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August 30, 2011

Donald M. Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1525-P / RIN 0938-AQ26
PO Box 8013
Baltimore, MD 21244

Submitted electronically to: www.regulations.gov

Re: **Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements:** Proposed Rule. 76 Fed. Reg. 42170 (July 18, 2011).

Dear Dr. Berwick:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on two major issues within this Proposed Rule. ANA is the leading professional organization representing the interests of the nation's 3.1 million registered nurses, the largest group of health care professionals, and represents RNs in all roles and practice settings through our state and constituent member nurses associations and affiliated nursing specialty organizations. Our members include advanced practice nurses (APNs) such as nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs).

X. Proposed Policies on the Supervision Standards for Outpatient Services in Hospitals and Critical Access Hospitals

ANA appreciates efforts by CMS to undertake modifications in this Proposed Rule regarding the direct physician supervision of outpatient services, and make them more practical and realistic. However, we continue to believe that these policies -- that began with the 2000 Outpatient Prospective Payment System (OPPS) final rule, were expanded in the 2009 OPPS final rule, and continue to evolve -- create an unnecessary layer of supervision which is not required in current accepted practice, ignore the levels of professionalism of the therapy provider, and impose an undue administrative and clinical burden for hospitals and other health care providers.

We urge CMS to re-examine these policies, particularly in light of the current Executive Orders and related policies directing federal agencies to reconsider policies and regulations which impose undue administrative burdens, and reinstate the previous policies that had been in effect for many years. We also consider it inappropriate to refer questions regarding appropriate levels of supervision for clinical services to the Federal Advisory Ambulatory Payment

Classification (APC) Panel. ANA would welcome the opportunity to meet in person with CMS officials, to discuss these issues.

CMS should rescind the increased supervision requirements for outpatient services.

We commend CMS for expanding the health professionals in a supervisory role to include certain nonphysician practitioners, including NPs, CNSs, and CNMs. However, an unnecessary layer of supervision of nursing practice creates a severe hardship for nurses and their patients who need to receive chemotherapy, IV therapy, and other important treatments in observation and other hospital outpatient areas. This is particularly true in rural communities where patients and their health care providers must travel long distances. Consequently, ANA is pleased to see that CMS has extended its non-enforcement policy for Critical Access Hospitals and small rural hospitals, through 2012.

There is sound rationale for rescinding the direct supervision requirements for outpatient services. Registered nurses and other licensed health care professionals are subject to their own profession's scope of practice, established standards of care, code of ethics, and management structures. RNs are educated, trained and licensed to independently perform many aspects of direct patient care, and receive consultation, assistance and supervision from their nursing peers and nursing managers. RNs must practice within the law and the regulations of their State Board of Nursing. We are also required to follow professional rules of practice as embodied in ANA's *Nursing: Standards and Scope of Practice*, as well as the ANA *Code of Ethics*. RNs must exercise a significant degree of independence, responsibility, and accountability. Nurses have an ethical, and legal, duty to exercise their own judgment about the care they provide, and to refuse to follow orders when doing so would endanger the health, safety, or well-being of their patients. RNs are independently liable for their actions – and simply following orders is not an acceptable defense. And every RN is educated, trained, and has a duty to independently perform cardiopulmonary resuscitation, use an automatic defibrillator, and provide rescue-breathing in emergency situations.

In many outpatient health care arenas, nurse managers, not physicians, are responsible for providing ongoing supervision of patient care provided by RNs. Nurse managers play a particularly valuable role in hospital observation units, and many hospital outpatient clinics. In observation units, a physician or nurse practitioner with responsibility for numerous patients cannot possibly supervise the RNs who provide nursing care for their patients, around the clock. As a practical matter, no hospital could function 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) medication, 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, physicians are not prepared to assume responsibility for the care nurses provide, such as the preparation of chemotherapy for IV administration.

The 21st century brings greater recognition of the importance of evidence-based, outcome-oriented health care. The presumption of the ongoing need for physician supervision of RNs stems from the erroneous notion that any physician is more capable of providing care than every other type of health care professional. There is no support for this either in evidence or scientific research. Many patients now receive extensive, high-quality care from a wide array of

highly qualified, educated, and experienced providers, all of whom play a significant role in ensuring safe, quality patient care. Physician supervision does not necessarily guarantee safe care. In fact, physicians have been implicated in the increase in wrong-patient and wrong-site surgical errors since the Joint Commission adopted a three-step “universal protocol” in 2004, which mandates a pre-procedure verification, site marking, and “timeout.” Errors were attributed to failure to comply with protocols, poor communication and “lack of physician leadership.” LaMar McGinnis, MD, past president of the American College of Surgeons and its representative to the Joint Commission, said “This is where top-down leadership comes in. The chief of surgery needs to make a stand that this will be done – no ifs, ands, or buts.”¹ Historically, the medical profession has been intransigent in opposing innovations designed to improve patient safety, not the least of which was its refusal to adopt hand washing to prevent infection, even when performing surgery.

Two-phase supervision for “extended duration services” is a major improvement. In the 2011 OPPTS/ASC final rule, CMS established a new category of services, “nonsurgical extended duration therapeutic services,” (also known as extended duration services), which have a substantial monitoring component. *Direct* supervision is required during the initiation phase of these services, but after the patient is stable, the service can continue under *general* supervision. If the existing direct supervision rules and policies continue to remain in effect, we believe that this two-phase approach can be very helpful in significantly decreasing the burden in application of the direct supervision requirements.

In previous comments, ANA urged CMS to apply the “two-phase” approach to all independent nursing interventions, and not just for a limited number of “extended duration services.” We continue to advocate for CMS to expand the approach in this manner. As noted above, every day nurses independently and competently assess patients, identify patient problems, and plan, implement and evaluate nursing care, all of which is within the exercise of the scope and standards of nursing practice and expertise, without physician supervision. ANA would be happy to work with CMS to define “independent nursing interventions” which should be subject to the two-phase approach.

There are several aspects of this two-phase approach, as described previously by CMS, which ANA believes contribute to a fair and open process and input from the affected parties. In general, we are supportive of the creation of an independent advisory review process, to consider requests for assignment of supervision levels other than direct supervision for specific outpatient hospital therapeutic services. And we agree that this could properly be a subregulatory process, rather than adhere to the strict once-a-year annual rulemaking process. In addition, we appreciate CMS’ plans to provide an opportunity for public comment on the proposed decisions. We also commend CMS for contemplating and providing for reevaluation of such decisions.

ANA is profoundly disappointed that CMS has decided to apply a presumption of “direct supervision,” rather than establishing a “default supervision standard of general supervision for all therapeutic services” – for the many reasons previously noted. CMS has stated that “direct supervision is the most appropriate level of supervision for most hospital outpatient therapeutic services due to the ‘incident to’ nature of most hospital outpatient therapeutic services.” The agency admits in the Proposed Rule that “the statute does not explicitly mandate direct

¹ O’Reilly, K.B. (2010). Wrong-patient, wrong-site procedures persist despite safety protocol. *American Medical News*, Nov. 1, 2010, 2. American Medical Association. Accessed at: <http://www.ama-assn.org/amednews/2010/11/01/pr121101.htm>.

supervision.”² Why, then, has CMS chosen to interpret the policy in a manner that is largely unsupported by health care providers, and unsupported by evidence indicating a need for additional layers of supervision – which in and of themselves, have not been shown to increase patient safety or outcomes?

Additionally, we have serious concerns about the selection and role of the independent review body.

The Independent Review Panel must have a clinical focus and adequately represent nurses and other health care professionals who provide outpatient therapy services.

In the Proposed Rule, CMS proposes to designate the Federal Advisory Ambulatory Payment Classification (APC) Panel as the independent review entity to consider and make recommendations with respect to inquiries about appropriate levels of supervision. Another option mentioned for the review entity was the Relative Value Scale Update Committee (RUC). We understand the budget constraints under which federal agencies are currently operating, which may severely limit CMS resources to create a new, independent advisory review board. However, we have serious concerns about the appropriateness of the APC Panel to serve in this capacity (and believe these concerns would also apply to the RUC as well). Specifically:

1. The focus, expertise, and current qualifications of the APC Panel relate to reimbursement, not clinical care. As noted in the Proposed Rule, “the review entity should base its recommendations on any clinical evidence that is available. It should also take into consideration any known impacts of supervision on quality of care.”³ We wholeheartedly agree that *clinical* considerations are paramount in the independent review panel and its process. Unfortunately, that is not the type of background required for membership on the APC Panel. Rather, APC Panel members are chosen on the basis of their expertise regarding *payment and reimbursement*.

Advisory Panel on Ambulatory Payment Classification Groups

* * *

All members must have technical expertise that shall enable them to participate fully in the work of the Panel. Such expertise encompasses hospital payment systems, hospital medical-care delivery systems, outpatient payment requirements, APCs, Current Procedural Technology codes, and the use/payment of drugs and medical devices in the outpatient setting—as well as other forms of relevant expertise. However, it is not necessary that any member be an expert in all of the areas listed above.⁴

2. There is a conflict of interest between reimbursement and supervision issues. Reimbursement experience has negligible relevance to clinical issues; in fact, the two issues are often directly in conflict. Level of supervision is exclusively a question of clinical expertise, not reimbursement. Level of supervision may result in a higher or lower reimbursement, and this should not be a factor in the supervision decision. How would the APC members be able to separate these issues, either consciously or unconsciously? We assert that they cannot possibly be expected to do that.

² Proposed Rule, 76 Fed. Reg. at 42281.

³ Id.

⁴ CMS Website,

https://www.cms.gov/faca/05_advisorypanelonambulatorypaymentclassificationgroups.asp

3. The APC Panel lacks adequate representation of RNs and other key health care professionals who provide outpatient therapy services. In administering intravenous medications and chemotherapy, RNs are the largest contingent of providers of outpatient therapy services. Physical therapists (PTs), occupational therapists (OTs), and respiratory therapists (RTs) also account for a substantial portion of outpatient therapy services. These health professionals are the experts in what they do, and must be able to provide their crucial input in determining appropriate levels of supervision for their services. Unfortunately, the current/most recent make-up of the panel lacks any PTs, OTs, or RTs, and includes only one RN.

The APC Panel is comprised primarily of physicians, plus technical/policy experts who lack any clinical background. As of June 2011, 8 of the 15 APC Panel members, in addition to the CMS representative, were medical doctors. The two other health care professionals were a registered nurse (Kathleen Graham, RN, MSHA, CPHQ, ACM) and a pharmacist (Agatha Nolen, PhD, MS, FASHP). The other 5 members – 1/3 of the panel -- appeared to have no clinical expertise: a certified public accountant (Kari Cornicelli, CPA, FHFMA); health care executive (Patrick Grusenmeyer, ScD, FACHE); two experts in health information technology (Judith Kelly, BSHA, RHIT, RHIA, CCS, and Daniel Pothen, MS, RHIA, CPHIMS, CCSP, CHC); and a payment and coding specialist (John Marshall, CRA, RCC, RT). While we trust these 5 individuals bring laudable experience and credentials in their respective fields of significant value to the Panel's payment issues, they have no place participating in decisions of a purely clinical nature.

4. CMS must either select or create another review panel, or significantly amend the APC Panel's charter. For the foregoing reasons, it is incumbent upon CMS to either create a more appropriate, clinically-focused advisory panel to make supervision determinations, or select an existing panel which currently advises the Agency for Healthcare Research and Quality; Centers for Disease Control and Prevention; Department of Health and Human Services; the Health Resources and Services Administration, etc.

Alternatively, CMS would need to significantly alter the APC Panel's charter to ensure adequate representation and appropriate decision-making by adding amendments that would: a) Add clinical expertise as a qualification for all panel members who participate in supervision decisions; b) Create additional positions designated for RNs, PTs, OTs, RTs, and other providers of outpatient therapeutic services; c) Exempt non-clinical members from participating in discussions or voting regarding appropriate levels of supervision; and d) Clarify that reimbursement shall not be a factor in decisions regarding levels of supervision.

XIV. Hospital Outpatient Quality Reporting Program Updates and ASC Quality Reporting

General principles applied for the development and use of measures. In the Proposed Rule, CMS states the following:

Pay-for-reporting, public reporting and value-based purchasing programs should rely on a mix of standards, processes, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience of care measures. To the extent practicable and appropriate,

outcome and patient experience of care measures should be adjusted for risk factors or other appropriate patient population or provider characteristics.

The American Nurses Association supports public reporting and pay for quality programs across settings.⁵ However, the ANA supports the use of Donabedian's framework, that structural, process, and outcome measures are all necessary to fully assess the quality of care, including transitional care, across all clinical settings.⁶ The link between structures of care, such as nurse staffing and skill mix, and improved patient outcomes, is supported by over two decades of research in acute care, which ANA has specified in comments on the Inpatient Prospective Payment System (IPPS) proposed rule in 2011. Interprofessional teams in outpatient settings provide health care to diverse populations with complex acute and chronic illnesses. Patients need the right mix of clinicians and staffing to provide safe, effective care in these settings and in transition to self-care. Additional structural supports, such as a safety culture, are also essential to ensure patient safety outcomes.

ANA applauds the expansion of quality measures into the outpatient prospective payment system (PPS), including the ambulatory surgical care (ASC) and emergency department settings. Prevention of healthcare acquired conditions (HCAC) and ensuring that patient-centered care is provided is important in these rapidly expanding areas. Moreover, the ANA supports the following comments submitted by the Association of periOperative Nurses (AORN), which focus on the quality measures proposed in the OPSS and ASC Proposed Rule:

Comments of Association of periOperative Nurses (AORN)

The AORN supports continued progress by CMS in expanding the use of quality related measures in OPSS and ASC as these are important lower cost and rapidly growing outpatient surgical settings available for Medicare beneficiaries. We encourage CMS to address a strategy to reach the safety and quality needs for the growing area of office based surgery as well.

Patients' Experience-of-care Measures:

While process of care, structural and outcomes measures are important we are disappointed that CMS has not moved more quickly with patients' experience-of-care measures as this presents the best opportunity for assessing our movement toward a more patient centered model of care. We encourage CMS to move more rapidly to allow OPSS and ASCs to provide on a voluntary basis patients' experience-of-care measures.

Transparency and Comparisons:

One important aim of reporting quality measures is the opportunity to present publically the results and for patients and their families to have information to compare quality (and cost) of providers. We encourage CMS to accelerate the timeframe for making measure results for surgical care in the OPSS and ASC publically available.

The compare system needs to be patient centered, NOT provider center. Thus where the patient has choices among sites of setting – i.e. ASC or OPSS for surgical or preventive procedures, CMS should provide easy access to compare these choices –

⁵ American Nurses Association (2010). Principles for Pay for Quality. Washington, DC: Nursesbooks.org.

⁶ Donabedian, A. (1988). The quality of care: How can it be assessed? *Journal of the American Medical Association*, 260,1743-1748.

especially for higher volume procedures. To achieve this goal of transparency and comparisons, CMS needs to specifically address a strategy for harmonizing measures between different types of surgical settings.

ASC Measure Comments:

ASC 1-6: Fully support. Consider harmonizing/requiring for OPPS.

ASC 7 (antibiotic selection): This is a physician level measure and would impose an additional burden on the ASC to report. ASC 5 addresses timing and is in the purview of the ASC. A similar but not identical measure is in place for inpatient and OPPS. What procedure codes would allow best comparisons?

ASC 8 (SSI): Support with two concerns: 1) the CDC's NHSN system is designed for hospitals and creates an unnecessary burden on ASCs; thus a NHSN system needs to be modified specifically for ASCs. 2) many procedures captured currently are not provided in ASC. How does this impact transparency and comparisons?

ASC 9 (checklist): Fully support.

ASC 10 (procedure volume reporting): Fully support and need to harmonize with OPPS for high volume surgical procedures.

ASC 11 (vaccination): Need to limit burden to ASC staff, not to all personnel.

ASC Measure reporting and timing:

The timeframe for initial reporting is too aggressive since CMS has not provided any details on how to submit claims. CMS should either make the reporting for the first year voluntary, or not impose penalties until after a 12 to 18 month phase-in period of the claims-based system. The agency should specifically allow and establish parameters for a registry system of submission. As mentioned earlier, the NHSN system needs to be modified and streamlined for the more narrow and smaller range of services the ASC presents.

OPPS measures:

Checklist: Fully support.

Procedure volume reporting: Fully support and need to harmonize with ASC for high volume surgical procedures.

Pay for Quality in the Emergency Department. ANA also supports quality measures for pay for quality in the emergency department (ED). The Emergency Nurses Association (ENA) convened a diverse group of nine key stakeholders that signed onto a consensus statement, "*Definitions for Consistent Emergency Department Metrics.*"⁷ ANA supports the importance criteria and definitions for ED quality measures noted in this document. The ENA position statement noted:

⁷ Emergency Nurses Association (ENA). (2011). *Definitions for Consistent Emergency Department Metrics.*

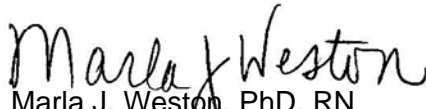
The emergency department (ED) has become the “portal to the community” and the entry point where most patients are introduced to the health care system. It is also a logical place to expedite needed reform to ensure universal access to essential health care services. This situation has led the undersigned stakeholder organizations to develop metrics that will aid in helping to alleviate the critical situation facing our emergency departments in the care of their patients.

We urge CMS to utilize importance criteria and definitions in the ENA position statement when choosing quality measures for value-based purchasing, to better evaluate the quality of care provided by interprofessional teams.

Conclusion

We appreciate the opportunity to share our views regarding this Proposed Rule. We would be happy to speak with CMS leadership and staff further about these comments, and we would particularly welcome an opportunity to dialogue about the need to rescind the supervision requirements for outpatient services. Please feel free to contact Eileen Carlson, RN, JD, Associate Director, ANA Government Affairs, at eileen.carlson@ana.org or (301) 628-5093. For questions regarding quality reporting, please contact Maureen Dailey, DNSc, RN, CWOCN, Senior Policy Fellow, National Center for Nursing Quality, ANA, at maureen.dailey@ana.org or (301) 628-5062.

Sincerely,



Marla J. Weston, PhD, RN
Chief Executive Officer
American Nurses Association

Cc: Karen A. Daley, PhD, MPH, RN, FAAN
President
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