AMERICAN NURSES ASSOCIATION
600 Maryland Avenue S.W. Suite 100 West
Washington, D.C. 20024

October 7, 2002

Timothy J. Muris, Chair
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20001

Re: Possible Anticompetitive Efforts to Restrict Competition on the Internet

Dear Mr. Muris:

As Nurse Practice Counsel, Office of General Counsel, American Nurses Association, I am offering comments on possible anticompetitive efforts to restrict nursing practice by competitors on the internet. I have been informed of the testimony of the American College of Nurse Practitioners, therefore, I will attempt to address other areas of concern related to registered and advanced nursing practice.

Internet and Managed Care Pharmacy Practice and Advanced Practice Nursing

The American College of Nurse Practitioners provided extensive and comprehensive written and oral testimony on this matter, however, I would like to highlight some aspects of this issue that have not been addressed in the previous testimony. Specifically, I would like to address the use of state pharmacy and physician licensure laws to preclude and limit the practice of nurse practitioners who are required to use managed care pharmacies in states where nurse practitioners have not been granted the same level of prescribing authority as the out-of-state prescribing nurse practitioner. Many states have two-tiered systems that clearly make distinctions in law and regulation to determine appropriate prescribers, with many states giving deference to out-of-state dentists, osteopaths, physicians, podiatrists and veterinarians, to varying degrees, while refusing to give similar deference to advanced practice nurses.[1] Even though the scope of practice and prescribing authority may vary for some generally accepted licensees[2], state attorneys general, in large part, refuse to address disparity in the treatment of

[1] 1977 Conn. AG Lexis 107 (November 21, 1977). See also HRS §328-17.6(2002) Hawaii; Va. Code Ann. §54.1-3303(2002) Virginia; Rev. Code Wash. (ARCW) §69.41.030 (2002) Washington..

[2] Podiatrists scope vary, based on whether the state includes the ankle in the definition of the area of practice.

prescribing advanced practice nurses, citing the differences in state law regulating advanced practice nurses.

State interpretations of pharmacy law have been fairly consistent. Attorneys generals and general counsel to boards of pharmacy view this issue and others related to managed care pharmacies as a matter of state licensure law. The regulation of these pharmacies, it is believed, is a state-based matter. We disagree. It is our contention that the activities of national pharmacies which provide services to a number of states are matters should be regulated under the commerce clause of the United States Constitution.

California and Connecticut are some of the states that have recognized and acknowledged the conflict created by the use of managed care of out-of-state pharmacies. And, their attorneys generals looked at whether these types of pharmacies are regulated solely through the state of jurisdiction or fall under the Commerce Clause of the U.S. Constitution. In a 1989 attorney general opinion about an out-of-state prescription drug benefit[3], Clarine Nardi Riddle, Acting Attorney General of the state of Connecticut notes that the United States Supreme Court interpreted the Commerce Clause to limit the power of the states to erect barriers to interstate trade[4]. She states:

> "When a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry . . . When however, a statute has only indirect effects on interstate commerce and regulates evenhandedly, we have examined whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142, 90 S.Ct. 844, 847, 25 L.Ed. 2d 174 (1970)."[5]

It is our contention that the treatment of advanced practice nurse prescribers when compared to other out-of-state prescribers requesting similar treatment, is subjectively biased and anticompetitive. Both categories of licensees are out-of-state prescribers, yet the state provides an exemption for non-nurse practitioners. Even though some states contend it is because that individual can be easily tracked through his/her DEA number or because state licensure law provides flexibility for practice for that prescriber, it is our contention that the two-tiered treatment reflects a state bias and undermines traditional protected state interest arguments, and clearly requires careful scrutiny of the practices which discriminate against nurses authorized to

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[3]1989 Conn. AG Lexis 7 (May 25, 1989).

[4]See also *Lewis v. B.T. Managers, Inc*. 447 U.S. 27,35 (1980).

[5]Ibid.

prescribe in relation to the mandates of the Commerce Clause.[6] Legislative action that is motivated by "simple economic protectionism" is per se invalid. _Philadelphia v. New Jersey_ 437 U.S. 617, 623-24 (1987).

California reviewed a similar issue and conducted extensive analysis of the application of the Commerce Clause to the state issue of regulation of nonresident licensees and pharmacies.[7] In attempting to balance the state's interest in health and safety against the commerce clause application, the state attorney general noted that:

> "Where the avowed purpose of the regulation is not illusory or suspect, the court will, even in the health and safety context, proceed with a balancing test. 'Regulations designed for that salutary purpose may further the purpose so marginally, and interfere with commerce so substantially, as to be invalid under the Commerce Clause.'"[8]

When these attorneys general opinions were written, many states were concerned about whether managed care or mail-order pharmacies should be treated as insurance programs, as many were started by and through managed benefit entities or services, which were considered part of "insurance" packages.[9] As such, it was believed that the managed care pharmacy service activities were protected from antitrust/anticompetition limitations in federal statutes. However, the industry has evolved and the managed care/mail order pharmacies are free-standing, independent national businesses.[10] With this change, states are developing legislation and regulation to protect state-based pharmacies from out-of-state and internet-based entities.[11]

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[6]See also 1989 Conn. AG Lexis 7 (May 25, 1989), specifically see pages 21-22. See also _Brown-Forman Distillers v. New York Liquor Authority_, 476 U.S. 573, 579 (1986).

[7]1992 Cal. AG Lexis 10; 75 Op. Atty Gen. Cal. 41 (March 3, 1992).

[8]Ibid, with citation to _Kassel v. Consolidated Freightways_ Corp. (1981) 450 U.S. 662, 670).

[9]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), but case law is divided on the question of whether this mandate provided protection to managed care pharmacies. See _Hahn v. Oregon Physician Service_, 689 F.2d 840 (9th Cir., 1982).

[10] See attached charts with selective listing of current sales and acquisitions of managed care pharmacies, not by insurers or other managed care entities, but instead by internet pharmacies and other medical related business entities.

[11]La. R.S. 46:2622 _et.seq._ (2002) and La. R.S. 37:1232 (2002); O.C.G.A. §34-9-124.2 (2002); Fla. stat. §499.01 (2002); KRS §315.0351(2001); S.C. Code Ann. § 40-43-83 (2001) and Utah Code Ann. §17a-619. There is also Attorney General opinion on imposing state taxes on mail order pharmacies, see 2001 Ala. A.G. Lexis 158 (August 15, 2001).

Clearly, now is the time for the federal government to intervene and develop regulations which allow all practitioners authorized by their state to prescribe to have equal access to this service.

One of the arguments proffered by pharmacies and those regulating the pharmacy industry in the unavailability of verifiable information about advanced practice nurse licensees. There is fear that the pharmacy will be sanctioned for allowing unauthorized nurses to prescribe drugs. The advanced practice nurse has as much or more to lose if he or she is allowed to improperly prescribe. In addition to fear of lawsuits, the nurse could be disciplined by the state board of nursing and reported to the National Practitioner Data Bank. Likewise, there are alternatives to verify licensure and prescribing status, to include state boards of nursing, state nursing organizations, state drug enforcement organizations, federal agencies, including the Drug Enforcement Administration and the Department of Health and Human Services.

We further contend that the growth and development of the mail order/managed care pharmacy industry, combined with the ancillary and related internet pharmacy industry has been exponential and that the inability to effectively practice and provide drugs through this means impedes the ability of the advanced practice nurse to practice independently and compels that nurse to look into employment arrangements. As indicated in the American College of Nurse Practitioner testimony, the advanced practice nurse who prescribes has to enter into a relationship with a physician provider to obtain mail order or managed care pharmacy services. Or, the patient of that nurse practitioner or advanced practice nurse has to purchase the drug from a local pharmacy, which may mean a higher cost per prescription for the patient or the lost of the managed care pharmacy benefit. Regardless, the state laws add to the cost of health care and diminish competition. We further contend that the industry should not control or structure work relationships, especially when such structuring impedes full competition, limits alternative and cost-effective health care business enterprises and otherwise limits the evolution of practice in a manner consistent with state law.

It should be noted that in some instances, state boards of pharmacy are claiming conflicts in the law of the state of the licensed provider and law of the state of the pharmacy locale. While I am not a scholar on conflict of law interpretations, it is my understanding that the state with the most significant interests law would apply. Thus, the law of the state where the patient resides (and probably where the practitioner is licensed and provided the care), would be the state with the most significant interest exists as that state establishes regulation to protect is residents. Thus, the mail order pharmacy would have an obligation to follow the law of the jurisdiction of the consumer and practitioner. If the licensure law of that jurisdiction conflicted with the dispensing law of the mail order pharmacy state, then one would believe that the mail order pharmacy state would defer to the state with the most significant interests, if there is no federal statute to clearly address this type of interstate commerce. In many instances the dispensing law of the state was enacted prior to the creation of the licensing class or totally ignored the advanced practice class of licensure. Thus, there is no conflict in the law, but instead no law covering the practice. In that instance, it is inappropriate for the Boards of Pharmacy or corporations to create an interpretation when the law clearly did not address the issue. Instead, the corporation and/or the Board of Pharmacy should request an opinion from the state attorney general or work to

obtain enactment of legislation to clearly address the void left in the law. However, problems continue to arise when the neither the state boards nor the companies have clear direction in law.

Telemedicine Regulatory Impediments on Advanced Nursing Practice

Although few institutions will formally acknowledge how the market has changed nursing practice, data clearly reinforces corporate organizational and demographic trends stressing the preeminence of registered nurses as primary care providers in managed care. Multiple providers are used to reduce the cost of care and, in many instances, nurses are disproportionately utilized in managed care settings to address the primary care needs of the patient population. An article in the Journal of the American Medical Association noted that "increasing amounts of health care that in the past, have been provided principally by physicians" is now being provided by non physicians clinicians.[12] In other articles, it has been reported that by year 2005 that the number of nurse practitioners in clinical practice will equal the number of general practitioners; that national distribution of nonphysician providers mimics that of physicians, but for nurse anesthetists, which suggests that advanced practice nurses will continue to compete directly with physicians for certain managed care positions, as the numbers of physicians in training are decreasing.[13] While other data suggest that there is a shortage of staff nurses, which will substantially affect care in the 21st century, it is clear that the APN and specialty workforces are growing.[14] These figures tend to suggest that there is an emerging reliance on advanced practice nurses as primary care providers within the managed care setting which will continue and will reinforce the added responsibilities of advanced practice nurses. Combined with workforce changes is the growing professional interest in expanded use of advanced practice nurses. Nurses and other health professionals are joining specialty organizations, pursuing research and defining the field of genetics nursing practice. With this added responsibility comes the increased obligation to address issues related to the use of technology. Using technology on a daily basis, the advanced practice nurse is more sophisticated and attuned to technological advances and support. Concurrently, health care is being provided within a more technological arena. In addition to the utilization of computers within managed care and other health delivery companies are using technology to track patients and care. Thus, more patient records are computerized and more corporate providers are developing databases to better facilitate care. More and better technology continues to support clinical information linkages and leads to better integration of care and integration of patient records. Medical

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[12]Richard A. Cooper, MD, Tim Henderson, MSPH and Craig L. Dietrich, BS "Roles of Nonphysician Providers as Autonomous Providers of Patient Care" Journal of the American Medical Association (September 2, 1998) 280:9 795-802.

[13]Richard A. Cooper, MD, Prakash Laud, PhD and Craig L. Dietrich, BS "Current and Projected Workforce of Nonphysician Clinicians" Journal of the American Medical Association (September 2, 1998) 280:9 788-794.

[14]Ibid

records are becoming more patient centered than provider centered.[15] And institutional providers are more compelled to incorporate more information into one's patient records. Patient records are retained in a manner that makes them more transferrable and accessible during a patient's life and more individuals within the health delivery system have access to patient records. All of these factors create an environment where the regulation of access to patient information is essential.

To better understand the nursing concerns associated with telemedicine or telehealth, we must understand the regulation of patient information. All states have laws which provide some form of protection of the privacy of patient records and the confidentiality of patient-provider discussions, however, there is little consistency in state law. Federal laws and proposed regulations have been recently addressed which provide some protections for health information; and there are state telehealth laws. All make up the foundation for protecting patient health information. These laws sometimes conflict and commentators have identified gaps within this complex regulatory scheme. While we cannot provide a comprehensive analysis of the differing systems to protect patient privacy, we can provide some discussion and analysis of these laws and direct identify issues which require nurses to research the law to assure that patient information is properly protected.[16]

State regulatory schemes to protect privacy and confidentiality vary considerably. While most states have general law which regulates disclosure and inappropriate transfer of patient information, a number of states also have laws which regulate health information databases.[17] State confidentiality statutes are universal and have many similarities. However, the terms, breadth and level of specificity varies considerably.[18] Some state laws define health care providers or the type of provider covered, while others infer coverage based on access. Some

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[15]Waller at page 147.

[16]For more information on state privacy and confidentiality laws, see Roth, Jarquin and Palmer "Confidentiality Issues Affecting Practitioners in Telemedicine: What Someone Else Does Not Know Could Hurt You" and Scanlon, Colleen "The Legal Implications of Genetic Testing" (March 1998) RN . On issues related to the HIPAA and regulations, see Waller, "Preparing for the Complexities of Administrative Simplification Under HIPAA" Health Law Handbook: 1999 Edition, Alice G. Gosfield, editor (West Group: St. Paul, Minnesota) and ANA Comments on the HIPAA regulations submitted to the Department of Health and Human Services (February 17, 2000).

[17]37states have legislative mandates to collect hospital data. States vary in how they implement these mandates from utilization of state agencies, contracting with independent agencies, working with hospital associations to implement the mandate or working with AHCPR's Healthcare Cost and Utilization Project National Inpatient DataBase. Information for D. Love, National Association of Health Data Organizations, per e-mail (March 14, 2000).

[18]Roth, Jarquin and Palmer at 664.

confidential relationships are created by state statute, however, it should be noted that the nurse-patient confidentiality is inferred from case law, although it has not been specifically articulated in any rule or statute.[19] Maryland has specific, precise laws associated with protection of health information while California's Medical Information Act is very general and designed to address "any individually identifiable information in possess of or derived from a provider of health care."[20] Other states list out the individuals who are held accountable under state law. And the statutes vary on the permitted disclosures of health information, to include (1) for purposes of obtaining payment for health services from an insurer health plan; (2) for purposes of diagnosis and treatment of a patient, including emergency treatment; (3) for the sale of a medical practice or health care facility, or (4) for minors to receive special treatment under state codes.[21] In short, the statutes are far from uniform and require review by all nurses in each state where she practices.[22]

After reviewing and analyzing these complex and sometimes conflicting statutory requirements, nurses then must determine whether the ability to practice by electronic means across state lines is authorized by state nursing and medical licensure laws. While there is inconsistency in state nursing practice acts, most nurses can get clear direction on their scopes of practice directly from the statute, however, many find that they cannot practice telehealth in a state because physician licensure laws have been amended or a telemedicine statute has been added to define the practice to include all healthcare within its purview.[23] Thus, nurse practitioners licensed in states where this confining definition of telemedicine has been adopted have their own scopes of practice limited. We believe that these statutes have been clearly designed to forestall any perceived encroachment on the practice of medicine and are clearly anticompetitive.

In conclusion, we believe that these issues have evolved and national intervention is needed. Although we are strong proponents of state legislation, inconsistency in the regulation of matters related to the internet has clearly limited the scope of practice and business

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[19]Fuetz-Harter at 74.

[20]Roth, Jarquin and Palmer at 664.

[21]Roth, Jarquin and Palmer at 664 and ANA Comments on the HIPAA regulations submitted to the Department of Health and Human Services (February 17, 2000).

[22]For additional discussion of the regulation of telemedicine, see Daley, Healther A. "Telemedicine: The Invisible Legal Barriers to the Health Care of the Future", 9 Ann. Health L. 73 (2000).

[23]Idaho, Indiana, New Hampshire, North Carolina, Pennsylvania and Arizona treat telehealth as the practice of medicine, per Guttman-McCabe, Christopher, "Telemedicine's Imperilled Future? Reimbursement, Licensing and Privacy Hurdles Face A Developing Technology" 14 J. Contemp. Health L. & Policy 161 (Fall, 1997).

opportunities available to the nurse practitioner. Subsequently, these impediments curb growth and development of cost-effective, safe and appropriate health care options for consumers.
Sincerely,

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Nurse Practice Counsel

cc: Alice Bodley, General Counsel
American College of Nurse Practitioners
Jan Towers, American Academy of Nurse Practitioners