (best)
  - AHI stands for Associate Healthcare Interpreter
- The National Board of Certification for Medical Interpreters
  - CMI or Certified Medical Interpreter, Qualified Medical Interpreter (QMI) or Screened Medical Interpreter (SMI)
  - Question contact info@certifiedmedicalinterpreters.org
Guide to Understanding Interpreting

- A Guide to Understanding Interpreting and Translation in Health Care is an excellent resource for HR staff

- Has requisite skills and qualifications of a translator and an interpreter

- Discusses certification for interpreters and translators

- Discusses how to hire an interpreter or translator

- Discusses standards of practice for an interpreter and a translator

- What skills are needed for interpreters and translators
How to Hire an Interpreter

X. HOW TO HIRE A HEALTH CARE INTERPRETER

During the hiring process, many organizations face the challenge of identifying qualities an interpreter should possess, whether the person is serving in a dual role or interpreter capacity within the organization. Traditional indicators of a person’s ability to do the job are not yet available in the health care interpreting field. Thus, an employer may not be able to rely on certification, training, or even experience dependant upon the geographic location and particular community and language. At this time, then, the big question is, “What should I look for in a qualified interpreter?” Six components that can help guide you in the successful hiring of interpreters are:

- Language proficiency levels in primary and secondary languages;
- Problem solving techniques;
- Interpersonal skills (including but not limited to customer service);
- Knowledge of health care systems and compatibility with the health care organization’s culture;
- Evaluation of the quality of the interpreting skills; and
- Cultural competence.

a. Language Proficiency Levels
The linguistic skills of an interpreter are first and foremost. It is important to first recognize the level of language expertise an interpreter needs in both working languages. Often, it is assumed that conversational proficiency in a second language is sufficient to interpret. However, in a health care setting there are many nuances with language and terminology, along with a fast pace and a variety of subjects that demand that interpreters command their second languages as though it were their native tongue.

b. Problem Solving
The ability to problem-solve is crucial to being a successful interpreter. Looking at how a potential interpreter handled adversity or challenges in the past or how well he/she has worked in diverse settings will be important in determining his/her future success as an interpreter. Because health care is filled with a wide variety of people and personalities, an interpreter must be very clear of their role and purpose when assisting provider and patient. It is important to understand how the candidate is going to represent both him/herself and your organization.

c. Interpersonal Skills
Interpersonal skills (such as customer service) are essential to being a successful interpreter. Interpreters are sometimes the first contact patients make with an organization. They are often the primary contact between the various departments and the language access departments they serve. How interpreters present themselves and their people skills should be key points to consider in a candidate.
Standard: The hospital communicates with patients when providing care

Rationale:

- Patient-provider communication is important for patient safety
- Studies show patients with communication programs are at an increased risk for medical error
- 70% of all errors have found the root cause to be communication errors
- Patients with LEP are more likely to have an adverse event than English speaking patients
EP1 Hospital identifies the patient’s oral and written communication needs

- This includes the patient’s preferred language for discussing healthcare
- Patient may have hearing needs and need an amplifier on the phone or have their hearing aid brought in
- Patient may be hearing impaired and need a deaf interpreter or TDD phone (telecommunication device)
- Patient may have visual needs and need enlarged copies of important document or magnifying glasses or glasses brought to the hospital
- Patient may be intubated and need white board to write on
Hearing impaired patient (deaf or HOH) may need a sign language interpreter

Ask the patient “Do you have any hearing aids, glasses or other devices you use routinely to communicate?”

Reading some of the DOJ and OCR settlement agreement give lots of ideas hospitals can do to provide equipment or auxiliary aids and services to ensure good patient provider communication (see later)

Hospital may want to include this question on their ED triage form and admission assessment form
PC.02.01.21

- EP2 Hospital communicates with the patient in a manner that meets the patient’s oral and written communication needs
  - Patients get to converse in the language they pick
  - This is patient centered care because the focus is on what the patient wants
  - The focus is not on what is easiest for the hospitals
  - Need to find out what language the patient refers to converse in such as patient requests Spanish
PC.02.01.21 Ideas

- Have a patient handbook
- Have a P&P on interpreters and translators
- Make sure staff educated on P&P during orientation and annually including ED training
- Make sure staff know how to easily access interpreters
- Ensure prompt call for interpreters such as call within 10 minutes
- Want to ensure an interpreter is present during vital or critical parts of care
**PC.02.01.21 Ideas**

- Vital or critical parts of care
  - might include informed consent discussions, H&P, explanation of advance directives, discharge, explanation of procedures and tests, explanation of new medications and how to take, explanation of follow up treatment, provision of behavioral health assessment, education, blood or organ donation etc.

- Make sure the sign language interpreter is qualified
- Do not use a child or family member
- Use captioned televisions
- Special measures for deaf or HOH rea fire alarms
Often referred to as the documentation chapter

Standard: The medical record must contain information that reflects the patient’s care

EP 1 Includes information that the medical record must contain regarding demographics
  ▪ Patient’s name, address, date of birth, sex, etc
  ▪ Added the patient’s communication needs including preferred language for discussing health care
  ▪ Patient picks the language they want to converse in

EP 28 Must collect race and ethnicity information
The RC chapter requires that you document the information received

- If patient is a minor then ask the parent
- If patient has a DPOA or guardian because they are incapacitated then check with them
- If patient speaks English but guardian, DPOA, or parent does not then you need to ask them what is their preferred language
RI.01.01.01

- Standard: Hospital respects, promotes, and protects patient rights
- EP28 The hospital allows a family member or friend to be with patient during the course of stay for emotional support
  - As long as does not infringe on the other patients’ rights
  - Does not have to be the patient surrogate or legal decision maker
- CMS has changes to the hospital CoP regarding visitation rights
- Patients should be able to define who they want to visit
Patient Falls
Falls

- Hospitals should consider having a falls team
- Ensure fall team members get evidence based information on falls
- Have a falls policy
- Ensure all staff are educated on the falls policy
- Make sure staff know what is the definition of a fall
- Measure falls and reduce the number and severity of falls
Falls

- Have a special falls incident report
- Have a post fall procedure so everyone knows their role when the patient has fallen
- Evaluate the program
- Patient and family should be educated on the falls program
- Patients get an assessment and risk category and strategies are based on that risk assessment
Falls Program

- Provide in-service education to all nurses yearly and in orientation
- Provide patient education on falls such as call before you fall
- Consider toileting, sitters, and hourly rounds for high risk patients
- Audit charts for compliance with fall program
- Consider computerized system for falls
- Every unit should have a falls champion that can do the quarterly education
Please press the call button
for your nurse to help you go to the bathroom.
We don’t want you to fall and get hurt.

Available in Spanish and Somali
Falls and Mobility

- The goal should focus on prevention and severity of injury from falls and decrease immobility
- We need to get patients up and moving
- Immobility causes increased LOS, delirium, pressure ulcers, functional loss, and readmissions
  - Foley catheters increase fall risk
- Study showed 30% of elderly patients had an initial order of bedrest
- Another study showed median amount of time standing or walking is 43 minutes
Falls and Mobility

- Translation means that up ad lib means 97% of the time patients are immobile or 23 hours 17 minutes.
- Immobility or deconditioning may explain why so many patients fall when toileting.
- Immobility creates an increased risk when patients do need to mobilize.
  - Brown CJ et al. The Under recognized Epidemic of Low Mobility During Hospitalization. JAGS 2009;57:1160-1665
  - Early Ambulation and Length of Stay in Older Adults Hospitalized for Acute Illness. Arch Int Med 2010;170:1942-1943
Joint Commission Issues

- Two TJC standards on falls in PC and PI chapter
- TJC Sentinel Event Alert on falls
- TJC data on falls
- TJC Recommendations for Falls
- Requirements for RCA
- TJC Matrix on falls as to what to cover
- TJC brochure to reduce your risk of falls
- TJC FAQs on falls
Falls was as a Joint Commission **National Patient Safety Goal** in 2009 but moved to standard in 2010 under PC.01.02.08

PC.01.02.08 The hospital assesses and manages the patient’s risks for falls

EP1 Hospital must assess the patient’s risk for falls based on the patient population and setting (elderly, behavioral health, pediatric patients)

EP2 Hospital implements interventions to reduce falls based on the patient’s assessed risk
TJC Standard

- PI.01.01.01 The hospital collects data to monitor its performance

- EP 38 The hospital evaluates the effectiveness of all fall reduction activities including assessment, interventions, and education.

- Note: Examples of outcome indicators to use in the evaluation include number of falls and number and severity of fall-related injuries.
Joint Commission Fall Standard

- Generally a fall assessment is done as part of the initial nursing assessment
- Based on the assessment a plan of care is developed
- The patient interventions are based on what their score is on the fall tool
- Most have two or three types of interventions depending on the risk
- Joint Commission abbreviated TJC since no longer called JCAHO
Each year, millions of people are injured by falls. People at risk of falling include hospital patients, nursing home residents and those who are recovering from an illness or injury at home. This brochure includes tips and actions you can take to reduce your risk of falling, whether at home or in a medical facility.

The Joint Commission is the largest health care accrediting body in the United States that promotes quality and safety.

Helping health care organizations help patients

www.jointcommission.org/PatientSafety/SpeakUp
Why do falls happen?

- Person is weak, tired or ill
- Person is not physically fit
- Person may have problems seeing
- Medicines may cause weakness, sleepiness, confusion or dizziness
- Slippery or wet floors or stairs
- Obstructed pathways
- Darkness

How to reduce your risk of falling

Take care of your health

- Exercise regularly. Exercise builds strength.
- Prevent dehydration. Dehydration can make it easier to lose your balance.
- Have your eyes checked. Make sure you do not have any eye problems or need a new prescription.
- Talk to your doctor if your medicine makes you sleepy, light-headed, sluggish or confused. Ask how to reduce these side effects or if you can take another medicine.

Take extra precautions

- Turn on the lights when you enter a room. Do not walk in the dark.
- Make sure your pathway is clear.
- Use the handrails on staircases.
- Sit in chairs that do not move and have arm rests to help when you sit down and stand up.
- Wear shoes that have firm, flat, non-slip soles. Do not wear shoes that do not have backs on them.
- Replace the rubber tips on canes and walkers when they become worn.

Make small changes to your home

- Install timers, “clap-on” or motion sensors on your lights.
- Use night lights in your bedroom, bathroom and the hallway leading to the bathroom.
- Keep the floor and stairs clear of objects such as books, tools, papers, shoes and clothing.
- Remove small area rugs and throw rugs that can slip. Rubber mats are a good replacement.
- Put frequently used items in easy-to-reach places that do not require using a step stool.
- Make sure your bed is easy to get in and out of.
- Apply non-slip treads on stairs.
- Apply non-slip decals or use a non-slip mat in the bathtub or shower.
- Install grab bars near the toilet and the bathtub or shower.

A home care agency, personal care and support agency, or community program may be able to help make changes to your home if you live alone and need help.

Take extra precautions in the hospital or nursing home

Many falls occur when patients or residents try to get out of bed or to go to the bathroom or walk around the room by themselves. If you need to get out of bed:

- Use your call button to ask for help getting out of bed if you feel unsteady.
- Ask for help going to the bathroom or walking around the room or in hallways.
- Wear non-slip socks or footwear.
- Lower the height of the bed and the side rails.
- Talk to your doctor if your medicine makes you sleepy, light-headed, sluggish or confused. Ask how to reduce these side effects or if you can take another medicine.
TJC Video on Reduce Risk of Falling

www.jointcommission.org/multimedia/speak-up-reduce-your-risk-of-falling/