



Memo

To: Members of the American College of Nurse-Midwives
From: Patrick Cooney, ACNM Federal Representative
Date: May 11, 2012
Re: Final Rule on Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation

The American College of Nurse-Midwives (ACNM), in conjunction with other groups representing advanced practice registered nurses (APRNs) and the American Nurses Association, have been waiting since December 2011 for the Centers for Medicare and Medicaid Services (CMS) to issue final regulations updating portions of the Medicare Hospital Conditions of Participation. These are the rules that hospitals are required to comply with in order to maintain eligibility to participate in the Medicare and Medicaid programs.

On May 10, 2012, CMS posted its final rule for inspection. While it is clear that CMS believes hospitals should be utilizing midwives and APRNs to a greater extent and encourages hospitals to do so, the updated regulations will not solve all problems, since it falls short of requiring hospitals to place midwives and APRNs on medical staffs. It is probably best to characterize the rule and its accompanying narrative as a strong signal to hospitals that they should utilize midwives and APRNs as members of their medical staffs.

Summary of the Major Provisions

Revisions to Allow Flexibility and Eliminate Burdensome Conditions of Participation (CoPs): CMS has attempted to reduce burden to providers and suppliers by modifying, removing, or streamlining current regulations that CMS has identified as excessively burdensome.

- Single governing body for multiple hospitals: CMS 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 medicals staffs of individual hospitals in the system.

- Reporting of Restraint-Related Deaths: CMS has 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. CMS has 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.

- Role of other practitioners on the Medical Staff: CMS has broadened the concept of “medical staff” and have allowed hospitals the flexibility to include other practitioners as eligible candidates for the medical staff with hospital privileges to practice in the hospital in accordance with State law. All practitioners will function under the rules of the medical staff. This change will clearly permit hospitals to allow other practitioners (e.g. APRNs, PAs, pharmacists) to perform all functions within their scope of practice. CMS has required that the medical staff must examine the credentials of all eligible candidates (as defined by the governing body) and then make recommendations for privileges and medical staff membership to the governing body.

- Medical staff leadership: CMS has allowed podiatrists to be responsible for the organization and conduct of the medical staff. This change will allow podiatrists to assume a new leadership role within hospitals, if hospitals so choose.

- Nursing care plan: CMS has 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: CMS has 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: CMS has 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. CMS believes that this clarification will make the requirement consistent with current standards of practice.

- Orders by other practitioners: CMS has allowed for drugs and biologicals to be prepared and administered on the orders of practitioners (other than a doctor), in accordance with hospital policy and State law, and have also allowed orders for

drugs and biologicals to be documented and signed by practitioners (other than a doctor), in accordance with hospital policy and State law.

- Standing Orders: CMS has allowed hospitals the flexibility to use standing orders and have added a requirement for medical staff, nursing, and pharmacy to approve written and electronic standing orders, order sets, and protocols. CMS has required that orders and protocols must be based on nationally recognized and evidence-based guidelines and recommendations.
- Verbal Orders: CMS has eliminated the requirement for authentication of verbal orders within 48-hours and have deferred to applicable State law to establish authentication timeframes.
- Authentication of Orders: CMS has made permanent the previous temporary requirement that all orders, including verbal orders, must be dated, timed, and authenticated by either the ordering practitioner or another practitioner who is responsible for the care of the patient and who is authorized to write orders by hospital policy in accordance with State law.
- Infection Control Log: CMS has eliminated the obsolete requirement for a hospital to maintain an infection control log. Hospitals are already required to monitor infections and do so through various surveillance methods including electronic systems.
- Outpatient services director: CMS has removed the burdensome and outdated requirement for a single Director of Outpatient Services position that oversees all outpatient departments in a hospital. Hospitals already have separate directors for individual outpatient departments, so having a single overall Director position is duplicative and unnecessary.
- Transplant Center Process Requirements: CMS has eliminated a duplicative requirement for an organ recovery team that is working for the transplant center to conduct a “blood type and other vital data verification” before organ recovery when the recipient is known. The verification will continue to be completed at two other times in the transplant process.
- Critical Access Hospital (CAH) Provision of Services: CMS has eliminated the burdensome requirement that CAHs must furnish diagnostic and therapeutic services, laboratory services, radiology services, and emergency procedures directly by CAH staff. This will allow CAHs to provide such services under arrangement.

Clarifying Changes: CMS has clarified several requirements in the hospital and CAH CoPs to ensure that they are consistent with the statute as well as with other, more current CoP requirements.

- Pharmaceutical Services: CMS has made a technical change to replace the term “quality assurance program” with the more current term “quality assessment and performance improvement program.”

- Infection Control: CMS has made a technical change to replace the term “quality assurance program” with the more current term “quality assessment and performance improvement program.”
- CAH Personnel Qualifications: CMS has aligned the definition of “clinical nurse specialist” that is in the rule with the definition that is in the statute.
- CAH Surgical Services: CMS has clarified that “surgical services” are an optional service for CAHs.

Changes Made to Rules Relating to Medical Staffing (§482.22)

The CMS CoP on “Medical staff,” at §482.22, concerns the organization and accountability of the hospital medical staff. CMS proposed three revisions to the Medical staff CoP.

First, CMS proposed to redesignate §482.22(a)(2) as §482.22(a)(5) and revise it by adding language to clarify that a hospital may grant privileges to both physicians and non-physicians to practice within their State’s scope-of-practice law, regardless of whether they are also appointed to the hospital’s medical staff. That is, technical membership in a hospital’s medical staff would not be a prerequisite for a hospital’s governing body to grant practice privileges to practitioners.

ACNM Comment: This does not appear to materially change the existing requirements for hospitals today which have the authority to place CNMs/CMs on medical staff or provide them clinical privileges without being placed on the medical staff. It does represent, however, a strong push from CMS to hospitals to consider midwives and APRNs for their medical staffs, affording them voting rights and a larger role in hospital operations.

Second, CMS also proposed to require that those physicians and non-physicians that have been granted practice privileges within their scope of practice, but without appointment to the medical staff, are subject to the requirements contained within this section.

ACNM Comment: This does appear to materially change the existing requirements to say once provided clinical privileges, a midwife or APRN would be under the bylaws, rules and regulations that deal with medical staffs regardless of whether they are on the medical staff.

The third area in which CMS is proposing changes concerns the more direct responsibilities for the organization and accountability of the medical staff. These requirements are set forth at §482.22(b)(3). Presently, the hospital may assign these management tasks to either an individual doctor of medicine or osteopathy or, when permitted by the State in which the hospital is located, a doctor of dental surgery or dental medicine. CMS proposed to allow a hospital the option of also assigning the leadership of the medical staff to a doctor of podiatric medicine when permitted by the State law of the State in which the hospital is located.

ACNM Comment: This change only impacts podiatrists in that they can now be appointed to leadership of the medical staff.

CMS indicates that comments received were overwhelmingly supportive of the proposed changes to the Medical staff CoP at §482.22(a) that would broaden the concept of “medical staff” to include other practitioners who are granted hospital privileges to practice in the hospital in accordance with State law, not only those who are actually appointed to sit on the medical staff. CMS acknowledges, however, that a number of commenters, while supportive of the proposed changes, recommended that CMS go further with its revisions in this area. Specifically, they referenced ACNM’s comments that 1) medical staffs must be representative of all types of health professionals who have privileges, including Advanced Practice Registered Nurses (APRNs) and Certified Nurse Midwives/Certified Midwives (CNMs/CMs), and who provide services to a hospital’s patients, and as they are authorized to provide services under State law and to the extent of their full scope of practice; 2) Non-physician members of the medical staff must be accorded the same rights and protections as physician members, including full voting privileges, membership on committees, ability to appeal, and due process; 3) the credentialing and privileging process and the selection process for medical staff membership must be transparent and follow established criteria; 4) each application for privileges must be completely reviewed and a determination made within a 60-day period; and 5) the applicant must be notified of the determination in writing with an explanation of the determination.

Conversely, CMS also received a significant number of comments from those who were adamantly opposed to the proposed changes. A majority of the dissenting opinions took the form of comments expressing serious concerns about allowing non-physician practitioners to obtain hospital privileges without becoming members of the medical staff. These commenters continued by stating that “allowing some providers to circumvent medical staff oversight will detrimentally impact patient safety and quality afforded to Medicare beneficiaries and all patients.”

In responding, CMS stated that based on the public comments received, CMS revised its proposed medical staff requirements in this final rule to better address the many valid issues that were raised by both those who supported this section of the proposed rule and those who opposed it. While CMS agrees with the Institute of Medicine’s report on the Future of Nursing that CMS amend its requirements to ensure that advanced practice registered nurses are eligible for hospital privileges and membership on medical staff, CMS respectfully disagreed with suggestions that CMS needs to add additional requirements that would guarantee both non-physician practitioner representation on the medical staff as well as specific rights for those non-physician practitioners. In addition, CMS also disagrees with the recommendations offered in the comments that CMS add very specific and highly prescriptive requirements pertaining to a hospital’s credentialing and privileging process, stating that current requirements already provide for a transparent process based on established criteria.

Rather, CMS feels the rule is intended to encourage hospitals to be inclusive when they determine which categories of non-physician practitioners will be eligible for appointment to their medical staff. Under the new requirements, an individual hospital would be allowed to include midwives and APRNs as members of the medical staff.

ACNM Comment: Again, this does not appear to materially change the existing regulations that have governed hospitals to this point relating to appointment of midwives and APRN to medical staffs. But we appreciate the push from CMS for hospitals to change their previous policies in this area. It may still be necessary for ACNM and other groups to consider legislative remedies that go beyond what CMS is able to do in this regulation. That shouldn't devalue the message CMS is sending to hospitals, midwives and APRNs here in this rule.

Therefore, in this final rule, CMS is both modifying the proposed changes to the Medical staff requirements as well as revising portions of the current requirements of this section in the following manner:

- Removing the proposed concept of physicians and other practitioners being privileged to practice without appointment to the medical staff;

ACNM Comment: I spoke with CMS officials today who confirmed that hospitals will still have the option of providing midwives and APRNs with clinical privileges without placing them on medical staff. The wording of the previous bullet point is unfortunate because it could leave the impression with some that if you receive clinical privileges from a hospital you ARE on the medical staff.

- Removing the proposed regulatory language that the granting of privileges is done in accordance with “hospital policies and procedures;”

ACNM Comment: It appears this is to emphasize the role state law should play as hospitals look at categories of professionals eligible for medical staffing. We should see this as positive but it does not eliminate the ability of hospitals to set their own policies beyond those of state law.

- Aligning 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;

ACNM Comment: All midwives and APRNs should be on notice that this rule places the responsibility of determining which categories of professionals may be on the medical staff in the hands of the hospital's governing body. In other words, get to know the members of your hospital's governing body really well and start advocating for inclusion of midwives and APRNs.

- Revising 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, and with medical staff bylaws, rules, and regulations;

ACNM Comment: The one big new requirement CMS imposes on hospitals is to REQUIRE applications of midwives and APRNs who apply for clinical privileges to be reviewed by the medical staff and for the governing body of the hospital to make a determination. Note that such a determination would be discoverable.

- Revising 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.

ACNM Comment: Instead of different rules and processes in the hospital for medical staff and non-medical staff, all professionals provided clinical privileges will be governed by the bylaws and regulations of the medical staff. For some this could be welcome news, but for others this may add a level of oversight not experienced before. It will likely be different in each facility. That is why ACNM has been pushing for midwives and APRNs to be ON the medical staff rather than just subject to the medical staff.

The regulatory language that CMS is finalizing here emphasizes the collaborative nature that must exist between the medical staff and the governing body of a hospital. It is a system of checks and balances between the governing body and the medical staff. The governing body has the authority to establish the categories of practitioners (regardless of the terms used to describe those categories) who are eligible for privileges and medical staff appointment, but must rely on the medical staff to apply the criteria for privileging and appointment to those eligible candidates and to make their recommendations before the governing body makes a final decision to appoint or not appoint a practitioner to the medical staff.

The changes also leave room for a hospital or a governing body, after considering the recommendations of its medical staff, to appoint non-physician practitioners to the medical staff and to grant them privileges that are in alignment with their professional education and training to the full extent allowed under State licensing and scope-of-practice laws. CMS encourages medical staff and hospitals to take advantage of the expertise and skills of these non-physician practitioners when making recommendations and appointments to the medical staff.

CMS further encourages physicians and hospitals to enlist qualified non-physician practitioners to fully assist them in taking on the work of overseeing and protecting the health and safety of patients. This applies not only to the “work” of the medical staff—such as quality innovation and improvement, best practices application, and establishment of professional standards—but also to the everyday duties of caring for patients. As many of the commenters expressed, CMS also believes that an interdisciplinary team approach to patient care is the best model for patients.

CMS estimates these changes will reduce hospital costs by \$330 million annually. The rule states the potential savings will be achieved by allowing hospitals to ***“...broaden the concept of “medical staff” through the appointment of non-physician practitioners to the medical staff so that they may perform the duties for which they are qualified through training and education and as allowed within their State scope-of-practice laws. For hospitals that choose this option, significant savings might be achieved as non-physician practitioners will enable physicians to more effectively manage their time so that they may focus on the more medically complex patients.”***