



8515 GEORGIA AVENUE, SUITE 400
SILVER SPRING, MARYLAND 20910-3492
301 628-5000 • FAX 301 628-5001
www.NursingWorld.org

KAREN A. DALEY, PhD, MPH, RN, FAAN
PRESIDENT

MARLA J. WESTON, PhD, RN
CHIEF EXECUTIVE OFFICER

August 30, 2012

Honorable Marilyn Tavenner, MHA, RN
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1590-P / RIN 0938-AR11
PO Box 8013, Baltimore, MD 21244-8013
Sent via email to: <http://www.regulations.gov>

Re: **Medicare Physician Fee Schedule/Part B Proposed Rule, Revisions, and Payment Update for Calendar Year 2013.** 77 Fed Reg. 44722 (July 30, 2012).

Dear Administrator Tavenner:

ANA welcomes the opportunity to provide comments on this proposed rule. As the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, ANA is privileged to speak on behalf of its state and constituent member associations, organizational affiliates, and individual members. As you are no doubt aware, RNs serve in multiple direct care, care coordination, and administrative leadership roles, across the full spectrum of healthcare settings. ANA members include advance practice registered nurses (APRNs) such as nurse practitioners (NPs), certified registered nurse anesthetists (CRNAs), clinical nurse specialists (CNSs), and certified nurse-midwives (CNMs).

As detailed below, ANA urges the Agency in its final Physician Fee Schedule rule to support the nursing profession through the adoption of:

- CPT codes, and Medicare reimbursement, for transitional care management and chronic care coordination services;
- Provider-neutral language and attribution policies capturing the work of RNs & APRNs;
- Direct Medicare reimbursement for chronic pain management services by CRNAs;
- Clarification that NPs, CNSs, and CNMs may order portable X-ray services;
- New policies allowing NPs, CNSs and CNMs to order durable medical equipment and conduct the face-to-face encounter for their patients; and
- Part B coverage for Hepatitis B vaccine for diabetics.

I. Care Coordination

ANA urges CMS to adopt the new CPT codes for transitional care management and chronic care coordination services and consider the RUC's value recommendations.

ANA applauds CMS for taking the initiative to recognize the inherent value of post-discharge transitional care management, by proposing a HCPCS G-code and related values for this service. We urge CMS to adopt the new CPT (Current Procedural Terminology) codes that have been approved for transitional care management as well as chronic care coordination services. These codes were developed through the joint efforts of many specialty societies representing professionals who provide these services, including ANA. We also fully endorse and support the comments of the American Medical Association Specialty Society RVS Update Committee (RUC) regarding these codes. We urge CMS to give serious consideration to the value recommendations which the RUC plans to issue at its next meeting, October 5-6, 2012.

ANA has participated in the development of the CPT codes for transitional care management and chronic care coordination services, and their valuation, through its representation of the nursing profession on the RUC and CPT Editorial Panel's Health Care Professionals Advisory Committees ("HCPACs").¹ ANA also is a voting member of the RUC Practice Expense Subcommittee,² as well as various RUC and CPT workgroups. Since the creation of the CPT Editorial Panel and the RUC, CMS has generally adopted CPT codes within HCPCS, and has taken RUC value recommendations – for work, practice expense, and malpractice insurance – into account in arriving at Medicare values for CPT codes. We see no reason for CMS to diverge from its longstanding practice with respect to these services.

For many years, ANA has stressed fundamental importance of care coordination and transitional care for our patients, the pivotal role that registered nurses play, and how care coordination is an integral part of nursing practice. Many RNs provide care coordination as a key component of their nursing practice, in various nursing roles and across all health care settings. Many full-time care coordinators, patient navigators, case managers, etc., are RNs. Moreover, ANA sees a particular need for expanded recognition and reimbursement for care coordination services, as well as transitional care management, as our population ages and becomes more saddled with obesity and inactivity; as we face a burgeoning of health insurance coverage under the Affordable Care Act; and as our health care system becomes more complex – making it difficult for patients and families to coordinate their own care.

Standard 5A of the Nursing Scope and Standards of Practice states that "The registered nurse coordinates care delivery" and details six related competencies:

The registered nurse:

- Organizes the components of the plan.
- Manages a healthcare consumer's care in order to maximize independence and quality of life.
- Assists the healthcare consumer in identifying options for alternative care.
- Communicates with the healthcare consumer, family, and system during transitions in care.
- Advocates for the delivery of dignified and humane care by the interprofessional team.
- Documents the coordination of care.³

RNs and APRNs, particularly Mary Naylor, PhD, RN, FAAN, Professor of Gerontology and Director of the New Courtland Center for Transitions and Health at University of Pennsylvania School of Nursing, have been at the forefront in developing transitional care models that improve quality of care, while reducing readmissions and overall costs of care. Dr. Naylor's transitional care model in particular has generated considerable interest.⁴ Indeed, Dr. Naylor's

¹ The RUC HCPAC makes relative value recommendations for services provided exclusively by non-physician practitioners.

² The RUC Practice Expense Subcommittee recommends appropriate nursing staff levels and time for the clinical staff component of PE relative value units (RVUs).

³ American Nurses Association. (2010). *Nursing: Scope and Standards of Practice, 2nd edition, Standard 5A*. Silver Spring, MD: Nursesbooks.org, 40.

⁴ See, e.g.: Naylor, M.D., Broton, D.A., Campbell, R.L., Maislin, G., McCauley, K.M., Schwartz, J.S. (2004). Transitional care of older adults hospitalized with heart failure: A randomized controlled trial. *Journal of the American Geriatric Society*, 52(5), 675-684.

work inspired section 3026 of the Affordable Care Act, the Community Based Care Transitions Program.

ANA has been engaged in a thorough review of the central role of RNs in care coordination, which culminated in the recent release of a Position Statement and White Paper. ANA's Position Statement, entitled "*Care Coordination and Registered Nurses' Essential Role*," is instructive and emphatic.

(1) Patient-centered care coordination is a core professional standard and competency for all registered nursing practice. Based on a partnership guided by the healthcare consumer's and family's needs and preferences, the registered nurse is integral to patient care quality, satisfaction, and the effective and efficient use of health care resources. Registered nurses are qualified and educated for the role of care coordination, especially with high risk and vulnerable populations.

(2) In partnership with other healthcare professionals, registered nurses have demonstrated leadership and innovation in the design, implementation, and evaluation of successful team-based care coordination processes and models. The contributions of registered nurses performing care coordination services must be defined, measured and reported to ensure appropriate financial and systemic incentives for the professional care coordination role.⁵

The ANA White Paper, entitled "*The Value of Nursing Care Coordination*,"⁶ reviews the literature regarding the experience of nurses in care coordination. As stated therein, RNs and APRNs have been performing care coordination as a core part of the nursing discipline since the turn of the 19th century, two hundred years ago. The evidence supporting the essential value that registered nurses bring to care coordination today includes: reductions in emergency department visits; noticeable decreases in medication costs; reduced inpatient charges; significant increases in survival with fewer readmissions; lower total annual Medicare costs; increased patient confidence in self-managing care; improved quality of care; increased safety of older adults during transition from an acute care setting to the home; improved clinical outcomes and reduced costs; and improved patient satisfaction overall.

MedPAC, the Medicare Payment Advisory System, in its June 2012 Report to Congress also supported the inherent value of care coordination:

Gaps exist in care coordination in fee-for-service (FFS) Medicare because of the fragmentation of service delivery, the lack of tools to help communicate across settings or providers, and the lack of a financial incentive to coordinate care. These gaps are particularly important in Medicare because beneficiaries are more likely to have multiple chronic conditions than younger patients, requiring more interaction with the health care system. The effects of poor care coordination include beneficiaries having to repeat medical histories and tests, receiving inconsistent medical instructions or

⁵ American Nurses Association (2012). *Care Coordination and Registered Nurses' Essential Role*. Silver Spring, MD: www.nursingworld.org/position/care-coordination.

⁶ American Nurses Association (2012). *The Value of Nursing Care Coordination, A White Paper Of The American Nurses Association*. Silver Spring, MD: www.nursingworld.org/carecoordinationwhitepaper. Annotated Bibliography: www.nursingworld.org/carecoordinationannotatedbib.

information, experiencing poor transitions between sites of care, and using higher intensity settings when it is not necessary.⁷

MedPAC gave no formal recommendations on care coordination reimbursements. And the report noted and discussed the pros and cons of alternative payment methods, including capitation, capitation for special patients only, care coordination businesses, payments for transitions only, and outcomes based incentive payments, which would be indifferent to how good care coordination outcomes are produced.

Nevertheless, the Commission noted that despite mixed results from recent Medicare demonstrations, “Restructuring the way care is provided may be necessary to achieve good care coordination, but such restructuring is difficult in a FFS environment” and new initiatives like accountable care organizations and bundled payment initiatives “will take time to develop. In the interim, it may be necessary to take intermediate steps to improve care coordination and provide explicit payments for the related activities that primary care clinicians do but that are not currently paid for under the FFS system.”⁸ Such options could include “billing codes in the physician fee schedule to direct resources toward care coordination activities” as well as “transitional care payments for patients being discharged from the hospital.”⁹

II. Language & Methodology Recognizing Contributions of RNs & APRNs

CMS should consistently adopt provider-neutral language and record-keeping procedures which fully recognize the contributions of RNs and APRNs.

A growing number of APRNs are enrolled as Medicare and Medicaid providers. For 2010, CMS reported that 51,843 nurse practitioners, clinical nurse specialists and certified-nurse midwives directly billed Medicare Part B carriers alone. Many of these APRNs serve as primary care providers, particularly for underserved populations and in rural areas, and are thus charged with ensuring their patients receive appropriate, well coordinated care. These APRNs deserve to see their efforts rewarded when they provide transitional care management and chronic care coordination services, for their sickest and most complex patients.

Given the increasing level of primary care services billed directly by Medicare non-physician providers, and the growing emphasis on true team-based care, ANA urges CMS to clarify that transitional care services can be provided by “physicians or other qualified healthcare professionals.” CMS should employ provider-neutral language elsewhere in the notice of proposed rulemaking (NPRM), as well, wherever this is appropriate. This should be changed uniformly throughout the proposed regulation, to reflect current practice.

Furthermore, ANA believes that it is important that the administrative records/claims identify the NPI of the performing care coordinator, who might be any member of the primary care clinical team. As we have indicated before, many times the actual care coordinator will be a registered nurse. In order to evaluate and improve care coordination methods, it will be crucial to identify the types of clinicians who actually effect care coordination. Simply listing a primary care practice NPI will obscure the evidence needed to study care coordination to understand and enhance its effectiveness.

⁷ Medicare Payment Advisory Commission (June 2012). *Report to the Congress: Medicare and the Health Care Delivery System*. Washington, DC, 33.

⁸ *Id.* at 34.

⁹ *Id.*

III. Certified Registered Nurse Anesthetists and Chronic Pain Management Services**5**

ANA joins its organizational affiliate, the American Association of Nurse Anesthetists, in strongly urging CMS to continue direct Medicare reimbursement to CRNAs who provide valuable chronic pain management services.

ANA applauds CMS for clarifying that chronic pain management is within the scope of the statutory Medicare benefit for services by certified registered nurse anesthetists (CRNAs). We also fully endorse the position of our organizational affiliate, the American Association of Nurse Anesthetists, in their comments on this issue. We urge CMS to give very careful consideration to the AANA's considerable expertise on this issue.

For several years, Medicare directly reimbursed CRNAs for the essential chronic pain management services which they provided to Medicare beneficiaries. This service is critically needed by many patients, particularly those who live in rural or underserved areas of the country, who would otherwise not have access to clinicians to provide this care. The Institute of Medicine (IOM) has reported that 100 million Americans suffer from chronic pain, at an annual economic and health care cost exceeding \$600 billion per year. IOM also says that not enough healthcare professionals are available to provide this needed service.¹⁰ Furthermore, chronic pain management services lie within the scope of practice for CRNAs. Nurse anesthetists providing these services have obtained specialized training in addition to their comprehensive anesthesia education. Referring physicians rely upon the expertise of such CRNAs in caring for their patients.

In fact, as early as 2003, the Part B Medicare Carrier Claims Processing Manual noted that pain management services could be provided by CRNAs. Despite that history, in 2011, two Medicare Administrative Contractors (MACs) issued bulletins denying direct reimbursement for CRNA chronic pain management services. By failing to take action to reverse these decisions, the Medicare program essentially put patients at risk of losing access to very necessary care. Fortunately, Medicare has taken a positive step in restoring patient access to chronic pain management services provided by CRNAs, and we applaud the agency for this effort. In the proposed rule CMS acknowledges that CRNAs "have moved into other practice settings" beyond the surgical, and some "now offer chronic pain management services that are separate and distinct from a surgical procedure." In deferring to states on what constitutes care "related to anesthesia," Medicare should not burden states with more red tape to secure Medicare reimbursement for CRNA pain management services within their scope of practice. By supporting access to CRNA pain care in the community, Medicare will help keep patients from having to consider much less favorable alternatives. These include long distance travel to unfamiliar providers at great cost to where alternative care is available, costly and extensive surgery, institutionalization in a nursing home, and significant detriment to quality of life.

Chronic pain management is a one of the biggest challenges in health care today. Even physicians cannot agree on which specialties and/or certifications are appropriate or should be required. In the meantime, patients with intractable, debilitating and life-altering pain continue to be at a loss for what to do. CRNAs have the education, clinical training, professional experience and expertise to make a real difference for many of these patients. They are already permitted to provide "related services" such as Swan Ganz catheters, central venous

¹⁰ Institute of Medicine (2011). *Relieving Pain in America*. Washington, DC: The National Academies Press, 1.

pressure lines, pain management, emergency intubation, and pre-anesthetic exams and evaluations. Chronic pain management should clearly fall within permitted “related services.”

IV. Ordering of Portable X-Ray Services

ANA fully supports CMS’ clarification that portable x-ray services can be ordered by Clinical Nurse Specialists, Certified Nurse-Midwives, and Nurse Practitioners.

ANA commends CMS for clarifying that nonphysician practitioners and physicians other than MDs and DOs, acting within the scope of their Medicare benefit and State law, are allowed to order portable X-ray services. We support the revisions to the Medicare Conditions for Coverage at 42 CFR 486.106(a) and (b), permitting portable x-ray services to be ordered by a physician or nonphysician practitioner in accordance with the ordering policies for other diagnostic services under 42 CFR 410.32, for which several technical changes were also proposed.¹¹ We also are encouraged by the agency’s recognition that “Nonphysician practitioners have become an increasingly important component of clinical care, and we believe that delivery systems should take full advantage of all members of a healthcare team, including nonphysician practitioners.”¹²

ANA was among the stakeholder groups which informed CMS of the considerable confusion resulting from the December 2011 report of the Health and Human Services Office of Inspector General, *“Questionable Billing Patterns of Portable X-Ray Suppliers,”* which revealed inconsistencies between payment policies and the Medicare Conditions for Coverage. The report concluded that “Medicare paid at least \$6.6 million for portable x-ray services that were ordered by nonphysicians and therefore not covered.” It specifically noted that NPs ordered \$4.3 million of these services and suggested that “overpayments” should be collected. In fact, Medicare contractors had long recognized NP authority to order portable x-rays based on regulations promulgated in 1997. ANA, along with other professional organizations representing APRNs, met with staff from the Center for Program Integrity and suggested that this NPRM be used to clarify that the OIG report was based on limited interpretation of earlier provisions stating that portable x-ray examinations are performed on the order of an MD (medical doctor) or DO (doctor of osteopathy). We appreciate that the Agency has taken this opportunity to do so.

The report also indicates that some patients are receiving portable x-rays, the same day they are also receiving services in a hospital, physician office, or other clinical setting. In the notice of proposed rulemaking, CMS says this raises an issue about the validity of the statement of need required for the portable x-rays. In some cases, a portable X-ray on the same day is clinically warranted. For example, a patient that has a standard chest X-ray in the clinical setting may go into arrest and require intubation. A portable X-ray would be ordered post-intubation to ensure proper placement of the endotracheal tube. Similarly, patients with nasogastric tubes would require a portable X-ray to verify proper placement.

¹¹ The proposed rule does not change the definition of “nonphysician practitioners” in 42 CFR 410.32(a)(2): “Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.”

¹² 77 Fed. Reg. at 44790.

The possibility of multiple trips by suppliers to the same facility was also found to be of concern. Therefore, CMS is considering developing new monitoring standards, and conducting data analysis to prevent abuse of this service. CMS also encourages providers, “as with any diagnostic test, to proactively determine and document the medical necessity for this testing.”¹³

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We applaud the agency’s plan to conduct data analysis of ordering patterns for diagnostic services and to carry out additional provider audits and fraud investigations. This approach is more appropriate and likely to be more successful in revealing fraud and abuse, than relying upon, or deferring to, physician oversight and documentation of other practitioners.

V. Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

ANA urges CMS to support policy changes permitting Clinical Nurse Specialists, Certified Nurse-Midwives, and Nurse Practitioners to order durable medical equipment and conduct the related face-to-face encounters.

The proposed rule implements provisions of the Affordable Care Act that require a face-to-face encounter as a condition of payment for certain durable medical equipment (DME). ANA is aware of the impact of fraud and abuse on healthcare spending and fully supportive of effective efforts to identify and end healthcare fraud. We understand that DME is an area of particular concern and agree that a face-to-face encounter with the beneficiary to substantiate that the beneficiary’s condition warrants the covered item of DME may well reduce the risk of fraud, waste and abuse. However, the requirement that a *physician* document that encounter is an unnecessary and unwarranted requirement.

We understand that the requirement for physician documentation is a statutory one, and that it is the responsibility of the agency to promulgate the necessary rules to implement this provision of the Act. Nevertheless, ANA cannot support any of the proposed options because of this fundamental flaw, and urges reconsideration of this wasteful and unnecessarily narrow requirement.

ANA implores the agency (as we have also advocated to Congress) to shift the focus away from *physician* accountability to *provider* accountability. The time to shift perspective on this fundamental issue has clearly arrived. In this particular context, nurse practitioners (NPs), clinical nurse specialists (CNSs) and certified nurse-midwives (CNMs, not named in this provision) are all well-qualified to make the appropriate assessment to order DME. There is no evidence that requirements for physician oversight or supervision increase quality or reduce fraud. We do know that unwarranted requirements for physician supervision lead to delays in care and duplication of services. As our healthcare system evolves to a team-based model of care that depends more heavily on interprofessional collaboration, our laws and regulations must evolve. Requirements for physician documentation of an assessment made by another qualified provider are a holdover from a 20th – or even 19th -- century healthcare system.

Moreover, NPs, CNSs and CNMs who have a closer relationship, and more day-to-day contact, with their patients than physician providers, are in a better position to accurately assess a patient’s condition and need for DME. Additionally, NPs, CNSs and CNMs generally have no business or financial arrangements with DME suppliers, so have fewer incentives to commit fraud, waste or abuse in ordering unnecessary equipment or supplies. Furthermore, advanced

¹³ Id.

practice RNs are authorized to order other services and products for their patient under Medicare and Medicaid laws, regulations and other policies, without the signature of a physician, including the ability to order portable x-rays per CMS' proposed rule.

As noted above, certified nurse-midwives (CNMs) are not expressly identified in the face-to-face requirements detailed by the proposed rule with respect to DME. We note, however, CNMs are included in the face-to-face requirements proposed for ordering home health services as required by Section 10605 of the ACA. CNMs do periodically need to order DME products for their Medicare and Medicaid patients and such activity is well within their scope of practice and clinical judgment. Again, we realize the agency is implementing a flawed statute, but we urge the Secretary to carefully consider the impact on patients of CNMs, particularly in rural and urban underserved areas, if CNMs are not able to fulfill the face-to-face requirement for DME products. Thus, we ask the Secretary to expand upon the proposed rule to allow CNMs to meet the face-to-face requirements of ordering DME products and supplies as the Secretary has done with respect to the face-to-face requirements for ordering of home health services.

VI. Hepatitis B Vaccine for Diabetics


ANA supports Part B coverage for the Hepatitis B Vaccine for diabetic patients.

ANA supports the proposed changes to 42 CFR 410.63(a)(1), to include under Medicare Part B coverage of the Hepatitis B vaccine for persons diagnosed with diabetes mellitus. As a liaison member of the Advisory Committee on Immunization Practices (ACIP), ANA supports inclusion of the committee's recommendations in Medicare payment policy enacted by CMS. ANA advocates for equitable coverage of all ACIP recommended vaccines for all Medicare beneficiaries, especially the herpes zoster vaccine.

VII. Conclusion

ANA sincerely appreciates this opportunity to share our views and expertise on these important issues. We would be happy to discuss these issues further if you should have any questions. Please feel free to contact Eileen Shannon Carlson, RN, JD, ANA Associate Director of Regulatory Affairs, at eileen.carlson@ana.org, or 301-628-5093.

Sincerely,



Marla J. Weston, PhD, RN
CEO, American Nurses Association

cc: ANA President, Karen A. Daley, PhD, MPH, RN, FAAN