Introduction

The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule in the October 24 Federal Register that revises the requirements – commonly referred to as Conditions of Participation (CoPs) - that hospitals and critical access hospitals must meet to participate in the Medicare and Medicaid Programs.

CoPs are designed to protect patient health and safety and ensure quality of care, and can sometimes limit or prohibit nurses from practicing to the full extent of their education and training. The reason for the review and revision was Presdient Obama's Executive Order 13563 "Improving Regulations and Regulatory Review".

CMS requested comments on these proposals, and received thousands of comments, including from ANA. The final rule was issued in the May 16 Federal Register, and included a detailed summary of the comments and CMS' response to them. ANA has analyzed this narrative and the final rule in light of our comments and particular issues that impact nurses. In some cases, ANA's comments and suggestions were successful.

Overall, the revised CoPs represent a significant acknowledgement of nursing's contribution and leadership in hospital care, however, efforts are still needed to ensure nursing is a full partner in the transformation of health care. ANA will continue to its advocacy to CMS to assure nursing's voice in hospital care and leadership.

PART 482—CONDITIONS OF PARTICIPATON FOR HOSPITALS

Proposed Section 482.12: Condition of participation: Governing Body

Proposed CoP Language:

§ 482.12 Condition of participation: Governing body.
There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

Final CoP Language (Change highlighted in yellow):

§ 482.12 Condition of participation: Governing body.
There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. The governing body (or the persons legally responsible for the conduct of the hospital and carrying out the functions specified in this part that pertain to the governing body) must include a member, or members, of the hospital's medical staff.

ANA Analysis

Although ANA did not specifically comment on this section, we were disappointed that CMS chose to only include a member of the medical staff as a requirement for

representation on the governing body. While ANA agrees that requiring clinical staff on the governing body will enhance continuity and regular communication, ANA believes CMS should have broadened the requirement to include representatives from the nursing services staff. While the current requirement of a member, or members, of the medical staff does open the door for an APRN who is a member of the medical staff to be the representative, nursing itself should be recognized with a leadership role. It is unfortunate that with all the progress CMS made with this regulatory review of the CoPs, this particular example highlights how this revision falls short in being a thorough demonstration of federal recognition of nursing contributions to hospital care and leadership.

Proposed Section 482.13: Condition of participation: Patient's Rights

Proposed CoP Language:

§ 482.13 Condition of participation: Patient's rights.

* * * * *

(g) * * *

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must report to CMS by recording in a log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints; and

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

ANA Comment:

ANA urged CMS to reconsider the proposed change in the reporting requirement for patient deaths after soft wrist restraints have been used. ANA argued that the material used in a restraining device should not change a hospital's accountability for reporting patient deaths while in such restraints. Furthermore, ANA commented that the desired reduction in administrative burden associated with such reporting would be negligible, as hospitals would need to set up two separate systems for reporting deaths. In any event, any such savings would be more than outweighed by the implicit reduction in accountability for patient safety. Consequently, we recommended adoption of proposed section 482.13(g)(1), and rejection of proposed section 482.13(g)(2).

Final CoP Language:
§ 482.13 Condition of participation: Patient's rights.
* * * * *
(g) * * *
(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:
(i) Each death that occurs while a patient is in restraint or seclusion.
(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.
(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:
(i) Any death that occurs while a patient is in such restraints.
(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

ANA Analysis

The final rule is basically unchanged from the proposed rule. The only modest changes were (1) a clarification that the reporting log for patient deaths while in soft restraints be "internal" and not subject to public reporting; and (2) that the data requirement for the attending physician's name to be logged should be expanded to include the name of the practitioner responsible for the patient's care, regardless of whether s/he is a physician. CMS writes:

> 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 such deaths. This log must be made available to CMS immediately upon request. We have indicated that the log is internal to the hospital and that the name of the practitioner responsible for the care of the patient may be used in the log in lieu of the name of the attending physician if the patient was under the care of a non-physician practitioner and not a physician.

CMS rejected ANA's concerns, declaring that it was not aware of any reports or evidence – even anecdotal – of patient deaths related to soft wrist restraints. It maintains that such restraints are used to keep patients from pulling out nasogastric tubes and central lines and would not be a proximal cause of death in any patient. It also rejected ANA's position that the reduction in administrative burden would be negligible, arguing that facilities would be relieved of the burden of reporting to CMS such deaths within 24 hours, a rationale supported by CMS's claim that deaths in soft restraints are not proximally caused by the restraints. CMS did not address ANA's concern that the numbers of overall deaths reported of patients in restraints (which does

not include use of restraints where no death occurs) suggests widespread disregard for that the requirement for the least restrictive form of restraint should be used only if no alternatives exist.

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Proposed Section 482.22: Condition of participation: Medical staff

Proposed CoP Language:

§ 482.22 Condition of participation: Medical staff.
The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.
(a) *Standard: Composition of the medical staff.* The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.
* * * * *
(5) The medical staff must examine the credentials of candidates applying for practice privileges and medical staff membership within the hospital, as well as the credentials of practitioners applying only for hospital practice privileges, and make recommendations to the governing body for the appointment of these candidates and the approval of these privileges in accordance with State law and hospital policies and procedures. A physician or nonphysician practitioner who has been granted practice privileges by the governing body for practice activities authorized within his or her State scope of practice is subject to all medical staff requirements contained in this section.
(b) * * *
(3) The responsibility for organization and conduct of the medical staff must be assigned only to:
(i) An individual doctor of medicine or osteopathy,
(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located; or
(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.
* * * * *

ANA Comment

ANA recommended that CMS revise section 482.22(a) *Standard : Composition of the medical staff* to require hospitals to include practitioners other than physicians on their medical staffs. We urged CMS to change the word “may” in this provision to “shall.”

ANA also recommended that language be added to ensure that all practitioners are granted clinical privileges and accorded all categories of medical staff privileges, including voting rights and full due process.

ANA endorsed the recommended change to Section 482.22(a)(5) and suggested further strengthening this section by:

- Adding assurances that hospital policies and procedures are transparent, objective and timely and that decisions are made in a 60-day time period. Any rejection of an application should include a written explanation and include the option for an appeal and fair hearing.

- Require that if privileging occurs through a process that does not involve the medical staff, such as through a human resources department, the health care professional has the right to serve on hospital committees, to cast a vote on policies that affect their privileges and to a fair and impartial hearing if privileges are denied.

ANA proposed the following modifications to section 482.22(b)(3), to allow hospitals the flexibility to follow a truly interdisciplinary model of care in their medical staff composition.

> Proposed § 482.22(b)(3) The responsibility for organization and conduct of the medical staff should be assigned to a member of the medical staff with appropriate skills to perform the necessary oversight activities.

Barring acceptance of this approach, ANA recommends adding a new subsection (b)(3)(iv), to make explicit that APRNs may serve in this capacity:

> Proposed § 482.22(b)(3)(iv) An advanced practice registered nurse, when permitted by State law of the State in which the hospital is located.

ANA supported CMS's decision to not amend the existing rule regarding the history and physical examination of patients at the time of admission or registration.

Final CoP Language:

(a) Standard: Eligibility and process for appointment to medical staff. The medical staff must include doctors of medicine or osteopathy. In accordance with State law, including scope of-practice laws, the medical staff may also include other categories of non-physician practitioners determined as eligible for appointment by the governing body.
* * * * *
(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.
* * * * *
(b) * * *
(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:
(i) An individual doctor of medicine or osteopathy.
(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.
(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

[Note: Summary of changes

- Removal of the proposed concept of physicians and other practitioners being privileged to practice without appointment to the medical staff;
- Removal of the proposed regulatory language that the granting of privileges is done in accordance with "hospital policies and procedures;"
- Alignment of the new regulatory language at §482.22(a) with that currently found in the Governing body CoP (§482.12(a)(1)) regarding the governing body requirement to determine, in accordance with State law, the categories of practitioners who are eligible for medical staff appointment;
- Revision of existing §482.22(a)(2) to require the medical staff to examine the credentials of all eligible candidates and make recommendations for medical staff membership to the governing body in accordance with State law, including scope of practice laws, with the medical staff bylaws, rules and regulations; and
- Revision of existing §482.22(a)(2) to require that a candidate recommended by the medical staff and appointed by the governing body be subject to all medical staff bylaws, rules, and regulations in addition to the requirements in this section.]

ANA Analysis:
The final rule is unchanged in the sense that it contains the word "may" rather than, as ANA and others suggested, "shall," when referencing the inclusion of practitioners other than MDs or DOs.

In the preface to the rule, CMS noted the revisions proposed by ANA, ACNM and others to promote due process and transparency with regard to privileging, spelling those suggestions out in a bulleted list. They, however, disagreed with the recommendations and characterized them as "very specific and highly prescriptive requirements pertaining to a hospital's credentialing and privileging process." CMS went on to say that "The current requirements already provide for a transparent process based on established criteria," and they "do not believe there is sufficient evidence" to require the 60 day time frame, notification of applicants, etc.

ANA is disappointed that the arguments provided were not compelling, but this is a reminder of the need to continue to collect evidence of the manner in which the current process limits APRNs ability to be appropriately credentialed and privileged. However, we are pleased that CMS did not agree with commenters who stated CMS' goal in modifying this chapter was to "replace physicians with non-physicians". CMS restated their goal was to give flexibility to hospitals to maximize the medical staff opportunities for all practitioners.

Section 482.23: Condition of participation: Nursing services

Proposed Section 482.23(b): Staffing and delivery of care

Proposed CoP Language: None

ANA Comment

Although proposed changes were not made to this section by CMS, ANA strongly urged CMS to consider adding additional provisions to section 482.23(b) to support and ensure safe and adequate nurse staffing in Medicare and Medicaid hospitals. To that end, ANA recommends that CMS add requirements to help assure that hospitals provide adequate numbers of registered nurses and other staff to provide the best quality care to patients. ANA offers the following recommendations for CMS's consideration, for inclusion in the CoPs. ANA is prepared to work with CMS to further develop and implement these crucial elements to ensure a high standard of nursing care for all Medicare and Medicaid hospital patients:

- A requirement that all hospitals implement a hospital-wide staffing plan that will establish an appropriate number of registered nurses on each unit to meet the needs of the patients and expectations of those units. The plan should take into account factors present on each unit during each shift, such as:
    - Number of patients, and level and variability of intensity of care, with consideration to admissions, discharges, and transfers during each shift;
    - Level of education, training, and experience of those registered nurses providing direct patient care;
    - Availability of personnel and services associated with nursing care or augmenting care;
    - Non-patient care-related duties that nurses oversee (e.g. nursing students, orientation of new employees);
    - Competency of nursing staff assigned to particular units to handle patient care needs of those units;
    - Contextual issues, including architecture and geography of the environment;
    - Available technology; and
    - Establishing adjustable minimum numbers of registered nurses based on an assessment of the level and variability of intensity of care required by patients under existing conditions.
- A requirement that hospitals conduct, no less than annually, an evaluation of the staffing plans based upon an assessment of patient outcome data that are nursing sensitive.
- A requirement that hospital staffing plans are made publicly available.

Final CoP Language:
None

ANA Analysis:
CMS acknowledged ANA's comments regarding staffing. In response, they stated

> …the regulation already requires the hospital to have adequate numbers of nurse to provide nursing care as needed, and makes it the responsibility of the director of nursing services to determine the types and number of nursing personnel and staff necessary to provide nursing care for all areas of the hospital. Therefore, we do not see the need to require any additional or more prescriptive regulations to address the nursing issues expressed by the commenters.

However, CMS also acknowledged ANA's comment that staffing plans should be evaluated no less than annually based on assessment of patient outcomes, and that staffing plans be made public. CMS did not change any specific language in the regulations, yet, they did state:

> We agree with the commenters that hospitals should evaluate their nursing staffing plans… We believe that it is implicit in the requirement for the director of nursing to determine the types and numbers of nursing personnel necessary [SIC] that the directorof nursing would periodically re-evaluate staffing plans to ensure that the nursing care needs of the patients are met.

ANA interprets CMS' comment to verify the importance of the nurse administrator to maintain responsibility and demonstrate leadership on nurse staffing.

ANA did not anticipate that CMS would alter the CoPs regarding staffing, as they were not part of the proposed revisions. However, it is important to keep the issues of nurse staffing and the inadequacies of accrediting bodies' interpretation of the staffing CoPs on the record for CMS.

Proposed Section 482.23(b)(4): Nursing care plan

Proposed CoP Language:

(b) * * *

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.

ANA Comment

ANA supports CMS's proposed language requiring a hospital to "ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient."

Final CoP Language: No change

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Proposed Section 482.23(c): Preparation and administration of drugs

Proposed CoP Language:

(c) *Standard: Preparation and administration of drugs.* (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, and only if the hospital has granted them privileges to do so.

(ii) Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of § 482.24(c)(3).

ANA Comment

ANA commends CMS for the changes in proposed section 482.23(c)(1)(i).

ANA also commended CMS for recognizing the value of standing orders and protocols.

Final CoP Language:
No Change

ANA Analysis:
CMS stated they received numerous comments in support of expanded use of standing orders. ANA is satisfied that many other organizations and individuals see the value in this policy. CMS did receive comments opposing the expansion of the types of practitioners who are able to administer drugs and biological, particularly as it relates to anesthesia and pain management." According the CMS, the commenters opposition was rooted in concern of exacerbation of the problem of prescription drug abuse. CMS stated they "respectfully disagree" and made no changes as a result of this opposition.

Proposed Section 482.23(c)(4): Blood transfusions and intravenous medications

Proposed CoP Language:

(4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

ANA Comment

ANA supports reference to, and reliance upon, State law and hospital policies and procedures regarding the administration of blood transfusions and intravenous medications, but with a caveat. Those state laws and regulations, and hospital policies must provide adequate safeguards to prevent errors in administration.

Final CoP Language: No Change

Proposed Section 482.23(c)(6): Self-administration of medications

Proposed CoP Language:

(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.
(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:
(A) Assure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration;
(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s);
(C) Instruct the patient (or the patient's caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s);
(D) Ensure the security of the medication(s) for each patient; and
(E) Document the administration of each medication in the patient's medical record.
(ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:
(A) Assure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital;
(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s), and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s);
(C) Identify the specified medication(s) and visually evaluate the medication(s)for integrity;
(D) Ensure the security of the medication(s) for each patient;
(E) Document the administration of each medication in the patient's medical record.

ANA Comment

ANA generally supports this provision, as long as hospitals are kept to very high standards in their required policies, and nurses retain the flexibility to determine which patients are capable of doing this on their own.

Final CoP Language:

No Change

Proposed Section 482.24 Condition of participation: Medical record services

Proposed CoP Language:

(c) * * *
(2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.
(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:
(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff in consultation with the hospital's nursing and pharmacy leadership;
(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff, in consultation with the hospital's nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols; and
(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.

ANA Comment

ANA applauds CMS's proposal to end the controversial policy requiring that verbal orders be physically signed or otherwise authenticated within 48 hours.

However, ANA is concerned about that the proposed language, "authenticated promptly in the patient's medical record," may be misinterpreted. However, this language could be interpreted to mean that *each individual patient* must have his or her own standing order for certain drugs or biologicals. Clearly, this would defeat the purpose of a standing order, if an ordering practitioner must create individual standing orders tailored to each patient. We do not believe this is the agency's intent, and urge CMS to add clarifying language to the regulation in the final rule.

ANA did recommend the following revision be made in both section 482.24(c)(3)(i) and (iii): deletion of the phrase "in consultation with the hospital's..." following the word "staff" and preceding the word "nursing."

Final CoP Language: (changes highlighted in yellow)

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(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:
(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;
(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;
(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and
(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care for the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

[Note: Summary of change
Removal of words "in consultation with" after "staff" and before "hospital's"]
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ANA Analysis:

CMS acknowledged ANA's comments regarding concerns with the language "authenticated

promptly", and stated they "appreciate the commenters concern about how some individual could interpret the language in 482.24(c)(3)(iv)." They went on to state that:

> Requiring a separate subsequent authentication, which simply makes reference to the included order as the subject of authentication, also should not prove burdensome for practitioners. Both the current requirements and standards of practice regarding medical records dictate that any patient order given by a practitioner authorized to do so becomes a required part of the patient's medical record and must be documented to reflect this, regardless of whether it is contained in pre-printed or electronic standing orders, order sets, or protocols, or whether it is a written or verbal order.

ANA is satisfied that CMS has clarified their intent in this narrative, and will provide resources when needed to nurses, nurse administrators or others who experience a misinterpretation of the CoP in their setting. ANA will also request that CMS provide this clarification in any interpretive guidelines they produce. ANA will remain vigilant that any subsequent use of this CoP by accrediting bodies in applicable standards/elements of performance will be interpreted as CMS has stated in the final rule.

CMS specifically recognized our concern with the language "in consultation with the hospital's nursing and pharmacy leadership", and stated they agreed that nursing and pharmacy leadership should be full partners in approving and reviewing standing orders. They followed ANA's recommendation and change the final language to state "medical staff, and the hospital's nursing and pharmacy leadership." ANA is very satisfied that CMS noted the concern, and expressed support for interprofessional collaboration on this important policy consideration.

Although ANA did not raise this issue in its comments, we are pleased CMS removed the phrase "as specified under § 482.12(c)" from 482.24(c)(3)(iv) at the request of other commenters. CMS stated that it was concerned that this language was inappropriately inserted into this section, and deletion was warranted because the practices in this section (i.e. standing orders) apply to "all patients and not Medicare patients exclusively." This gives leeway to other practitioners that are charged with patient care to authenticate orders, even if they did not specifically write those orders, and to enable the prompt authentication that CMS requires in the CoPs.

Section 482.25: Conditions of participation: Pharmaceutical services

Proposed CoP Language:

(b) * * *

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.

ANA Comment

ANA suggested CMS consider the following revision (underlined) for the final rule:

- Proposed § 482.25(b)(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician <u>or other provider responsible for the patient</u>.

Final CoP Language:
No change

Proposed Section 482.42: Condition of participation: Infection control

Proposed CoP Language:

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.
* * * * *
(b) * * *
(1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and

ANA Comment

ANA supported CMS's proposal to allow infection control officers to develop their own system "for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel."

Final CoP Language:
No change

Proposed Section 485.604: Personnel qualifications

Proposed CoP Language:

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who—Show citation box
(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and
(2) Holds an advanced degree in a defined clinical area of nursing from an accredited educational institution.

ANA Comment

ANA fully supported and endorsed the position and comments of its organizational affiliate, the National Association of Clinical Nurse Specialists (NACNS).

Final CoP Language (Changes highlighted in yellow):

§485.604 Personnel qualifications.
* * * * *
(a) Clinical nurse specialist. A clinical nurse specialist must be a person who—
(1) Is a registered nurse and is licensed to practice nursing in the State in which the

clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and
(2) Holds a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.

ANA Analysis

CMS acknowledge that many commenters had suggested an addition to the language regarding State nurse licensing laws and regulations, allowing the State Boards of Nursing to determine whether the nurses' educational program "is congruent with a CNS education." The additional phrase "will ensure than an existing CNS will continue to be evaluated based on their State licensing laws and regulation." NACNS' s concerns regarding the availability of certification were recognized in that national certification will not be required unless the state requires it.

Proposed Section 485.639: Conditions of participation: Surgical services

Proposed CoP Language:

If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section.

ANA supports CMS's modification of section 485.639, clarifying that surgical services are optional for CAHs.

Final CoP Language:
No change