DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-28-Hospitals
REVISED 05.20.11

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(c)(3))
  - Immediate reporting of medication administration errors, adverse events, and incompatibilities (42 CFR 482.25(b)(6))

Background

The final FY 2011 Inpatient Prospective Payment System (IPPS) rule was published on August 16, 2010 (*75 FR 50042*) and effective on October 1, 2010. The FY 2011 IPPS final rule contained revisions to the Hospital Conditions of Participation (CoPs) governing rehabilitation and respiratory care services. SC-11-04-ALL summarized these changes, which are now being incorporated into Appendix A of the SOM.

In addition, we are clarifying our guidance related to training requirements for personnel administering blood transfusions and intravenous (IV) medications, and to the requirement for immediate reporting of drug administration errors, adverse drug events, and incompatibilities. Attached is an advance copy of the SOM Appendix A reflecting these updates. The final version of Appendix A will be issued at a later date, and may reflect some changes from this advance copy.

Training for Personnel Administering Blood Transfusions and IV Medications

The Nursing Services regulation at 42 CFR 482.23(c)(3) states "…If blood transfusions or intravenous (IV) medications are administered by personnel other than doctors of medicine or

osteopathy, the personnel must have special training for this duty." Requests have been made to clarify the Centers for Medicare & Medicaid Services' (CMS) expectations regarding the special training.

CMS recognizes the administration of blood transfusions and IV medications is generally performed by the hospital's nursing staff, consistent with State law governing scope of practice and hospital policies and procedures. We also recognize that the hospital's policies and procedures and other training related to administration of blood transfusions and IV medications by nursing staff are typically addressed in the general hospital orientation provided to each member of the nursing staff. If the hospital provides training on blood transfusion and IV medication administration to nursing staff in its general hospital orientation or other continuing education programs and documents this competency in each applicable employee record (i.e., records for those nursing staff members who administer blood transfusions and IV medications), then the hospital meets the requirement to provide special training.

Immediate Reporting of Drug Administration Errors, Adverse Drug Reactions, and Incompatibilities

The Pharmaceutical Services regulation at 42 CFR 482.25(b)(6) states "Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program."

A wide range of events, with varying implications for the safety of patients, may be categorized as "drug administration errors," or "adverse drug reactions." Our guidance for both the pharmaceutical services and quality assessment and performance improvement (QAPI) CoPs generally takes a very broad view of what constitutes a medication error or adverse event. However, for the purposes of compliance with this immediate reporting requirement, CMS expects such immediate notice to occur in those cases where harm to the patient has already occurred, or where there is a known potential for harm as a result of the medication administration error. Additionally, if the outcome of the error is unknown, the physician must also be notified immediately. The hospital must have policies and procedures that provide detailed guidance for hospital staff on the criteria to be employed when determining if an immediate report to the attending physician is necessary. Our guidance continues to permit a report to the covering physician when the attending physician is not available.

The regulation envisions a two-step reporting process. The immediate report of a significant drug administration error, adverse drug reaction, and/or drug incompatibility must be made to the attending (or covering) physician. Addressing the needs of the patient must be the priority. The second step in the process is reporting of such events to the hospital's QAPI program. For QAPI program purposes, hospitals must define medication administration errors and adverse events broadly. The same systems errors that led to a "near miss" or a medication error that did not harm a patient in one case could, in other circumstances, result in serious patient harm.

In addition, there may be external reporting requirements governed by State law with which the hospital must comply, in accordance with the requirements of 42 CFR 482.11.

Questions concerning this memorandum may be addressed to Mary Ellen Palowitch at maryellen.palowitch@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of this memorandum.

Training: This policy should be shared with all survey and certification staff, their managers and the State/RO training coordinator.

/s/
Thomas E. Hamilton

Attachments

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal **(Advance Copy)** **Date:**

SUBJECT: Revised Appendix A: Conditions of Participation and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Updated guidance is provided to reflect regulatory changes concerning Rehabilitation and Respiratory Care Services; clarification of guidance concerning nursing services and pharmacy requirements is provided.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

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.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/§482.23(c)(3) Standard: Nursing Services
R	Appendix A/§482.25(b)(6) Standard: Pharmaceutical Services
R	Appendix A/§482.56(b) Standard: Rehabilitation Services
N	Appendix A/§482.56(b)(1) Standard: Rehabilitation Services
N	Appendix A/§482.56(b)(2) Standard: Rehabilitation Services
R	Appendix A/§482.57(b)(3) Standard: Respiratory Services
N	Appendix A/§482.57(b)(4) Standard: Respiratory Services

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2011 operating budgets.

IV. ATTACHMENTS:

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

A-0409

(Rev.)

§482.23(c)(3) - Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

Interpretative Guidelines §482.23(c)(3)

Generally intravenous (IV) medications and blood transfusions are administered to patients by nursing staff, consistent with State law governing scope of practice, and approved medical staff policies and procedures. Education and training regarding these procedures are typically included in the nurse's hospital orientation. Nursing staff who receive training for intravenous medication administration and/or blood transfusion administration during hospital orientation or during other continuing education programs would meet the requirements of this regulation.

The competencies must be documented in the nurse's record. Content of the training must be based on nationally recognized standards for intravenous medication administration and blood transfusion and must address at least the following: fluid and electrolyte balance; venipuncture techniques, including both demonstration, and supervised practice; and, for blood transfusion training: blood components; blood administration procedures based on hospital policy, State law, and nationally recognized standards of practice; requirements for patient monitoring, including frequency and documentation of monitoring; the process for verification of the right blood product for the right patient; and identification and treatment of transfusion reactions.

All State law and scope of practice requirements must be met regarding the administration of intravenous medications and blood transfusions, as applicable.

Survey Procedures §482.23(c)(3)

- Review the *blood* transfusion and intravenous medications practices:
    - *Does the hospital include training for administering blood transfusions and intravenous medications during nursing orientation or through other continuing education programs?*
    - *Does the training include the following content:*
        - *Fluid and electrolyte balance,*
        - *Venipuncture techniques, demonstrations, and supervised practice*
        - *With respect to blood transfusions:*
            - *Blood components,*
            - *Blood administration procedures per hospital policy, State law, and nationally recognized standards of practice;*
            - *Patient monitoring requirements, including frequency and documentation of monitoring;*
            - *Process for verification of the right blood product for the right patient; and*

Transfusion reactions: identification, treatment, and reporting requirements.

- Are blood transfusions and IV *medications* administered in accordance with State law and approved hospital *and medical staff* policies and procedures?
- Are blood transfusions and IV *medications* administered by personnel who are trained and working within their scope of practice in accordance with State law and hospital *and medical staff* policies?

- Review *a sample of medical records*. Determine the identity of *staff* who administered blood *components and IV medications* and review their *employee* records.
    - Do they have *documentation of completion of blood transfusion and IV administration training during hospital orientation or through other continuing education programs?*

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§482.25 Condition of Participation: Pharmaceutical Services

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A-0508
(Rev.)

§482.25(b)(6) - Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

Interpretive Guidelines §482.25(b)(6)

Hospitals are required to ensure that the attending physician is made immediately aware of drug administration errors, adverse drug reactions, and incompatibilities. When the attending physician is unavailable, the covering physician must be notified. When the covering physician must be notified, the patient's attending physician must be notified as soon as he/she is available. In addition, when appropriate, such events must also be reported to the hospital-wide Quality Assessment and Performance Improvement (QAPI) program.

The hospital must adopt policies and procedures that identify the types of events that must be reported immediately to the attending physician, as well as those to be reported to the QAPI program.

- *Drug administration error:*

  The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

- *Adverse drug reaction:*

  The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:
  1. *Requires discontinuing the drug (therapeutic or diagnostic)*
  2. *Requires changing the drug therapy*
  3. *Requires modifying the dose (except for minor dosage adjustments)*
  4. *Necessitates admission to a hospital*
  5. *Prolongs stay in a health care facility*
  6. *Necessitates supportive treatment*
  7. *Significantly complicates diagnosis*

8. *Negatively affects prognosis, or*
9. *Results in temporary or permanent harm, disability, or death.*

Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs."

- *Drug incompatibilities*

  A drug incompatibility occurs when drugs interfere with one another chemically or physiologically. Drugs known to be incompatible must not be mixed, administered together, or administered within a timeframe where they will interfere with each other.

  When IV medications are administered with known incompatibilities, an error has occurred and it needs to be reported to the attending physician immediately. Any unexpected reaction that occurs between IV medications not previously identified as incompatible also needs to be reported.

  Hospitals can minimize the risk of administering incompatible medications by making available pertinent resources, such as drug incompatibility charts and online incompatibility references. The incompatibility information needs to be readily available to staff administering medications. The information needs to be kept up-to-date as the information is frequently updated by drug manufacturers.

The immediate reporting requirement applies to drug administration errors, adverse drug reactions or incompatibilities that have harmed or have the potential to harm the patient. If the outcome of the drug administration error is unknown, the physician must also be notified without delay.

Drug administration errors that result in no or insignificant harm to the patient must also be documented in the medical record but do not require immediate reporting to the attending physician. For example, if an analgesic dose is missed during the night shift, it can be reported first thing in the morning. Hospital staff are expected to use their clinical judgment, based on patient presentation and assessment in accordance with hospital policy and procedures, to determine whether immediate reporting is required.

On the other hand, for purposes of reporting to the hospital's QAPI program, hospitals must, in accordance with the requirements of the QAPI CoP at 42 CFR 482.21(c)(2), track and report not only the errors that cause or risk harm to the patient, but also those which do not. Such "near misses" and suspected ADRs may reveal important information about systems vulnerabilities that the hospital should address in order to avoid events that result in harm.

Hospitals must establish policies and procedures for reporting of medication errors, ADRs, and incompatibilities, and ensure that staff are aware of the reporting process. For those events that

require immediate reporting, the hospital's policies must establish timeframes for reporting that are based on the clinical effect of the error on the patient.

To improve staff willingness to report medication error incidents, hospitals are encouraged to adopt a non-punitive approach that focuses on system issues rather than individual health care professionals. A non-punitive approach is likely to encourage reporting by those who otherwise may fear retribution or hospital disciplinary action.

In addition to employing broad definitions of medication errors and ADRs for QAPI tracking purposes and encouraging reporting of medication errors, ADRs and drug incompatibilities, the hospital must take additional steps to identify these events as part of its QAPI program. Reliance solely on incident reporting fails to identify the majority of errors and adverse reactions. Proactive identification includes observation of medication passes, concurrent and retrospective review of a patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event.

The hospital must have a method by which to measure the effectiveness of its systems for identifying and reporting to the QAPI program medication errors and ADRs. Such methods could include use of established benchmarks for the size and scope of services provided by the hospital, or studies on reporting rates published in peer-reviewed journals. Hospitals are encouraged, and may be required by State law, to participate in statewide and national reporting of drug administration errors, adverse drug reactions, and incompatibilities. National organizations include, but are not limited to, the Food and Drug Administration's (FDA) MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. These organizations, along with other patient safety organizations, collect and analyze data, identify trends, and provide feedback and recommendations to health care organization to reduce the risk of medication related errors and events.

Survey Procedures §482.25(b)(6)

- *Does the hospital have policies and procedures that define medications errors, ADRs, and drug incompatibilities? Do they address the circumstances under which they must be reported immediately to the attending physician, as well as to the hospital's QAPI program? Do they address how reporting is to occur?*

- Are *all medication errors and suspected ADRs* promptly recorded in the patient's medical record*, including those not subject to immediate reporting?*

- *If upon review of a sample of records, a suspected ADR or medication error is identified, determine if it was reported immediately to the attending or covering physician, in accordance with the hospital's written policies and procedures. If it is reported to a*

covering physician, determine if it was also reported to the attending physician when he/she became available.

- *Ask hospital staff what they do when they become aware of a medication error, ADR or drug incompatibility. Are staff aware of and do they follow the hospital's policy and procedures?*

- *Ask hospital staff how they manage drug incompatibilities. What tools do they use in the clinical setting to minimize the risk of incompatibilities? How is the information related to drug incompatibilities made available to the clinical staff administering IV medications (posters, online tools, etc.)? How often is the information updated to ensure accuracy?*

- Interview *hospital* staff to ascertain awareness of the *hospital's* policy on reporting and documentation of medication errors and adverse drug reactions.

- *How does information regarding medication errors, adverse drug reactions, and incompatibilities get reported to the hospital QAPI program? Ask staff to speak to the process.*

- *For QAPI reporting purposes, is the hospital's definition of an ADR and medication error based on national standards?*

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§482.56 Condition of Participation: Rehabilitation Services

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A-1132
(Rev.)

***§482.56(b) Standard*: Delivery of Services**

Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

Interpretive Guidelines §482.56(b)

Rehabilitation services must be ordered by a qualified and licensed practitioner who is responsible for the care of the patient. The practitioner must have medical staff privileges to

write orders for these services. Privileges must be granted in a manner consistent with the State's scope of practice law, as well as with hospital policies and procedures governing rehabilitation services developed by the medical staff and approved by the governing body.

Practitioners who may be granted privileges to order rehabilitation services include physicians, and may also, in accordance with hospital policy, be extended to Nurse Practitioners, Physicians' Assistants, and Clinical Nurse Specialists as long as they meet the parameters of this requirement. Although the following licensed professionals are also considered "practitioners" in accordance with Section 1842(b)(18)(C) of the Social Security Act, they generally would not be considered responsible for the care of the patient or qualified to order rehabilitation services: Certified registered nurse anesthetist (Section 1861(bb)(2) of the Act); Certified nurse-midwife (Section 1861(gg)(2) of the Act); Clinical social worker (Section 1861(hh)(1) of the Act); Clinical psychologist (for purposes of Section 1861(ii) of the Act and as defined at 42 CFR 410.71); or registered dietician or nutrition professional.

Survey Procedures §482.56(b)

- *Review the medical staff policies and procedures for rehabilitation services privileging. Do they identify the types of eligible practitioners and their qualification criteria?*

- *Review medical records of patients receiving rehabilitation services. Determine who wrote the orders for the rehabilitation services. Determine if the practitioner is responsible for the care of the patient and privileged to write orders for rehabilitation services. Verify the practitioner meets hospital medical staff policies and procedures as well as State law for ordering rehabilitation services.*

A-1133

(Rev.)

§482.56(b)(1) All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.

Interpretive Guidelines §482.56(b)(1)

The patient's medical record must contain documentation of all rehabilitation services ordered. The medical record entries must comply with regulations at §482.24.

Survey Procedures §482.56(b)(1)

Review a sample of patient medical records who received rehabilitation services. Determine whether the rehabilitation service orders are legible, complete, dated, timed, authenticated, and meet all other medical record requirements specified at §482.24.

A-1134

§482.56(b)(2) The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of §409.17 of this chapter.

Interpretive Guidelines §482.56(b)(2)

The provision of rehabilitation services care and development of the plan of care for rehabilitation services can be initiated only after the order is written for services by a qualified licensed practitioner responsible for the care of the patient. Physical therapy, occupational therapy, or speech-language pathology must be furnished under a plan of care. The regulation at 42 CFR 409.17 specifies the following rehabilitation services plan of care requirements:

- *Establishment of the plan: "The plan must be established before treatment begins by one of the following: (1) A physician. (2) A nurse practitioner, a clinical nurse specialist or a physician assistant. (3) The physical therapist furnishing the physical therapy services. (4) A speech-language pathologist furnishing the speech-language pathology services. (5) An occupational therapist furnishing the occupational therapy services."*

- *Content of the plan: "The plan: (1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and (2) Indicates the diagnosis and anticipated goals."*

- *Changes in the plan: "Any changes in the plan are implemented in accordance with hospital policies and procedures."*

Also in accordance with 42 CFR 409.17, rehabilitation services must be provided by qualified physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists who meet the personnel qualifications defined in 42 CFR 484.4. Hospitals must have policies and procedures consistent with State law.

Rehabilitation services must be provided according to national standards of practice as established by professional organizations such as, but not limited to, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association.

Survey Procedures §482.56(b)(2)

- *Review medical records of patients who received rehabilitation services. Determine whether the required care plan was developed and implemented.*

- *Review employee personnel files to verify the rehabilitation service providers (i.e., physical therapists, physical therapy assistants, occupational therapists, occupational*

therapy assistants, and/or speech-language pathologists) have the necessary education, experience, training, and documented competencies to provide rehabilitation services.

- *Ask the hospital what national standards of rehabilitation practice provide the basis for its rehabilitation services. Is there supporting documentation?*

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§482.57 Condition of Participation: Respiratory Services

A-1163

(Rev.)

§482.57(b)(3) - *Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.*

Interpretive Guidelines §482.57(b)(3)

Respiratory care services must be ordered by a qualified and licensed practitioner who is responsible for the care of the patient. The practitioner must have medical staff privileges to write orders for these services. Privileges must be granted in a manner consistent with the State's scope of practice law, as well as with hospital policies and procedures governing respiratory care services developed by the medical staff and approved by the governing body.

Practitioners who may be granted privileges to order respiratory care services include physicians, and may also, in accordance with hospital policy, be extended to Nurse Practitioners, Physicians' Assistants, Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives as long as they meet the parameters of this requirement. (Although the following licensed professionals are also considered practitioners, in accordance with Section 1842(b)(18)(C) of the Social Security Act, they generally would not be considered responsible for the care of the patient or qualified to order respiratory care services: Clinical social worker (Section 1861(hh)(1) of the Act and as defined in 42 CFR 410.71); Clinical psychologist (for purposes of Section 1861(ii) of the Act); or registered dietician or nutrition professional.)

Survey Procedures §482.57(b)(3)

- *Review the medical staff policies and procedures for respiratory care services privileging. Do they identify the types of eligible practitioners and their qualification criteria?*

- *Review the medical records of patients receiving respiratory care services. Determine who wrote the orders for the respiratory care services. Does this individual hold*

privileges to order respiratory care services and is he/she responsible for the care of the patient?

- *Verify the practitioner writing respiratory care service orders meets hospital medical staff policies and procedures and State law requirements for ordering respiratory services.*

A-1164
(Rev.)

§482.57(b)(4)- All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.

Interpretive Guidelines §482.57(b)(4)

The patient's medical record must contain documentation of all respiratory care services ordered. The medical record entries must comply with regulations at 42 CFR 482.24.

Survey Procedures §482.57(b)(4)

- *Review a sample of patient medical records who received respiratory care services. Determine whether the respiratory care services orders are legible, complete, dated, timed, authenticated, and meet all other medical record requirements as specified at §484.24.*