FULL TEXT OF ESSAY RESPONSES TO QUESTIONS 50, 51, 52, 53, 54, 55, 56 AND 57 OF THE PED SURVEY INSTRUMENT

50. **In your opinion, what would be the benefits to creating a single state agency to perform all of the OLA's administrative and regulatory activities?**

As discussed below, the Board of Pharmacy does not see any appreciable benefit to its regulatory or administrative functions being absorbed into a single state agency.

51. **In your opinion, what would be the challenges of creating a single state agency to perform all of the OLA's administrative and regulatory activities?**

The Board of Pharmacy's activity centers on investigating and enforcing statutes and rules that govern a specialized, technical health-care practice, as well as setting regulatory policy for, and providing guidance and education to, practitioners in that field. Centralizing both administrative and regulatory functions would substantially reduce regulatory expertise, accessibility– both to those the Board regulates and to the general public – and operational efficiency. These reductions in expertise, accessibility, and efficiency would come at a cost to the public health and safety.

<u>Expertise</u>

- The work of the Board of Pharmacy requires that its members and its staff have specific expertise and experience in both the practice of pharmacy and the laws and rules that govern the practice.

- Five of the Board's members are licensed pharmacists in good standing, each of whom is highly experienced in the practice of pharmacy. These members, as experts in the regulated field, provide critical and irreplaceable direction and oversight of the Board's regulatory, inspection, and investigative priorities. These member experts set regulatory and rulemaking policy. They hear and decide cases in this specialized field. These critical functions simply could not be performed well, or even adequately, by regulators lacking this field-specific expertise. Moreover, by supervising Board staff, these member experts are able to ensure that these policy priorities, which can change rapidly in response to demonstrated threats to the public health and safety, are followed to the letter.

- Effective regulation of a specialized, complicated health care field like pharmacy requires that investigative and inspection staff be knowledgeable and specifically trained in often highly technical areas. Two licensed pharmacists serve on the Board's staff and are essential to guiding and supervising the Board staff's regulatory efforts. Furthermore, Board investigator-inspectors are trained in technical, pharmacy-specific areas crucial to effective enforcement activities. For instance, each year Board of Pharmacy investigative staff undergoes dozens of hours of intensive, hands-on training on United States Pharmacopeia sterile compounding standards. Such training and expertise is indispensable to protecting the public health and safety – as plainly demonstrated by 2012's New England Compounding Center tragedy (hundreds of patients nationwide were sickened or killed by contaminated compounded prescription drug products). Consolidating regulatory or administrative functions among diverse licensing boards would deprive the Board of Pharmacy (and thus the public) of this expertise. Generalist inspection and investigative staff simply would not be able to obtain this level of specialized training and expertise. The quality and scope of inspections and investigations of pharmacists and pharmacies would, necessarily, be reduced. The cost to the public could be catastrophic.

• Furthermore, Board investigative staff frequently must work closely with other agencies such as the federal Drug Enforcement Agency, the federal Food and Drug Administration Office of Criminal Investigations, where the need for specific, in-depth expertise in pharmacy practice and regulation is essential for effective investigation and regulatory action.

• Finally, capacity for innovation in the field of pharmacy practice would likely be stifled by non-expert regulators or administrators. Regulatory changes are often needed to permit or encourage practice advances. Non-experts would be less likely to recognize or appreciate such needs, at least in a timely way. Recent examples of the Board facilitating pharmacy practice innovation include: creation of the Clinical Pharmacist Practitioner credential (widely viewed as a national model), advances in pharmacy technician training responsibilities keyed to increasing pharmacists' ability to provide needed clinical services to patients, and rapid integration of technologies designed to improve patient care and access.

<u>Accessibility</u>

• A large portion of the Board's work is to provide immediate, thoughtful, and accurate information and guidance to both those we regulate and the general public. Interposing a barrier between those the Board regulates and those the Board serves would disrupt that rapid access to knowledgeable staff. Plainly, obtaining immediate, accurate guidance and advice prevents harm to the public health and safety.

• The North Carolina Association of Pharmacists, the four schools of pharmacy in North Carolina, and Carolinas HealthCare System (the largest health care system in North Carolina) have expressed concern that any consolidation of function – regulatory or administrative – with other Boards would jeopardize this ready access, with significant costs in time, resources, and protection of the public health.

• Members of the North Carolina Association of Pharmacists who are licensed in multiple states report that the North Carolina Board's accessibility, expertise, and level of service surpasses that of other state boards of pharmacy. As well, a majority of pharmacists who responded to a Board website feedback survey in 2013 reported that the Board's staff and on-line resources are more helpful and knowledgeable than those found at other state boards of pharmacy.

• The North Carolina-based schools of pharmacy report that their attempts to facilitate new graduates' licensure in neighboring states is often a slow, frustrating process attributable to access and expertise barriers inherent in the "umbrella" structure of licensing boards in those states.

• The Board's licensing staff constantly must interact with other state boards of pharmacy. Licensing staff find these interactions frustrating and slow, again owing to access and expertise barriers inherent in the "umbrella" structure of licensing boards in those states.

• The Board's investigative staff have on a number of occasions been forced to travel to other states to investigate serious allegations of unlawful behavior because the pharmacy's home-state "umbrella" board Is unable to respond quickly and expertly.

• The National Association of Boards of Pharmacy ("NABP") has noted that "based upon [its] over

100 years of experience in working with the state boards of pharmacy, in general, an autonomous board of pharmacy is more cost effective, responsive, fiscally prudent and responsible, and efficient than a consolidated board of pharmacy." Furthermore, NABP has noted that the "overwhelming number of complaints" that it receives from "patients who are unable to contact or resolve with their respective board of pharmacy complaints and threats to the public health" are made "against consolidated boards of pharmacy."

• Accordingly, both those the Board regulates and those the Board protects place extremely high value on, and rely heavily upon, ready access to knowledgeable staff. Consolidation, or interposition of non-expert bureaucratic layers, reduces that accessibility.

Efficiency

• The Board of Pharmacy has consistently provided efficient, reliable, and readily accessible service to those it regulates and to the general public. It does so without any cost to the State's general fund – *i.e.*, the Board is financed entirely by licensing fees and Board personnel are not state employees. The Board has done so without any increase in licensing fees since 2005, and without any need for increased fees anticipated for the foreseeable future.

• As discussed above with respect to expertise, part of the Board's efficiency derives from its flexibility. Investigative priorities in the health-care field can change rapidly as a result of demonstrated threats to the public health and safety. A consolidated occupational licensing agency would likely be unable to shift priorities and resources with the speed that is often required to protect the public from emergent threats in the health-care field.

• The regulatory flexibility and responsiveness afforded by independent status provides real public health and safety benefits. For instance, when the New England Compounding Center tragedy broke in 2012, the Board of Pharmacy was able to act to revoke the pharmacy's North Carolina out-of-state permit within an hour of learning the identity of the pharmacy – far faster than NECC's home state Massachusetts Board of Pharmacy could act. Massachusetts' actions were significantly delayed by the bureaucratic "umbrella" structure of its health licensing boards.

• The Board has developed and implemented efficient, tailored information technology systems that allow its licensees to conduct most activities on-line (e.g., submission of license applications, renewal of licenses, management of continuing education requirements, obtaining Controlled Substance Reporting System access). Furthermore, internal Board databases tracking various data sets – *e.g.,* licensee information, inspection activity, investigation activity, and disciplinary actions – are also integrated into this information technology architecture. Any consolidation of information technology resources would disrupt these systems at significant cost to the Board. Moreover, fragmentation of such databases would significantly hinder the Board's operational efficiency and enforcement efficacy.

• Similar concerns exist with respect to administrative functions, as will be discussed more fully below in the response to question number 53.

52. What would be the primary benefit of centralizing the administrative activities of the OLA's, while continuing to authorize each OLA with the responsibility and authority to administer its regulatory activities?

As discussed above, and as further discussed below, the Board of Pharmacy does not see any appreciable benefit to its administrative functions being absorbed into a single state agency.

53. **What would be the primary challenge of centralizing the administrative activities of the OLAs, while continuing to authorize each OLA with the responsibility and authority to administer its regulatory activities?**

The Board's response to question number 51 above describes the reductions in expertise, accessibility, and efficiency likely to flow from any consolidation of the Board's functions with other licensing bodies. And these reductions are likely whether the particular activity is deemed "regulatory" or "administrative." What follow are some additional commentary specific to what the survey instrument defines as administrative activity.

- Expertise is also essential to protecting the public health and safety in matters defined by the survey instrument as administrative. For instance, licensure application intake and review (and its corollary function of license examination administration) is defined in the survey glossary as an administrative activity. Processing an application for licensure as a pharmacist or a pharmacy, however, requires an in-depth review of qualifications, pharmacy services provided, criminal background, professional disciplinary history, civil malpractice liability, and other factors. Indeed, the Board is required to conduct hearings multiple times each year to review potential serious public health and safety risks disclosed – or hidden – in applications for licenses and permits. The kind of screening and evaluation required to prevent an unsafe actor from obtaining a license in North Carolina in the first instance simply cannot be performed effectively by a generalist administrative staff.

- The survey instrument characterizes "complaint intake" to determine "whether or not the Board has jurisdiction and whether or not there is probable cause that the reported allegation(s) violate existing laws or regulations and warrant further investigation" as an administrative task. But, in the context of regulating a highly technical and complicated field like pharmacy, this sort of review requires in-depth, sophisticated analysis by staff with specific expertise in the practice of pharmacy and its regulation. Review of this sort also serves a critical efficiency function. It is most efficient to have complaints reviewed substantively, and completely, by a small integrated staff of experts in the field rather than a two-step review, first by generalists and then by expert staff.

- In other words, consolidating "complaint intake" functions or "license application" functions would not reduce the need for expert review, it would simply create an additional layer of personnel to no apparent public health and safety end.

- With respect to "human resource management," consolidation would have significant expertise and efficiency costs. With respect to expertise, as noted in the response to question number 51, Board personnel must be expert in the field of pharmacy practice and the Board must retain its ability to ensure that its policies and enforcement priorities are being carried out by those personnel. Continuing control over personnel hires is essential to meeting these goals. Furthermore, making Board staff (who are not state employees) subject to the state personnel act and beneficiaries of the state health and retirement plans would simply create a new financial obligation of the state, with no apparent public health and safety benefit.

54. **Please provide a brief description of specific instances where an individual suffered severe physical or emotional injury as a result of <u>unlicensed</u> activity in an occupation licensed by the OLA, including a description of the injury and the associated financial impact on the public or individual, as applicable.**

Illegal activity by unlicensed pharmacies is a real, and continuing, threat to the public health and safety. This includes "pharmacies" (often Internet-based) that are not licensed in any jurisdiction, as well as pharmacies that may be licensed in some jurisdictions but that send dangerous drugs to North Carolina patients without being licensed in this state.

- Recent years have seen the proliferation of unlicensed, often (but not exclusively) Internet-based rogue "pharmacies" that traffic narcotics and other dangerous drugs. The physical and emotional toll on the public caused by such "pharmacies" is enormous and has been a priority enforcement focus of policymakers at both the federal and state level. These "pharmacies" are a significant contributor to the prescription drug diversion epidemic in the United States. As well, they frequently offer drugs that are contaminated, counterfeit, subpotent or superpotent, and/or possess harmful substances. Some tainted drugs tested from online unregulated pharmacies have been found to contain dangerous levels of arsenic, lead, tin, aluminum, and warfarin (rat poison). A recent FDA warning announced a potentially dangerous counterfeit version of Adderall (a Schedule II controlled substance used to treat ADD/ADHD in children and adults) being sold on the Internet.

- Some specific examples of physical and emotional harm suffered as a result of patients receiving services from unlicensed "pharmacies": (a) a 30-year-old man took two powerful drugs ordered from the Internet without a physician or pharmacist oversight, almost died, but suffered debilitating health effects including permanent brain damage; (b) a 24-year-old died because of a prescription drug overdose after taking a mix of prescription drugs that he easily obtained without a prescription from an illegal website; (c) a young woman became violently ill after taking a drug she ordered from an Internet site. She thought the site was a legitimate pharmacy, and ordered her regular allergy medication online for convenience, only to receive a product that caused her to suffer intense headaches and stomach problems, requiring attention from health-care providers.

- The Board of Pharmacy frequently must take regulatory action against pharmacies that may be licensed in some jurisdiction, but are not licensed to practice pharmacy in North Carolina. In the past year alone, the Board has taken dozens of regulatory actions against unlicensed pharmacies. Some actions focus specifically on dangers of the specific drugs being dispensed – *e.g.*, compounded drug products and narcotic drug products. And in many cases, the "prescriptions" for such products are found to be issued for purposes other than legitimate medical practice. Furthermore, such investigations often uncover other violations of North Carolina law that endanger the public.

- Indeed, the breadth and depth of physical and emotional injury caused by unlicensed pharmacies is almost certainly underreported. For instance, patients seeking narcotics through illegitimate channels are exceedingly unlikely to report problems with such channels to regulatory authorities.

55. **Please provide a brief description of specific instances where an individual or the public at-large experienced severe adverse economic consequences as a result of <u>unlicensed</u> activity in an occupation licensed by the OLA, including a description of the economic harm and the financial impact to the individual and/or public.**

• The types of physical and emotional harms described above in question number 54 plainly result in economic injury as well. The economic costs of abuse and diversion of narcotics alone likely runs into the billions of dollars annually. In addition, illegitimate, unlicensed practitioners charge patients millions of dollars for drugs that are unsafe, contaminated, or counterfeit. Patients with legitimate medical needs who are drawn in by illegal, unlicensed "pharmacies" are necessarily drawn away from pharmacies licensed in this State that are willing and able to provide high quality, safe care, to those pharmacies' economic detriment.

56. **Please provide recommendations or suggestions regarding opportunities where consolidation with other OLAs would serve to improve the overall efficiency and effectiveness of each OLA's operations.**

• There are no apparent gains to be realized by consolidating any other licensing board's functions into the Board of Pharmacy. The Board of Pharmacy already regulates all dispensing of prescription drugs, devices, and medical equipment to North Carolina patients.

57**. Is there anything else you would like the legislature to know about this issue?**

It was difficult to fully capture the scope and depth of the Board's regulatory mission in responses to the survey. Accordingly, the Board would welcome an opportunity to further discuss its mission and its activities with PED staff or other interested parties, or to provide any additional information.