August 5, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3295-P
PO Box 8013
Baltimore, MD 21244-8013
Letter Submitted On-Line at www.regulations.gov

RE: CMS–3295–P: Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

Dear Mr. Slavitt:

On behalf of the American College of Nurse-Midwives (ACNM) I am pleased to submit these additional comments in response to the proposed rule titled "Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care," published in the *Federal Register*, on June 16, 2016.[1] This letter should be considered as a supplement to our June 27, 2016 comment letter. We hope you find these additional comments helpful and look forward to your response in the final rule.

COMMENTS

In the proposed rule, CMS proposes to move requirements currently found under 485.641 under 485.631, without making substantive changes to either subparts of the regulation.

Under 42 CFR 485.631(b)(1)(iv) an MD or DO must review records for **all** inpatients treated by NPs, CNSs, CNMs and PAs, not just Medicare patients. The statutory basis for 42 CFR 485 is identified in 485.601 as Section 1820 of the Social Security Act. Section 1820 lays out requirements for CAHs, among them, staffing requirements (see 1820(c)(2)(B)(iv)). The staffing requirements established under Section 1820(c)(2)(B)(iv) are based, by reference, on those found at Section 1861(e).

The requirements of 1861(e)(4) stipulate that a hospital is defined as an institution that, among other things, "(4) has a requirement that every patient **with respect to whom payment may be made under this title** must be under the care of a physician..." Because 1820(c)(2)(B)(iv) refers to the provisions of Section 1861(e), properly understood, the staffing requirements of the CAH should reflect those of acute care hospitals.

[1] 81 FR 39448

In its State Operations Manual (Section A-0066 of Appendix A) CMS has made very clear that the COP for acute care hospitals that Medicare patients be under the care of an MD or DO does **not** apply to patients of a certified nurse-midwife who are covered by Medicaid or other payers. Specifically, it states that:

> "in a State that permits midwives to admit patients (and in accordance with hospital policy and practitioner privileges), CMS requires ONLY Medicare patients of a midwife be under the care of a doctor of medicine or osteopathy. CMS DOES NOT require Medicaid or other non-Medicare patients admitted by a midwife to be under the care of a doctor of medicine or osteopathy."

Given that the staffing requirements for CAHs are based on Section 1820, and Section 1820 references Section 1861, the way in which CMS has interpreted the application of the staffing requirements for acute care hospitals should inform how these staffing requirements are implemented for CAHs. Clearly, with regard to acute care hospitals, CMS has indicated that individuals under the treatment of a CNM who are not covered by Medicare need not be placed under the care of a physician.

ACNM believes that this same understanding should apply in the case of CAHs. Specifically, we believe that CMS should apply the requirement for acute care hospitals, that non-Medicare patients of a CNM be under their care and not that of an MD or DO, to the CAH setting, which should result in a modification of the CAH regulation eliminating the requirement that records for CNM patients by reviewed by a physician.

Inclusion of CNMs in List of NPPs Whose Inpatient Records Must be Reviewed by a Physician

In its final regulation, issued November 10, 2005 (70 FR 68712) CMS addressed comment received to the effect that MDs or DOs should only have to review a sample of inpatient records for patients treated by NPs, CNSs, CNMs or PAs as opposed to records for all inpatients. CMS responded to these comments by citing 1820(c)(2)(B)(iv)(III) as the basis for requiring the continued review of all NPP inpatient records by an MD or DO.

The precise language of 1820(c)(2)(B)(iv)(III) is: "(III) the inpatient care described in clause (iii) **may** be provided by a physician assistant, nurse practitioner, or clinical nurse specialist subject to the oversight of a physician who need not be present in the facility"

There is, within that sub-clause, no reference to CNMs. **The statute is silent with regard to the treatment of CNMs**. Furthermore, the statute uses the word "may" to describe the type of care that can be rendered by the enumerated non-physician practitioners (PAs, NPs, or CNSs), which leaves open the possibility that other NPPs (e.g., CNMs) may also provide care within the hospital, but not subject to the requirement for physician oversight.

The language of 485.631(b)(1)(iv) that requires review of all inpatient records for CNM patients thus goes beyond the very statutory language that CMS cites as a basis for this requirement. It is

notable that CMS proposed the language of 485.631(b)(1)(iv) in a proposed regulation issued July 25, 2005. The preamble discussion, beginning at 70 FR 42753, does not provide any basis whatsoever for CMS' decision to include CNMs within this regulatory provision when they were not included in the list of providers found in Section 1820(c)(2)(B)(iv)(III). It appears that CMS simply added CNMs to the list because NPPs are habitually treated together as a class, and not because there was a statutory or health outcomes-based reason for doing so.

Recommendation

CNMs are licensed to practice in all 50 states, the District of Columbia and the Territories. In 25 states and the District of Columbia they have been given full practice authority under state law or regulation, meaning that they are not required to enter into a formal or legalistic supervisory or collaborative relationship with a physician. CNMs are often the major provider of obstetric services in the CAHs where they work and obstetricians who works with them reportedly see the review of all inpatient records as an unnecessary administrative burden that detracts from their ability to spend time caring for patients.

There is no statutory or evidence-based rationale for requiring that all records of CNMs' CAH inpatients be reviewed by a physician. ACNM recommends that CMS modify the language of 485.631(b)(1)(iv) to require periodic physician review of a sample of records for CNM inpatients treated in a CAH only in states that require physician supervision of CNMs. This would bring the language of the regulation into line with the statutory requirements and would be reflective of the flexibility that CMS has already allowed in the outpatient setting.

CONCLUSION

We thank you for the opportunity to comment on this proposed rule. Should you have any questions regarding our comments, please reach out to me directly.

Sincerely,

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