
August 31, 2010

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health &Human Services
Attention:  CMS-1504-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically to [http://www.regulations.gov](http://www.regulations.gov/)

Re:    **Medicare Program: Changes to the Hospital Outpatient Prospective**

**Payment System and CY 2010 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Corrections; Final Rule, Notice, and Proposed Rule.** CMS-1504-P; RIN 0938-AP82.

75 Fed.Reg. 46169 (August 3, 2010)

Dear Administrator Berwick:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on the proposed Medicare rules for the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System (ASCPS).

The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, the single largest group of health care professionals in the United States.  We represent RNs in all roles and practice settings, through our state and constituent member nurses associations, and organizational affiliates.  ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and advocating before Congress and regulatory agencies on health care issues affecting nurses and the public.  Our members include Advanced Practice Registered Nurses (APRNs) such as Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Nurse-Midwives (CNMs), and Certified Registered Nurse Anesthetists (CRNAs).

**I. Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule**

1. **Direct Supervision Requirements**

Centers for Medicare Services (CMS) is considering several modifications to its “restatement and clarification” of the direct supervision requirements for outpatient therapy services, as formally adopted in last year’s OPPS final rule. ANA has previously commented on the severe hardship which these requirements can create for nurses and their patients who need to receive chemotherapy, IV therapy, and other important treatments in observation and other hospital outpatient units – particularly in rural areas where patients and their healthcare providers must travel long distances. (CMS subsequently issued a decision to delay, for a year, enforcement of this policy in critical access hospitals (CAHs).) We support the agency’s efforts to modify these requirements and make them more practical and realistic in light of current accepted practices.

**Current supervision requirements:** CMS adopted these **requirements in the 2009 Medicare Outpatient Prospective Payment System Final Rule, and they can now be found at** 42 CFR §410.27 of Medicare regulations. For outpatient hospital services furnished “incident to physician services”, “the physician or nonphysician practitioner must be present on the same campus” or the same “off-campus provider-based department” and “immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.  For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or osteopathy, as specified in §§ 410.47 and 410.49, respectively.”

The supervisory physician or nonphysician practitioner “may not be located in any other entity” and “immediately available” means that person may not be “so physically far away . . . that he or she could not intervene right away.”  While the supervisory practitioner does not have to be of the same specialty or department, he or she “must have, within his or her State scope of practice and hospital-granted privileges, the ability to perform the service or procedure.”

“Nonphysician practitioners” were defined to include nurse practitioners, clinical nurse specialists, and certified nurse-midwives – as well as clinical psychologists, physician assistants, and licensed clinical social workers. They may directly supervise hospital outpatient therapeutic services which they may “perform themselves within their State scope of practice and hospital-granted privileges, provided that they meet all additional requirements, including any collaboration or supervision requirements as specified in” the Medicare regulations.

Virtually every type of therapeutic service provided in outpatient settings is subject to the requirements, regardless of whether the same rules apply in other settings. CMS posited that “all hospital outpatient services that are not diagnostic are services that aid the physician in the treatment of the patient, and are called therapeutic services.”

**CMS should exempt independent nursing practices, particularly those not subject to supervision in other settings:** The notion that physicians should supervise care provided by other qualified health care providers with the education and scope of practice to provide the care in question is outdated and dangerous. It is based on the erroneous assumption that every physician is more capable of providing patient care than every nonphysician care provider. This is neither supported by evidence nor scientific research, and ignores the current state of health care in which many patients receive extensive and high-quality care from highly qualified and experienced nonphysician health care providers. Physicians are generally not responsible for supervising care delivered by registered nurses, therapists, or other licensed health care professionals. It is inappropriate to expect physicians, or any other provider, to accept responsibility for care they have not provided. And supervision rules are particularly problematic in rural and underserved areas where physicians are scarce, preventing patients from having access to care.

RNs are educated, trained and licensed to independently perform many aspects of direct patient care, and receive advice, assistance and supervision from their nursing peers and nursing managers. RNs must practice within the rules and regulations of their state Board of Nursing, and are required to follow professional rules of practice as embodied in ANA’s *Nursing: Standards and Scope of Practice*, and Code of Ethics. While charged with carrying out the orders of physicians and nonphysician practitioners, RNs are also expected to do so with a significant degree of independence, responsibility, and accountability. Registered nurses are also independently liable for the legal implications of their actions – and simply “following orders” is not a defense.

As a practical matter, no hospital could operate if nurses had to be constantly, directly supervised in delivering the myriad aspects of direct patient care. Consequently, RNs are customarily charged with independently administering -- pursuant to valid orders -- such crucial treatments as intravenous (IV) medications, including the programming and changing of medication devices such as patient-controlled anesthesia (PCA) pumps; blood transfusions; chemotherapy; as well as ongoing patient assessment and monitoring. Such practices do not require direct physician/nonphysician provider supervision in inpatient settings, and likewise should not require it in outpatient settings.

Moreover, a number of physicians/non-physician providers would be hard pressed to take over for a nurse in many of these situations, particularly in the preparation of chemotherapy for IV administration. Consequently, we support CMS’s proposal that “in order to furnish appropriate assistance and direction for any given service or procedure, we believe the supervisory physician or nonphysician practitioners must have, within his or her State scope of practice and hospital-granted privileges, the ability to perform the service or procedure.” We also believe that there must be an appropriate level of experience with such procedures, on the part of the supervising physician or practitioner.

However, apart from the question of independent nursing practice, we urge CMS to reexamine how this policy affects the patients. Many ANA members have expressed the hardships which their patients must endure – some driving many hours between chemotherapy treatments – because they could not receive sequential outpatient treatments without the onsite presence of a physician or nonphysician provider. We’ve also heard from providers who were immediately available within minutes – one even who lived directly across the street – but nevertheless did not fall within the limited definition of “physical presence.”

**Nursing interventions not exempt should be subject to general supervision:** For those independent nursing interventions which are not exempted from the supervision requirements altogether, we urge CMS to modify its “two-phase” approach to accommodate such services, and allow for general supervision after initiation of the therapy. ANA supports the general idea of the two-phase approach suggested in the proposed rule, for “nonsurgical extended duration therapeutic services.” There are many therapeutic services which warrant the availability of a higher degree of hands-on, direct supervision when they are begun, because of the risks they involve, but once undertaken, can be continued safely with a lesser degree of general supervision.

However, we believe that CMS has too narrowly circumscribed the criteria for services to qualify for this approach. CMS would limit such services to those that are: of extended duration/frequently extending beyond normal business hours; mostly monitoring typically conducted by nurses or other hospital staff; sufficiently low risk to not normally require direct supervision; and not be a surgical service.

As noted above, many nursing practices – other than general monitoring – are customarily performed independently by nurses without direct supervision by physicians or nonphysician practitioners, particularly the administration of IV medications. Is CMS truly suggesting that an RN is not capable of administering IV medications independently, without direct supervision of a physician?

1. **Preventive Services**

**Vaccines & vaccine administration:** CMS has proposed that vaccines and vaccine administration qualify for the waiver of deductibles and coinsurance, despite the granting of a grade B from the United States Preventive Services Task Force (USPSTF), more than 14 years ago. ANA, which has been actively engaged in promoting the preventive health effects of vaccines for many years, especially with its Bringing Immunity to Every Community initiative, strongly supports this decision. CMS’ proposal will likely improve immunization access for older adults, providing an important tool in the prevention of often dangerous, even deadly, diseases for our most vulnerable populations.

**Other preventive services:** CMS recommends continuing the deductible and coinsurance requirements for several preventive services which, while identified in section 1861 (ddd)(3)(A) of the Affordable Care Act, were not designated with a grade of A or B by the USPSTF. These are: (a) prostate cancer screening & digital rectal exam; (b) glaucoma screening for high risk patients furnished by, or under direct supervision of, an optometrist or ophthalmologist; (c) diabetes outpatient self-management training; and (d) barium enemas provided as colorectal cancer screening tests (these subject to coinsurance only).

It is well within CMS’ discretion to eliminate application of the deductible and coinsurance requirements for these important preventive services, and we urge the agency to do so. Encouraging Medicare beneficiaries to receive these crucial screenings – and particularly the diabetes self-management training – by providing them free of charge will no doubt ultimately save lives, and thereby decrease overall costs.

**Colorectal cancer screenings:** We also commend CMS for extending the waiver on the deductible to surgical services provided on the same date as a colorectal cancer screening test, such as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema, when these become diagnostic. This is consistent with section 4104(c) of the Affordable Care Act.

1. **Quality Measures for Hospital Outpatient Quality Data Reporting Program (HOP QDRP)**

CMS has proposed significant changes to the HOP QDRP program, including a proposed multi-year approach, to assist hospitals in planning for and complying with the program’s reporting requirements. Many of the new and revised measures have received endorsement from the National Quality Forum, and/or adoption by the Hospital Quality Alliance. ANA is a member of the National Quality Forum, and we strongly support adoption of measures appropriate to outpatient settings, which the NQF expert panels have endorsed.

**Chart-abstracted measures:** We also support the adoption of 6 new chart-abstracted measures involving efficiency in emergency departments (EDs), which include care coordination – an important function of many RNs employed in EDs and many other outpatient departments and facilities. By requiring EDs to report on certain times for treatment and diagnosis, discharge destinations, and patients who leave without seeing a provider, this will raise these items to a priority – and ultimately improve patient care.

**Measures for future consideration:**  ANA supports the future adoption of the following proposed measures, which relate specifically to care and services provided by nurses:

* Emergency Department Transfer Communication: Nursing Information
* Pneumococcal Vaccination Status
* Influenza Vaccination Status
* Medication Reconciliation
* Heart Failure: Patient Education
* Heart Failure: End of Life Care Plan
* Other quality measures to assess and prevent healthcare associated infections

**II. Ambulatory Surgical Centers Prospective Payment System (ASCPPS) Proposed Rule**

1. **CMS Should Expeditiously Initiate Mandatory Quality Reporting By Ambulatory Surgical Centers**

In the ASC proposed rule, CMS has again chosen to delay requiring ambulatory surgical centers to begin mandatory reporting of quality measures, citing the need for ASCs to adjust to the new payment system. The four-year transition period to the current payment system began in CY 2008, and will be fully implemented in calendar year 2011. Presumably, ASCs will also require a reasonable time period to implement new quality reporting measures.

According to the agency’s data, there are currently about 5,000 ASCs which are scheduled to receive $3.4 billion on Medicare reimbursement in CY 2011, and CMS is proposing five additions to the list of ASC covered procedures. Ambulatory surgical centers account for a significant proportion of many of the most common surgical procedures performed on Medicare beneficiaries, as well as other patients. These patients take for granted that they are receiving a high quality of care, and are likely unaware that ASCs are not subject to the same quality reporting requirements as hospitals.

While we have no reason to doubt that ASCs are capable of meeting high standards of quality of care, we find it particularly troubling that CMS has not begun to develop a mandatory quality reporting program for these facilities, and urge the agency to do so as expeditiously as possible.

**III. Conclusion**

We appreciate the opportunity to comment on this important rule.  If we can be of further assistance, or if you have any questions or comments, please feel free to contact Eileen Carlson, RN, JD, Associate Director, ANA Government Affairs, at Eileen.carlson@ana.org or 301-628-5093.

Sincerely,



Mary Jean Schumann, MSN, MBA, RN, CPNP
Chief Programs Officer
American Nurses Association