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October 24, 2011

Donald M. Berwick, MD Administrator, Centers for Medicare & Medicaid Services Department of Health & Human Services P.O. Box 8010 Baltimore, MD 21244-8010

Attention: CMS-9989-P

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

Re: Patient Protection and Affordable Care Act;

Establishment of Exchanges and Qualified Health Plans

CMS-9989-P; RIN 0938-AQ67, 75 Fed. Reg. 41866 (July 15, 2011)

Dear Administrator Berwick:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on this proposed rule. 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. Our members include Advanced Practice Registered Nurses (APRNs): Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Nurse Midwives (CNMs), and Certified Registered Nurse Anesthetists (CRNAs).

Our state nurses associations are key stakeholders in health care at the state level, providing leadership and expertise as states seek the most economically feasible options to increase access and improve the quality of health care in their state.

Effective Utilization of the Nursing Workforce is Crucial to Meeting Increased Demand for Care.

APRNs have a long history of providing high quality cost effective care – providing primary and preventive care and anesthesia services, diagnosing and treating ailments and managing many routine and chronic health issues. Many integrated health systems, including the Veterans Health Administration (VHA), Indian Health Service and federally qualified health centers have recognized the contributions of APRNs and are increasingly turning to APRNs in building their workforce. Health system reform has highlighted the potential for APRNs to play a critical role in system redesign through the Affordable Care Act's specific elucidation of their roles and participation in numerous health care models and settings from ACOs to primary care homes.

Unfortunately, numerous outdated regulations and policies prevent health systems from utilizing many health care providers to the full extent of their education and capabilities. This problem

was highlighted in the Institute of Medicine report, *The Future of Nursing: Leading Change, Advancing Health*. In section 3-37, "Outdated Policies of Insurance Companies," the report addresses the impact of "insurance companies' continued policy of not credentialing and/or recognizing nurse practitioners as primary care providers – and the federal government's refusal to mandate that they do so…." The report includes the following recommendation:

"• Require third-party payers that participate in fee-for-service payment arrangements to provide direct reimbursement to advanced practice registered nurses who are practicing within their scope of practice under state law."²

In addressing current impediments within the regulatory environment in a background paper for the IOM Committee, Barbara Safriet, J.D., LL.M. (formerly Associate Dean and Lecturer in Law at Yale Law School, now Visiting Professor of Law at Lewis & Clark Law School) wrote:

"For health care providers of all types (other than physicians), the framework defining who is legally authorized to provide and be paid for what services, for whom, and under what circumstances is among the most complex and uncoordinated schemes imaginable. It reflects an amalgam of regulations, both prescriptive and incentivized, at the state, local, and federal levels. The effects of these governmental regulations are further compounded by the credentialing and payment policies of private insurers and managed care organizations."

The creation of State Insurance Exchanges provides the federal government with an excellent and timely opportunity to simplify and standardize these regulations.

NAIC Managed Care Plan Network Adequacy Model Act

State Insurance Exchanges will build upon the strengths of the existing market, and should also minimize its limitations. CMS notes that when considering options for establishing network adequacy standards, several typical standards employed in the existing insurance market were examined. These include standards employed by state departments of insurance, Medicare Advantage, TRICARE; states that contract with Medicaid managed care organizations, and the NAIC Managed Care Plan Network Adequacy Model Act. The Model Act contains language that should help protect consumer's access to choose qualified providers, specifically:

"Section 3 Definitions

I. "Health care professional" means a physician or other health care practitioner licensed, accredited or certified to perform specified health services consistent with state law" (emphasis added).⁴

This language appropriately recognizes that truly patient-centered care is provided by an interdisciplinary team. While physicians and nurses have a critical role to play, definitions should be written to allow for the inclusion of psychologists, pharmacists, physical therapists and all types of licensed health care professionals.

³ Safriet, B. J. 2010. Federal options for maximizing the value of advanced practice nurses in providing quality, cost-effective health care. Paper commissioned by the Committee on the RWJF Initiative on the Future of Nursing, at the IOM (see Appendix H on CD-ROM).

¹ http://www.iom.edu/Reports/2010/The-Future-of-Nursing-Leading-Change-Advancing-Health.aspx.

[∠] Id. at p 116.

⁴ NAIC Managed Care Plan Network Adequacy Model Act, section 3.1.

The Model Act includes a drafting note that "states may wish to specify the licensed health professionals to whom this definition may apply." Historically, this sort of specification and the development of "laundry lists" has often created an unnecessary barrier to care. With the development of biomedical sciences and health care treatments unheard of just a couple of decades ago, the health care workforce has become increasingly complex. A specific list created today could well be obsolete tomorrow. State regulatory bodies are charged with the responsibility of protecting the public by ensuring that health care professionals – as noted in the proposed definition -- have the appropriate education, certification, and other necessary credentials to allow their ability to perform the services for which they are licensed.

The definition of a "primary care professional" is also appropriately inclusive, referring to "a participating health care professional designated by the health carrier to supervise, coordinate or provide initial care or continuing care to a covered person..."

Non-Discrimination in Health Care

Moreover, this inclusive language is consistent with section 2706 of the Affordable Care Act (Pub. L. 11-148), entitled "Non-Discrimination in Health Care." This section provides, in part, that "A group health plan and a health insurance offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law" (emphasis added). Successive language respects the ability of health insurers to contract with individual health care providers and to establish "varying reimbursement rates based on quality or performance measures." But the fundamental message remains clear, that the Act prohibits health plans from discriminating against particular types of providers whose participation would be consistent with their scope of practice.

Anti-Competitive Practices in the Health Care Marketplace

The IOM report cited earlier recognized the importance of competition in the health care market and, in particular, the Federal Trade Commission's expertise and experience in addressing undue and anticompetitive restrictions. The report recommended that the FTC and the Department of Justice "Review existing and proposed state regulations concerning advanced practice registered nurses to identify those that have anticompetitive effects without contributing to the health and safety of the public." It further recommended that "states with unduly restrictive regulations should be urged to amend them to allow advanced practice registered nurses to provide care to patients in all circumstances in which they are qualified to do so."

Recently, the FTC has examined a number of cases in which proposed legislation was thought to potentially limit health care access and raise prices to consumers by limiting competition among health care providers and professionals. As the FTC said in its recent letter to Texas Senators:

"FTC has closely followed issues relating to competition by health care providers such as nurse practitioners, physician assistants, and dental hygienists. Recently, FTC staff urged several states to reject or narrow restrictions that curtail competition among health care providers because they limit patients' access to health care and raise prices."6

See http://www.ftc.gov/os/2011/05/V110007texasaprn.pdf.

In commenting on bills that would have lifted restrictions to APRN practice, the FTC noted the "lower health care costs, greater access to care, and greater choice among settings where health care is provided," that would result and concluded that lifting those restriction "likely would improve access and increase choices for Texas health care consumers as well."7

There are a number of states that have some form of "any willing provider" (AWP) or "any willing class of provider" (AWCP) laws that ostensibly prevent discrimination against providers. The limitations of these laws, however, are indicated by the results of studies of insurers' contracting policies on NPs as PCPs,8 addressed in greater detail below. The private insurance market is a competitive one that has been controlled to a large degree by interests that seek to limit the ability of non-physician providers to contract directly with private insurers. The establishment of State Insurance Exchanges provides an opportunity to end anti-competitive practices that have limited consumers' access to their choice of providers.

Section 155.110: Exchange Governance

ANA fully supports CMS' intent to ensure that Exchange governing boards are clearly defined, transparent in their work, representative of consumer interests, and "not made up of a majority of voting representatives with a conflict of interest." We fully support the proposal that Exchanges must make publicly available a set of principles that include ethics, conflict of interest standards, accountability and transparency standards and disclosure of financial interest.

The specific rules regarding how to meet these requirements will require a delicate balance. Certainly states will need to have the flexibility to have the right people with the right expertise and competency to effectively execute a fair yet sustainable insurance market. However, in some states particular health provider professions such as APRNs have been restricted from practicing to the full extent of their education and licensure due to restrictive state regulations. The development of Health Insurance Exchanges through this Proposed Rule presents a critical opportunity to reverse that discrimination.

Certainly, many providers, specialties, industry experts, and consumer groups will advocate for an explicit designation on an Exchange's board. CMS will need to carefully weigh the merits of these designations, and ensure that prescriptive rules on board membership are applicable and useful in every state. Because nurses, especially APRNs, provide a significant percentage of care to the people most likely to be entered into an Exchange, CMS should consider requiring a nurse on every state-based Insurance Exchange board. The rationale for this inclusion is further supported by the IOM's recommendation around nurses leading change to advance health:

"Public, private, and governmental health care decision makers at every level should include representation from nursing on boards, on executive management teams, and in other key leadership positions."9

Hansen-Turton, et al. Insurers' Contracting Policies on Nurse Practitioners as Primary Care Providers: Two Years Later POLICY POLIT NURS PRACT 2008; 9; 241.

IOM Future of Nursing: 14.

For example, ANA's Chief Programs Officer, Amy Garcia, served several years ago as president of a self funded health and disability plan in Kansas. Ms. Garcia's experience as a nurse helped to inform and build trust with the governing board and unions as she translated and de-mystified the evidence related to effectiveness of procedures. She was able to build consensus to move the plan and plan members toward true preventive care, including payment for smoking cessation and weight control interventions, and full funding of immunizations and recommended screening tests. She also used her nursing skills to expand and strengthen the provider networks, institute controls related to multi-pharmacy use and institute nurse case management for members with complex conditions.

Section 155.1050: Establishment of Exchange Network Adequacy Standards

CMS has noted that access to primary care is a challenge in many communities, a situation that will become only more serious in 2014 when more consumers seek routine primary care. In furthering the goals of the ACA in supporting and ensuring broad access to primary care, CMS states that it seeks to "encourage States, Exchanges and health insurance issuers to consider broadly defining the types of providers that furnish primary care services (e.g. nurse practitioners)."

ANA applauds this advice to the states, but experience to date suggests that broadly defining types of providers will not be enough. Network adequacy standards must include the requirement that APRNs are providers. The most recent national survey conducted by the National Nursing Centers Consortium found that less than one-half of the insurers in the United States credential NPs as primary care providers (PCPs). As prior surveys have demonstrated, despite increases in the number of NPs who have been able to secure better credentialing status and reimbursement, the ability of patients to receive care from NP primary care providers will be limited "as long as laws forbidding provider discrimination are not enforced and as long as managed care companies view NPs as primary care providers of last resort." 11

As noted in the IOM report cited above, credentialing policies of private insurers currently create a significant barrier to care. With expansion of the private market, with millions more covered lives; these restrictive practices will need to change in order to ensure that sufficient numbers and types of provider are available. CMS can play a role by promulgating rules and policies that promote access. As the IOM report stated, "CMS should ensure that its rules and policies reflect the evolving practice abilities of licensed providers, rather than relying on dated definitions drafted at a time when physicians were the only authorized providers of a wide array of health care services." 12

In addition to seeking comments on sufficient numbers and types of providers, CMS seeks comments on "arrangements to ensure a reasonable proximity of participating providers to the residence or workplace of enrollees, including a reasonable proximity and accessibility of providers accepting new patients." "Arrangements" that facilitate APRN practice will help ensure such proximity. Rural, frontier and other underserved areas have long depended on APRNs to provide care. For example, in those areas, CRNAs are often the sole anesthesia

¹⁰ /www.phmc.org/site/index.php?option=com_content&view=article&id=372:nncc-research-shows-insurer-contracting-policies-threaten-success-of-health-care-reform&catid=29&Itemid=1465.

Hansen-Turton, et al. Insurers' Contracting Policies on Nurse Practitioners as Primary Care Providers: Two Years Later *POLICY POLIT NURS PRACT* 2008; 9; 241. http://ppn.sagepub.com/cgi/content/abstract/9/4/241.

¹² IOM Future of Nursing: 3-19.

professional. As the liability crisis has driven obstetrician-gynecologists from providing obstetric services, the existence of a midwifery practice has allowed many women to avail themselves of prenatal care and delivery services without driving many hours. "Loosening" restrictive regulations on APRNs will help ensure reasonable proximity and accessibility of providers.

While APRNs provide many of the same health care services as physicians, APRNs are not physician substitutes. Consumers, particularly those who have experienced care from an APRN, will often specifically request that type of care provider. For example, obstetrician-gynecologists and CNMs both provide prenatal care, childbirth services, and primary care for women, but women are often well aware of differences in the practice of the two professional groups and will actively choose one or the other. Women in search of midwifery care have sometimes been denied by insurers, as have midwives seeking credentialing, with the explanation that OB or women's health services are available from physicians. In order to ensure sufficient numbers and types of providers, insurance issuers should be required to credential qualified APRNs.

Section 155.140: Establishment of a Regional Exchange or Subsidiary Exchange

The ACA provides for the operation of an Exchange in more than one state and this proposed rule sets out criteria that the Secretary will use to approve such a Regional Exchange. CMS encourages states to consider how to achieve the cooperation that must occur to establish a Regional Exchange and also to consider how to provide consistent consumer protections across the states.

As noted above, the ability of APRNs to practice to the full extent of their education and training varies greatly from state to state. Laws and regulations governing scope of practice, that support insurance coverage for APRN services and that allow consumers direct access to certain providers, all need to be considered in the establishment of regional Exchanges. It is an unfortunate reality that there is a well-funded campaign to limit the scope of practice of non-physician health care providers, and that plays out at the state level. ANA encourages CMS to add language that would ensure that the restrictions present in one state not hamper consumer access to care in another state within the region.

Section 155.205: Required Consumer Assistance Tools and Programs of an Exchange

ANA supports the requirement that Exchanges maintain tools to facilitate consumer access to information, including a toll-free call center, an internet website and a provider directory. It is essential to the fundamental right of patients to have access and choice of a wide array of health care providers, that *all* credentialed providers be listed in such a directory, and that staff operating a call center are aware of how to connect consumers with the provider of their choice. Currently, with some private insurers, APRNs often face hours of bureaucratic hindrances to being listed within provider directories and websites.

Section 156.235: Essential Community Providers

CMS has requested comment on whether the definition of essential community providers (ECPs) should be expanded to include additional providers, with a focus on those that serve predominantly low-income, medically underserved populations. The draft regulation references a list of covered entities in Section 340B, and "look alikes" specified in section 1927(c)(1)(D)(1)(IV) of the Social Security Act. While the list of covered entities is, at first glance, a long one, many are relatively small and targeted programs (e.g. black lung clinics,

hemophilia diagnostic treatment center, and urban Indian organizations). ANA strongly encourages CMS to expand this list. Specifically, there are three innovative models of care, recognized in other provisions of the ACA, that ANA recommends be identified as ECPs.

Nurse-Managed Health Centers (NMHCs): The Affordable Care Act defines a "nurse managed health clinic" as a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center (FQHC), or independent nonprofit health or social services agency. There are over 250 NMHCs operating throughout the United States (several are also FQHCs) that are helping to meet two critical goals of health care reform: 1) building the health care workforce through their affiliation with schools of nursing and by acting as teaching and practice sites for nursing students and other health professionals; and 2) helping to reduce health disparities and expand access for the uninsured by providing care regardless of the ability to pay.

Despite serving these critical functions, NMHCs have struggled financially, in large part because approximately 58% of their patients are uninsured, Medicaid recipients, or self-payers. These are precisely the sort of patients who are likely to gain coverage through the Exchanges. In order for NMHCs to continue to expand and serve that population, NMHCs should be included in plans' networks as an essential community provider.

<u>School-Based Health Centers (SBHCs):</u> More than 1,900 SBHCs in the U.S. are key safety net providers, ensuring that more than 1.7 million children and adolescents have access to primary and preventive health care. Most SBHC users are members of minority and ethnic populations who have historically been under-insured. Congress recognized the crucial role SBHCs play by supporting SBHCs in the Affordable Care Act in two sections: section 4101(a) and 4101(b).

Many SBHCs participate in the 340B Drug Pricing Program through their sponsoring organization (including federally qualified health centers, disproportionate share hospitals, children's hospitals, and sole community hospitals), but not all are covered by this designation. Other sponsors include local health departments (15 percent), school systems (12 percent), and private nonprofit organizations (9 percent). To narrowly define essential community providers as those programs eligible for the Section 340B program creates an unnecessary distinction between 340B-eligible versus non-eligible SBHCs. Given that *all* SBHCs serve similar populations of vulnerable children and adolescents, regardless of their sponsor, the Department can eliminate this unnecessary distinction by defining all SBHCs as essential community providers.

<u>Freestanding Birth Centers</u>: Section 2301 of the ACA requires State Medicaid programs to cover free-standing birth centers, defined as a health facility licensed by the state to provide prenatal labor and delivery or postpartum care, as well as other related services. While the focus of this provision was to expand access to prenatal and childbearing services, improved coverage for freestanding birth centers in the private market will also increase access to primary and preventive care. CNMs who provide much of the care in birth centers have the requisite education and training to provide primary care services and serve as the PCP for many women. The *Future of Nursing* report includes a case study, Nurse-Midwives and Birth Centers,

¹³ Strozer, J., Juszczak, L., & Ammerman, A. 2007-2008 National School-Based Health Care Census. Washington, DC: National Assembly on School-Based Health Care: 2010.

highlighting both the improved outcomes and cost-savings achieved with this model of care, as well as the obstacles to widespread use.¹⁴

Section 156.245: Treatment of Direct Primary Care Medical Homes

CMS requests comment on what standards HHS should establish regarding coverage through a primary care medical home.

ANA has long supported the principles of a medical or primary care home: care that is patient-centered, comprehensive, coordinated, superbly accessible, and continuously improved through a system-based approach to quality and safety. Principles and recognition programs that create barriers to the creation of interdisciplinary teams (i.e. by referencing a "physician-led team") are outdated holdovers from a 20th Century health care system. As the concept has evolved, recognition programs from URAC,¹⁵ National Committee for Quality Assurance¹⁶ and the Joint Commission¹⁷ have all turned to language that recognizes the full spectrum of qualified primary care providers, including those who are not physicians.

CMS references comments made to the RFC regarding the primary care health home model in the State of Washington as an example of one that has increased access while controlling costs. ANA notes that Washington State specifically authorizes APRNs to serve as primary care providers and also recognizes the critical role of the RN as a member of the health care team. APRNs are able to play a significant role in providing primary and preventive care services in Washington State because they are unencumbered by statutory or regulatory barriers which limit the practice of APRNs in some other states.

Full Spectrum Support for Lifting Barriers to APRN Scope of Practice

The IOM is not the only prominent organization to call for lifting barriers to APRN practice. In August of 2009, the Engelberg Center for Health Care Reform at the Brookings Institute addressed the need to improve the health care workforce in their report, *Bending the Curve: Effective Steps to Address Long-Term Health Care Spending and Growth.* They suggested that policymakers, "Create incentives for states to amend the scope of practice laws to allow for greater use of NPs, pharmacists, PAs and community health workers." 18

Despite current controversy around health system reform, there is bipartisan support for addressing scope of practice barriers. In the Bipartisan Policy Center report, "Crossing our Lines: Working Together to Reform the U.S. Health System," Senators Howard Baker, Tom Daschle and Bob Dole made a number of recommendations, including: "Revise scope-of-

¹⁴ IOM Future of Nursing, p. 56-58.

¹⁵ URAC's Patient Centered Health Care Home Program is "an interdisciplinary clinician-led team approach." https://www.urac.org/healthcare/prog_accred_pchch_toolkit.aspx.

¹⁶ NCQA had recognized NPs as team members, and effective October 22, 2010, NCQA will recognize nurse-led primary care practices as patient centered medical homes under its PCC-PCMH recognition program in states that permit advance practice nurses to lead practices. www.ncqa.org.

¹⁷ The Joint Commission Primary Care Medical Home Program references, "the primary care clinician and

The Joint Commission Primary Care Medical Home Program references, "the primary care clinician and the interdisciplinary team members," who "function within their scope of practice." http://www.iointcommission.org/accreditation/pchi.aspx.

http://www.brookings.edu/reports/2010/10_btc_II.aspx.

practice laws that discourage use of advanced practice nurses, pharmacists, and other allied health professionals." ¹⁹

Consumers are also aware of the legal and regulatory changes needed to ensure their choice of providers, and they are lending their voice to the policy discussions. AARP has issued a policy statement that addresses the need to lift legal barriers that "are short-changing consumers." "Statutory and regulatory barriers at the state and federal levels that prevent scores of nurses from practicing to the full extent of their licensure must be lifted." Citizen Advocacy Center (CAC) has launched a project to "provide independent, third-party, economically disinterested input into processes and criteria for removing unjustified scope of practice restrictions." They have produced and made available on their website a number of resources, including Frequently Asked Questions for consumers, 21 and are advocating at the state level for laws and regulations that would ensure their ability to see the providers of their choice.

While some insurers have been slow to evolve in their credentialing policies, more are seeing the need to change policies, and getting support from physicians. In Working Paper 6, released July 2011, the UnitedHealth Center for Health Reform & Modernization states: "It also makes sense to strengthen multidisciplinary teamwork in rural primary care, freeing nurse practitioners, physician's assistants and others to practice using the full range of their skills, rather than being subject to outdated scope-of-practice licensing constraints. Our new national survey finds that a majority of rural primary care doctors agree with this approach."²²

In conclusion, we again quote Barbara Safriet:

"As decision makers at every level wrestle with the urgent need to broaden access to health care, three challenges have become clear. The care provided must be competent, efficient, and readily available at all stages of life; it must come at a cost that both individuals and society at large can afford; and it must allow for appropriate patient choice and accountability. Among the options available to promote these goals, one stands out: wider deployment of, and expanded practice parameters for, advanced practice nurses (APNs). The efficacy of this option is uniquely proven and scalable. These well-trained providers—including nurse practitioners, nurse midwives, nurse anesthetists, and clinical nurse specialists—can and do practice across the full range of care settings and patient populations. They have proven to be valuable in both acute and primary care roles, and as generalists as well as specialists. By professional training as well as by regulatory and financial necessity, they have emphasized coordinated and cost-effective care, and they have tended more than other providers to establish practices in traditionally underserved areas."

The creation of State Insurance Exchanges provides the states and the federal government an opportunity to scale up a proven option to increase access to cost-effective care.

¹⁹ http://www.bipartisanpolicy.org/sites/default/files/BPC Crossing Our Lines Report.pdf.

http://championnursing.org/resources/aarp-2010-policy-supplement-scope-practice-advanced-practice-registered-nurses.

²¹ http://www.cacenter.org/cac/SOP.

http://www.unitedhealthgroup.com/hrm/UNH WorkingPaper6.pdf.

We appreciate the opportunity to comment on this important proposed rule. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Lisa Summers, CNM, DrPH at <u>Lisa.Summers@ana.org</u> or 301-628-5058.

Sincerely,

Marla J. Weston, PhD, RN Chief Executive Officer

American Nurses Association

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

President

American Nurses Association