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September 12, 2011

Donald M. Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2348-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically to <http://www.regulations.gov>

Re: **Medicaid Program; Face-to-Face Requirements for Home Health Services;
Policy Changes and Clarifications Related to Home Health**
CMS-2348-P; RIN 0938-AQ36; 76 Fed. Reg. 41032 (July 12, 2011)

Dear Dr. Berwick:

The American Nurses Association (ANA) appreciates the opportunity to offer comments regarding 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 in the United States. We represent 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 registered nurses (APRNs) such as nurse practitioners (NPs), clinical nurse specialists (CNSs), certified registered nurse anesthetists (CRNAs), and certified nurse-midwives (CNMs).

ANA is fully supportive of efforts to align Medicare and Medicaid programs and understands the need for careful documentation of the need for home health services, particularly to prevent fraud and abuse. We appreciate that CMS is making an effort to simplify implementation of the face-to-face encounter requirements while avoiding the creation of unnecessary barriers to care. We offer these comments to promote simplicity while increasing access to critically needed home care services.

I. Face-To-Face Encounters

The proposed rule would add a new requirement under Medicaid that physicians must document a face-to-face encounter with the Medicaid eligible individual, within a reasonable time frame, to support a certification that home health services are required. This would implement section 6407 of the Affordable Care Act, and bring Medicaid policies in line with those of Medicare. Home health care is one of the "mandatory services," which states must offer to their citizens who are entitled to nursing facility services. Home health services include skilled nursing, home health aide services, medical supplies, equipment, and appliances, and may include therapeutic services as well.

A. The proposed regulation appropriately allows “nonphysician practitioners” to conduct the face-to-face encounter with the patient.

Section 440.70(f)(2) of the proposed regulation specifically authorizes the face-to-face encounter with the Medicaid patient to be conducted by the following designated “nonphysician practitioners,” in addition to the certifying physician and the attending physician for patients discharged from hospitals:

- (ii) A nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, working in collaboration with the physician described in paragraph (a) of this section, in accordance with State law;
- (iii) A certified nurse midwife, as defined in section 1861(gg) of the Act, as authorized by State law;
- (iv) A physician assistant, as defined in section 1861(aa)(5) of the Act, under supervision of the physician as described in subparagraph (a) of this section;

The proposed regulation also requires the nonphysician practitioner to “communicate the clinical findings of that face-to-face encounter to the ordering physician,” who must in turn “indicate the practitioner who conducted the encounter.”

We fully support this interpretation of the face-to-face encounter requirement. This is entirely consistent with, and reflective of, the care that is provided to patients every day – particularly with respect to transitioning to home health care. In many cases, it is the advanced practice registered nurse who is managing the patient’s care and most familiar with the patient’s health care needs and home environment. Requiring a physician to examine the patient would create the need for an unnecessary and duplicative encounter, not to mention wasting valuable and limited resources. Given the current shortage of primary care physicians, it could also result in a potentially costly delay in the patient’s discharge and transfer to home health care.

Advanced practice registered nurses are fully licensed professionals who practice within their legal authority and are accountable to their certifying bodies, professional societies, state licensing bodies, and to their patients.

B. “Nonphysician practitioners” should also be allowed to certify the need for home health services for their Medicare & Medicaid patients.

Under current law, only physicians are allowed to certify and initiate home health care for Medicare and Medicaid beneficiaries. Despite their proven track record of providing timely access to quality patient care, advanced practice registered nurses and physician assistants remain unable to order home health services for their Medicare and Medicaid patients. For many patients, a nurse practitioner or physician assistant is their primary care provider, responsible for providing and coordinating their direct care. Some of these patients may not even have direct access to a physician, particularly those living in rural and underserved areas, because of the well-documented and serious shortage of primary care physicians.

The decision about whether home health services are warranted should be made by the provider who is most familiar with the patient’s health care needs and home environment. The requirement that only a physician can order necessary home health care increases administrative burdens and creates more paperwork and unnecessary steps before a

beneficiary can get the home care they need. Current requirements can lead to needless delays in care. The mandatory involvement of a physician who is not familiar with a patient or otherwise involved in his or her care also adds an unnecessary layer of professional expenses, a particular concern with the growing prevalence and multiplying costs of home health services.

Legislation is pending before Congress to remedy this situation, and allow nurse practitioners, clinical nurse specialists, certified nurse midwives, and physician assistants to order home health care services, by signing the final plan initiating care, for Medicare and Medicaid beneficiaries. The Home Health Care Planning Improvement Act of 2011 (H.R. 2267/S. 227), which addresses Medicare, is supported by ANA, the National Association for Home Care and Hospice, the American Academy of Physician Assistants, the American College of Nurse Midwives, the American College of Nurse Practitioners, the American Academy of Nurse Practitioners, and the Visiting Nurse Associations of America. Similar provisions addressing Medicaid appear in other pending legislation.

C. CMS appropriately recognizes the potential need for telehealth face-to-face encounters.

Section 440.70(f)(5) of the proposed rule provides that “The face-to-face encounter may occur through telehealth, as implemented by the State.” ANA supports CMS’s decision to allow States to permit the face-to-face encounters to occur through the use of telehealth. Telehealth is an important tool to afford access to diverse health care services, particularly in rural areas, underserved metropolitan locations. It can be a life line for many patients, including those who are truly homebound. ANA supports this provision as a step in the right direction, and urges CMS to keep telehealth in mind as a factor to consider for each of its successive proposed rules and ongoing programs.

We also commend CMS for use of the term “telehealth,” which correctly describes the universe of health services provided by the diverse array of providers, versus “telemedicine,” which can be interpreted to focus on a more limited array of services offered by a particular set of providers. Unfortunately, there are many regulatory and procedural constraints which will need to be amended to enable full and successful implementation of telehealth services by all eligible healthcare providers, including registered nurses, advanced practice registered nurses, physical therapists, occupational therapists, speech-language-hearing professionals, and others.

II. Certified Nurse-Midwives should not be prohibited from ordering durable medical equipment (DME) for their patients.

CMS has taken this opportunity to align the definition of medical supplies, equipment and supplies, under section §440.70(b)(3) of the Medicaid regulations, with that of § 414.202 of the Medicare regulations. The proposed rule requires a face-to-face encounter, but specifically indicates this cannot be performed by a certified nurse midwife:

(g)(1) No payment may be made for medical equipment, supplies, or appliances referenced in paragraph (b)(3) of this section to the extent that a face-to-face encounter requirement would apply as durable medical equipment under the Medicare program, unless the physician referenced in paragraph (a)(2) of this section documents a face-to-face encounter with the recipient consistent with the requirements of paragraph (f) of this section except as indicated below.

(2) The face-to-face encounter may be performed by any of the practitioners described in paragraph (f)(2) of this section, with the exception of certified nurse-midwives, as described in paragraph (f)(2)(iii) of this section.

Medical supplies, equipment and appliances – also known as durable medical equipment (DME) are a very important component of the Medicaid home health benefit. Innovations in medical equipment are what allow many disabled and seriously ill individuals to remain in their homes and communities, and avoid having to spend their lives receiving care in a nursing home or other institution. The wide array of equipment currently available to assist with home care and activities of daily living – including ventilators, wound pumps, prosthesis, orthotics, wheelchairs, etc. -- is truly astounding.

ANA is aware of the serious potential for fraud and abuse by unethical DME suppliers, and the need to pose limits to prevent the waste and diversion of precious resources intended to support our neediest patients. We also understand, as CMS acknowledges, that the Affordable Care Act does not permit certified nurse-midwives to conduct face-to-face encounters for the purposes of ordering DME. We must, nevertheless, emphasize that there is no rational basis for singling out CNMs, and point out that this provision creates a particular hardship for their patients. We suspect that this is based on the inaccurate assumption that CNMs do not really need to order medical equipment for their patients.

The fact that certified nurse-midwives (CNMs) can conduct a face-to-face encounter for home health services but not for the ordering of DME is an inconsistency that negatively impacts the provision of health care. The inability of CNMs to order breast pumps is a particularly important example. The counseling and support that CNMs provide to pregnant and childbearing women is vital to meeting our national goal of increasing breastfeeding rates. Recent CDC data show that while 3 out of every 4 new mothers in the U.S. now start out breastfeeding, rates of breastfeeding at 6 and 12 months as well as rates of exclusive breastfeeding at 3 and 6 months remain stagnant and low. For the large number of women who return to the workforce, the use of a breast pump is critical to continue breastfeeding.

Another often overlooked and misunderstood fact is that many CNMs serve as primary care providers for their female patients, across their life span. How can they serve their patients fully, if they are unable to order the medical equipment and supplies they need for home health care? As a consequence, this exclusionary rule requires the intervention of another health care provider simply for the purpose of ordering equipment – effectively mandating an unnecessary additional expense.

III. ANA supports CMS's definition of home health services as not limited to homebound patients or home settings.

Section 440.70(c)(1) of the proposed regulation clarifies that home health services are not restricted to patients who are homebound, and services are not restricted solely to those provided in the home:

(c)(1) Nothing in this section should be read to prohibit a recipient from receiving home health services in any non-institutional setting in which normal life activities take place.

ANA applauds CMS for recognizing that such a restriction would, indeed, “ignore the reality that individuals with disabilities can and do live and function in the community.” We also agree that it is important to acknowledge that innovations in technology and services facilitate and support the ability of persons with even severe disabilities to participate in a wide variety of activities, which provides immeasurable benefits for their mental and physical health. Limiting the site of care would inhibit their participation in the community.

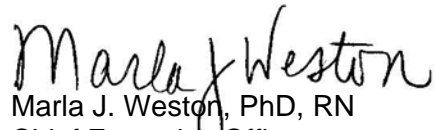
This has particularly important implications for the care that many nurses provide in the multitude of community settings. Community health and school nurses provide care to these patients every day. On their behalf, we particularly appreciate this clarification that Medicaid home health services may not be limited to services furnished in the home.

Home health services are an extremely valuable – and potentially cost-saving service – which allows patients to avoid long-term institutional care. Maintaining flexibility in its provision will also allow the States to make adjustments to address patients’ needs in the ever-evolving health care system.

IV. Conclusion

We truly appreciate the opportunity to provide our views regarding this important proposed 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, at eileen.carlson@ana.org or 301-628-5093; or Lisa Summers, CNM, DrPH, at Lisa.Summers@ana.org or 301-628-5058.

Sincerely,



Marla J. Weston, PhD, RN
Chief Executive Officer
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Cc: Karen A. Daley, PhD, MPH, RN, FAAN
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