Before commenting, I need to attach a disclaimer: I am an employee of the University of Nebraska College of Pharmacy and a prn pharmacist for Walgreens. I am also a member of several professional pharmacist associations. My comments are my own and do not reflect the views of my employers nor the associations in which I am a member.

I am pleased to see interest in health care professional scopes of practice. Much of the current legislative and regulatory language in states was written before the technology explosion and before cooperation and collaboration were the norm in provider education. I would like to address 4 of the questions asked in your request for comment:

**To what extend do professional regulations vary by state? Does state-by-state variation affect patient health, health care spending, or other important measures?**

The simple answer is that the 10th Amendment to the United States Constitution virtually guarantees that there will be 50 different sets of statute and regulation regarding health care professionals. Each state has the duty and the right to regulate at a level determined within that state to be necessary to protect the health of the public. While the regulations and statutes will be similar, there will always be differences. Organizations such as the National Association of Boards of Pharmacy produce model practice acts for the profession they represent, but there is little collaboration between and amongst these organizations to create an over-all model for state regulations of health care providers. The important question, however, does not focus on the variances; it focuses on the provision of health care. Does variation affect spend? Yes. Consider pharmacist provided vaccine. In some states pharmacists provide all approved vaccines under protocol with a diagnostician, licensed to prescribe. In other states pharmacists have a limited formulary of vaccine from which to choose or are limited by the age of the patient. States such as Washington and Nebraska were quick to allow collaboration and others still do not fully embrace the concept. In those states where patients are not allowed to seek vaccination at a pharmacy, the patient must pay an office-visit copay and the insurer must pay the remainder of the negotiated fee. Pharmacies don't charge copays to walk in the door, instead they charge only for the administration and cost of the vaccine. A review of vaccination rates shows that pharmacists have positively affected the number of vaccines provided for many contagious diseases especially influenza and pneumococcal pneumonia.

**To what extent are health care services being delivered in new formats and locations, such as retail clinics? What trends are projected in the future?**

Moving health care to new locations is not necessarily problematic, even in light of the variances in state regulations. Moving health care to new providers is often problematic. Point-of-Care testing for influenza and group a streptococcus is being piloted in community pharmacies in Nebraska, Minnesota and Michigan. The tests are CLIA waived at the federal level and care be made available to the public on demand, if the appropriate signs and symptoms are present and there is reason to

suspect infection. Completing the test takes less than 15 minutes and pharmacists have the ability to provide on-site treatment, under protocol with a diagnostician. In some states the pharmacist must have permission from a diagnostician to conduct the test, (e.g. Michigan) in others permission is only required for follow up dispensing (e.g. Nebraska) and in still others this process is not allowed (e.g. New York). Trends toward patient centered care, including improved access to care by increasing trained and qualified providers and utilizing facilities, such as community pharmacies with extended hours of operation will continue to challenge the imagination of those who want to expand quality care and decrease cost.

**What are the competitive implications of the increased use of retail clinics on the supply of services, cost, quality, and access to care?** While I appreciate a concern about competition and free enterprise, the focus of any exploration of health care has to be firmly centered on patient safety and quality of care. Once those are assured, then further discussion about economics and accessibility are reasonable. A review of curricula for many health care providers shows that academic growth is currently far outpacing regulatory acceptance of that growth. In my state recent legislative activity around Advanced Practice Nurses (Nurse Practitioners) and Optometrists serves to highlight that training and qualification on an academic level is often slow to be recognized at the regulatory level. In-fighting between health care providers representing the myriad of health professions frequently misrepresents the cooperation and collaboration seen in practice and all but ignores the desires of the patients. The increase in retailization of health care has many causes: access, hours of operation, lack of a primary care medical home, expense, etc. Retailization, in and of itself, is not a detriment to quality and rarely does it affect the provider-patient relationship if quality communication is built into the provision of care. Embracing collaborative practice and the development of an electronic health record where all health care providers are granted read/write access will all but eliminate concern about the site of care for many common, low intensity conditions. Further, the retail location – by seeing patients who do not have a traditional medical home – are in the perfect position to identify those patients requiring more intensive care. Pharmacists are involved in screening for Hepatitis C and HIV infections in order to get patients with reactive tests refereed for care. These screening activities can only exist in community pharmacies and other traditionally retail settings. This isn't an issue of competition; there are many more patients in need of health care than there are providers of the services required. In rural communities, in underserved areas rural or urban, for underserved populations and in health care shortage situations, pharmacists, in retail settings, are in the perfect position to help low acuity patients and to get referral for those needing more intensive therapies.

**Are there other factors that should be considered when analyzing the competitive implications of retail clinics, telemedicine, and other new models of health care delivery?** As stated before: full access with read / write capability for all providers is essential in the development of a comprehensive electronic medical record. Finally, when considering the variety of regulatory mechanisms

controlling the provision of health care do not underestimate the value of collaboration. Payment models will need to be developed to recognize the value of each partner in the collaboration, but this care model may be safer and less expensive than expanding scopes of practice. Continuing vigilance is necessary, at the federal level, to assure that turf protection for the sole purpose of turf protection is not allowed and to assure that all citizens have access to providers who are trained to provide the services requires.

Thank you for the opportunity to provide comment on your questions about safety, access, and the challenged presented with 50 differing sets of health care regulation.