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Re: Federal Trade Commission/Department of Justice Antitrust Division Proposed  
Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations  
Participating in the Medicare Shared Savings Program

Winifred Carson-Smith, on behalf of CarsonCompany, LLC, a health policy and advocacy organization submits these comments. Prior to setting up my consultancy, I served as Practice Counsel for the American Nurses Association for 15 years. In this capacity, I was responsible for working with state nurse associations on legislation, regulation and litigation of advanced practice nursing issues; and I researched, travelled and testified on behalf of the association on these issues.

Innovation has been the hallmark of advanced practice nursing. Working around and between barriers to practice, nurses in advanced practice have and continue to develop practices, procedures and techniques to expand their work. As we contemplate the future of nursing under healthcare reform, particularly the role of advanced practice nurses – nurse practitioners, clinical nurse specialists, nurse anesthetists and nurse midwives -- we should expand our discussion beyond team practices and arrangements, to address federal regulatory and legislative barriers to practice and the federal law's direct violation of state constitutional rights in the development of ACO arrangements which circumvent the state and federal constitutional dichotomy of rights and responsibilities and undermine state health licensure authority; and minimizes the natural growth and evolution of health delivery models which enhance care and reduce healthcare costs.<sup>i</sup>

As noted by Safriet (1992) and Hadley (1989), early nurse practice acts were generally constructed around their medical counterparts and were written to avoid conflict in professional practice. In the context of professional regulation, nursing scopes were structured to include narrowly defined independent functions and to mandate a dependent or complementary role for nurses.<sup>ii</sup> Not fully understanding the concerns of nurses, legislators and regulators continued to perpetuate a model of health regulation that confined nurses to a largely complementary role in providing health services. Although nurses made diagnoses and recommended care, and

often noted inappropriate diagnosis or medication errors, the role of the nurse as an equal partner in the assessment and evaluation process was neither emphasized nor acknowledged outside of the clinical setting.

However, in the 70's, states enacted laws which authorized the regulation and expansion of nursing practice to include licensure of nurse practitioners.<sup>iii</sup> Advanced practice nurses were authorized under state law to expand their practices to include more expansive scopes to include prescriptive authority. While some states continue to mandate collaboration, supervised or other relationships with physicians, approximately half of the states do not require such to practice<sup>iv</sup>. And, nurses in those states have established business which compete directly with physician practices and provide primary and specialized care. Advanced practice nurses have provided care in federally qualified health centers as primary care providers; and have established clinics, owned and run by nurses in commercial and academic settings. And, federal Medicare regulations for advanced practice nurse reimbursement have been structured to address state law.<sup>v</sup> Likewise, the Drug Enforcement Administration restructured its prescriber registration process to accommodate the distinctions in state law related to nurse prescribing.<sup>vi</sup> However, the ACO regulations do not recognize this growing and changing area of practice which has shown that it address quality and cost.<sup>vii</sup> Moreover, nurses have and continue to work in settings which call for physicians and have structured their practices to address this need, however, both the ACO and Medical Homes regulations ignore this factor and have been structured to undermine the Nurse-led ACO as a model. As many of the existing nursing clinics serve the underserved in areas of critical need, these clinics will be in direct competition with ACOs.

Moreover, both the NCQA and the Joint Commission, in deference to state law, recognize nurse-led medical homes, which are the precursor or alternatively, the foundations for ACO's. As noted in the state issued by NCCQA:

“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. NCQA already recognizes advanced practice nurses as members of teams in practices recognized as Patient-Centered Medical Homes.

This decision is prompted by the growing number of states that allow nurse practitioners to serve as primary care providers. In many of these states, primary care shortages are leading to this reevaluation of scope of practice. A number of states – including Maryland, Pennsylvania, and Colorado – have adapted the joint principles of patient-centered medical homes to include nurse-led practices.

Primary care scope of practice is determined by each state and NCQA will defer to state requirements on independence and supervision. We will apply the same standards, scoring and other features to nurse-led practices that we apply to physician-led practices.<sup>viii</sup>

Thus, if Medicare can pay for the services; the DEA can recognize the distinctions in practice and register nurses and the major accrediting organizations have developed standards for the services mandated under the affordable care act, it is our contention that all of the regulations supporting the Affordable Care Act, to include medical homes and ACO regulations should be structured to maximize the utilization of any provider, including advanced practice nurses, who are able to provide integrated health delivery systems.

This guidance should be changed to:

1. Provide for nurse-led ACOs; and
2. To address the limitations of state law which under which nurses in advanced practice may work in or direct ACOs.

Advanced practice nurses can direct and provide care within an ACO model and limitations should not be imposed on their practices. Nurse-led ACO can accommodate risk and provide integrated health delivery systems. In states which require advanced practice nurses to collaborate, utilize protocols or engage in a supervisory relationship, many advanced practice nurses have placed physicians on staff. The physicians are paid for the state legislatively mandated services, and the nurse assumes to business risks associated with owning and managing the clinic. Thus, the major requirements associated with ACOs and medical homes can be fulfilled and nurses in advanced practice, specifically, clinical nurse specialists and nurse practitioners who can provide primary care services, should not be precluded from doing so through ACO or medical homes regulation.

The DOJ/FTC guidance presented to us incorporates numerous presumptions that nurses will serve as employees and will not create, manage or assume the risks of establishing and guiding ACO's. For example, the DOJ/ FTC Guidance include the following statement.

“For an ACO to fall within the safety zone, independent ACO participants (*e.g.*, physician group practices) that provide the same service (a “common service”) must have a combined share of 30 percent or less of each common service in each participant’s PSA, wherever two or more ACO participants provide that service to patients from that PSA.<sup>26</sup> The PSA for each service is defined as “the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients]” for that service.”<sup>27</sup>

This provision does not make reference to or recognize a nurse-led ACO nor does the appendix include any reference to nurse practices or specialties. Immediately, I think about the nurse-led and managed clinics which have been in existence at the University of Michigan for at least 10 years. These clinics could not fall within in your safety zone, even if they had a combined share of 30 percent or less of each common service in each participant’s PSA because nurse clinics are not recognized by these regulations. Thus, an entity could move into the PSA of this nurse-led clinic, which well covers over 5,000 lives and includes paying and Medicaid patients, and undermine its established service area. This is not fair nor equitable especially since the clinic does not have the option of serving as an ACO.

Second, as mentioned earlier, nurses in approximately half of the states have to have:

- a) Collaboration agreements;
- b) Protocols ;
- c) Practice requirements; or
- d) Some type of supervisory arrangement

While a few states specifically mandate that nurse/physician arrangements are with like specialties, many of the arrangements do not require this mandate. The safety zone arrangement does not clearly address the unique structure of these arrangements. As mentioned above, many nurse practitioners pay for this service. Thus, the physician continues

to serve in his/her practice and the nurse practitioner works independently but for the required services which may be as minimal as reviewing the records of the nurse practitioner every 3 months. How would the safety zone be addressed if the nurse practitioner in a family practice has a relationship with a physician in a pediatric practice and that physician lives in the same zip code and is responsible for reviewing the NP's records? Would the NP's referral of the patient to that pediatrician for specialized care be reviewed to determine if the two providers have in excess of 30% of "common services" when one is a pediatrician and the other is a family services provider because they have the ancillary relationship which fosters/creates a business relationship between the two above and beyond the ACO structure?<sup>x</sup> (This example is based on the statutory mandates and known collaborative relationships which exist in Tennessee).

Alternatively, states like Connecticut which mandate that providers work under physicians with similar specialties create differing circumstances which could be perceived of as undermining antitrust law and protections. For example, what is a psychiatric nurse practitioner or clinical nurse specialist specializes in pediatric abuse and neglect and collaborates with a psychiatrist and that psychiatrist refers to her over 50% of his cases, as he/she is in a government-mandated ACO and has a disproportionately large number of pediatric abuse/neglect cases. If both have handled such cases for a small jurisdiction (fewer than 200,000 residents) and are known for their services, would this trigger antitrust review?

It is our recommendation that the guidance be rewritten to address the mandates associated with practice; and to likewise, address the limitations of such mandates. For example, a Missouri nurse practitioner left an established practice where she was the primary because her collaborator chose to undermine her work when given a corporate directive to utilize her services. Other physician providers chose not to collaborate with her and she lost her practice, for which she was paid a salary plus incentives based on her client base; and had to move 200 miles away to obtain a new physician collaborator. In another instance, a Kentucky nurse practitioner purchased a retiring physician's practice with an oral agreement that the retiring physician would serve as his collaborator until he was able to obtain another physician collaborator. Unfortunately, the retiring physician reneged on his promise and the nurse practitioner was unable to get another collaborator in the state. Although he was in a border practice, the state board of nursing refused to accept a physician collaborator from a border state and the nurse practitioner had to move and was unable to sell the practice. The physicians in the region who refused to collaborate immediately snapped up his client base.

Historically nurses have had problems litigating antitrust claims and only recently has the Federal Trade Commission started to address this issue. Until the FTC acted on anticompetition in the '90's nurses had to endure anticompetitive conduct. Nurse Midwifery Assocs. v. Hibbett, 918 F.2d 605, 614-15 (6th Cir. 1990) highlights this phenomena. This case involves two appeals arising out of an antitrust action brought by two nurse midwives, the obstetrician with whom they had affiliated, and three of their clients, against three Nashville hospitals, certain members of the medical staffs from two of the hospitals, another practicing obstetrician in Nashville, and a physician-controlled insurance company. The plaintiffs alleged that the hospitals and medical staff conspired to restrain their practices, in violation of section 1 of the Sherman Anti-Trust Act, 15 U.S.C. Sec. 1; and they successfully proved that the hospitals and medical staff retaliated against them and the physician who agreed to supervise their work. Another seminal nurse practitioner case was Minnesota Association of Nurse Anesthetists v. Unity Hospital, et al. 208 F.3d 655 (8th Cir. 2000) which highlighted inequities associated with mandated collaboration.

Minnesota law mandated supervision of nurse anesthetists, and for many years, hospitals submitted non-itemized bills to Medicare that included all anesthesia services related to a surgery, including the services of nurse anesthetists employed by the hospital as Medicare did not permit nurse anesthetists to bill directly.<sup>2</sup> If an anesthesiologist also attended a surgery, he or she would separately bill Medicare, and that bill did not necessarily indicate whether the anesthesiologist had administered anesthesia or simply supervised a nurse anesthetist. Therefore, accidental or intentional "double billing" was a real possibility. And, until the Federal Trade Commission recently drafted opinion letters to address anticompetitive proposals introduced in states by state medical associations, associations used legislative strategies reinforce more restrictive provisions to compel supervision of advanced practice.<sup>xi</sup>

In short, the failure to incorporate advanced practice nurses into antitrust/anti-competition law, regulation or guidance continues to stymie evolution of new delivery models, services and best practices. Restructure of these rules, as well as the Stark guidances, to ensure that advanced practice nurses are protected and utilized will enhance development of new health delivery models. Advanced practice nurses bring many skills, attributes to any integrated delivery system, but the rules should not be written with the presumption that the nurse is an employee and not a risk bearing partner in the ACO endeavor. And, consumers should have choices especially when such choice enhances care and addresses costs. For these reasons, I strongly recommend restructuring not just the guidance but also, the ACO and the ACA medical homes final regulations.

I thank you in advance for this opportunity to provide comment and should you desire additional information, please feel free to contact us.

Sincerely,

Winifred Y. Carson-Smith

cc: Alice Bodley, General Counsel, American Nurses Association

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<sup>i</sup> States regulate the practice of clinical care under the police power reserved by the Tenth Amendment to the U.S. Constitution. States have the authority to regulate activities that affect the health, safety, and welfare of citizens within their borders.<sup>2</sup> However, the states' power to regulate healthcare may not be absolute. The Commerce Clause of the Constitution <sup>2</sup> *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 792 (1975); *see, also, Ferguson v. Skrupa*, 372 U.S. 726, 731 (1963); *Dent v. West Virginia*, 129 U.S. 114, 122 (1889).<sup>7</sup> and the practice of healthcare has been held to be interstate trade for the purpose of antitrust laws.

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The potential conflict between the states' power to regulate health professionals and the prohibition against restraints on interstate commerce has not been addressed by the courts.

<sup>ii</sup> Hadley, E.A. "Nurses and prescriptive authority: a legal and economic analysis." *American Journal of Law and Medicine* 15:245- 299, 1989 and Safriet, B.J. "Health care dollars and regulatory sense: the role of advanced practice nursing." *Yale Journal of Regulation* 9:417- 488, 1992.

<sup>iii</sup> And, all but one of the 50 states has authorized nurse practitioners to prescribe. Thirteen states allow nurse practitioners to prescribe controlled substances without physician involvement. An additional 32 states allow nurse practitioners to prescribe controlled substances with some physician involvement. At least 12 states recognize nurses as primary care providers<sup>8</sup> and another 12 states have antidiscrimination laws to protect nurse practitioner practice and mandate nondiscrimination in privileging and credentialing

<sup>iv</sup> Physician organizations and licensure boards challenged state legislative changes, but consistently state attorney generals recognized the authority of state legislators to expand advanced practice.

<sup>v</sup> Department of Health and Human Services. HCFA Medicare Carriers Manual, Part 3-Claims Process, May 1992.  
HCFA Transmittal No. AB-98-15, April 1998.

<sup>vi</sup> Although we recognize that Congress removed all commerce clause limitations on the authority of the states to regulate "the business of insurance" when it enacted the McCarran-Ferguson Act, 15 U.S.C. §1012(a), case law is divided on the question of whether this mandate provided protection to other licensed functions. See *Hahn v. Oregon Physician Service*, 689 F.2d 840 (9th Cir., 1982).

To date, the only formal action taken on surcharges by an insurance commissioner on discrimination against advanced practice nurses has been In the Matter of National Capital Reciprocal Insurance Company 1991 Rate Filing. In this action, the physician-owned reciprocal insurance company contended they needed to add a surcharge on all physicians in collaborative relationships with nurse midwives, because there was added risk of lawsuits.

The District of Columbia Insurance Commissioner found the rate increase was based solely on the "judgement" of a physician board, which reviewed rates, thus the rates were not justified through relevant data. The Superintendent also held that the insurer could not impose a vic arious liability surcharge unless it could support a rate increase with statistical data. The insurance company could not.

<sup>vii</sup> See endnote 1.

<sup>viii</sup> Robert L. Phillips Jr., Doreen C. Harper, Mary Wakefield, Larry A. Green, and George E. Fryer Jr., "Can Nurse Practitioners And Physicians Beat Parochialism Into Plowshares?; A collaborative, integrated health care workforce could improve patient care", *Health Affairs* (September, 2002 - October, 2002).

<sup>ix</sup> **ANA Lauds Eligibility of Nurse-Led Clinics as Medical Homes**, Tuesday May 24, 2011 as found at Nurse.com, website for Gannett Company at <http://news.nurse.com/article/20110524/ALL01/106060004> , **NCQA Recognizes Nurse led Practices as Medical Homes** as found on the American Academy of Nurse Practitioners website at <http://www.aanp.org/NR/rdonlyres/CAD37402-48A6-4C5C-9123-D6EB547AC411/4480/PPCPCMHNurseLedPracticesFactSheet.pdf> and ANA Applauds Joint Commission Standards for „Medical Homes’ : Patients Gain with Decision to Include Nurse-led Clinics as found on the American Nurses Association website at <http://cms.nursingworld.org/FunctionalMenuCategories/MediaResources/PressReleases/2011-PR/Joint-Commission-Standards-for-Medical-Homes.aspx>

<sup>x</sup> A certified nurse practitioner in Tennessee is a registered nurse who has been issued a certificate of fitness by the state board of nursing. Under the general supervision of a licensed physician, an NP can prescribe

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certain medications and care for patients. The physician does not need to be present when the NP is caring for patients, but needs to be available at all times for consultation with the NP, should it be required. The physician needs to review the nurse practitioner's actions once every 10 business days if medically indicated, if the patient requests it or if the NP has prescribed controlled medication or taken action which falls outside the normal protocols.

<sup>xi</sup> See also FTC Staff Comment Before the Massachusetts Department of Public Health Concerning Proposed Regulation of Limited Service Clinics, 2 (Sept. 27, 2007), *available at* <http://www.ftc.gov/os/2007/10/v070015massclinic.pdf> ; **FTC Staff Comment to Representative Elaine Nekritz of the Illinois General Assembly Regarding House Bill 5372 Concerning the Regulation of Retail Health Facilities** (June 2008) (V080013)

*See, e.g.*, Letter from FTC Staff to Hon. Timothy Burns, *supra* note 12; Letter from FTC Staff to Elaine Nekritz, Illinois Legislature (May 29, 2008) (regarding proposed LSC regulations), *available at* <http://www.ftc.gov/os/2008/06/V080013letter.pdf>; Letter from FTC Staff to Massachusetts Dep't of Health (September 27, 2007) (regarding proposed LSC regulations), *available at* <http://www.ftc.gov/os/2007/10/v070015massclinic.pdf>. Many of these advocacy efforts have been successful in preserving competition. For example, following the above referenced advocacy letters, the Louisiana and Illinois legislatures rejected the proposed restrictions on competition, and Massachusetts followed FTC Staff recommendations in adopting its final LSC regulations.

*See, e.g.*, Letter from FTC Staff to Kentucky Cabinet for Health and Family Services (Jan. 28, 2010) (regarding restrictions on the scope of practice for nurse practitioners, and others, that would have applied in limited service clinics but not in other limited care settings, such as urgent care centers), *available at* <http://www.ftc.gov/os/2010/02/100202kycomment.pdf>; FTC Staff Comment Before the Alabama State Board of Medical Examiners Concerning the Proposed Regulation of Interventional Pain Management Services (Nov. 3, 2010) (regarding restrictions on the scope of practice of certified registered nurse anesthetists, a specialized sub-category of ARNPs), *available at* <http://www.ftc.gov/os/2010/11/101109alabamabrdme.pdf>.

*See, e.g.* Letter from FTC Staff on Florida House Bill 4103 (“H.B. 4103” or “the Bill”) and the regulation of Advanced Registered Nurse Practitioners (“ARNPs”) as found at <http://www.ftc.gov/os/2011/03/V110004campbell-florida.pdf>