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August 1, 2016

Common Sense Initiative

Dear Lt. Governor Taylor:

On behalf of the 4,900 family physician, family medicine resident and medical student members of the Ohio Academy of Family Physicians, I write to express our grave concerns about the Pharmacy Board's proposed regulations governing the use of compounding of nonhazardous drugs by prescribers in the office setting, OAC 4729-16-04 and 4729-16-13. We appreciate having the opportunity to submit comments to the Common Sense Initiative (CSI) about the negative impact these overreaching rules will have on our patients and our practices.

The US Pharmacopeial Convention (USP) is the leading scientific body responsible for establishing standards for the safe manufacturing, distribution and consumption of drugs in the US and worldwide. USP Chapter 797 governing Pharmaceutical Compounding—Sterile Preparations is currently undergoing a review. USP is expected to release a draft this fall with the potential for additional stakeholder comments. It is working with the leading scientists, health care providers and regulators to revise its standards on compounding and sterile protections. Why would we not wait to see how this review plays out? Why would we not make an effort to make standards align? Inconsistency with federal regulations certainly should not be the desired outcome.

Proposed compounding rules have created great confusion and concern particularly with regard to provision of vaccines in the primary care office. The original rules contained provisions that were so restrictive that primary care practices could have been forced to stop administering immunizations. We believe that the revised 6 hour immediate use provision filed with CSI has fixed that concern, but the larger point is that new regulations almost always have unintended, negative consequences.

Physicians and their practices are already regulated by the State Medical Board of Ohio, the principal agency that protects the public through effective regulation of medical practice in Ohio. More and more we are seeing the State Board of Pharmacy add layers of regulatory burden to the practice of medicine. In fact, we have complained for years that physicians do not have a seat on the State Pharmacy Board even though pharmacy board regulations heavily impact physician practices and the patients for whom they provide care, often with a negative effect.

Layers upon layers of regulation are confusing, complex, extremely burdensome and expensive to implement. Many primary care practices are small businesses that struggle to stay afloat – meeting payroll, paying bills, keeping the lights on while providing patients with the highest quality care. Increasing the costs of clinical care without correspondingly significant improvement in patient safety just doesn't make sense. In the materials submitted to the Common Sense Initiative, the Pharmacy Board admits to the substantial expense practices will incur to implement these new requirements. Many predict the actual expense will be much more than is documented in the Pharmacy Board's CSI filing.

In conclusion, let me say that this constant barrage of rules by multiple regulatory bodies contributes to a larger problem. Regulatory hassles, interference with the practice of medicine, the overwhelming burden of paperwork and the associated costs of requirements imposed on physicians and their practice teams are causing physician burnout. A recent survey of our members indicated the severity of this problem. The joy they experienced when they had the time and energy to interact and care for patients is diminishing - and the burden of regulatory requirements is one of the major contributing factors. We have to start addressing these regulatory hassles in medicine or we are going to have a greater problem in achieving and maintaining a sufficient primary care workforce to provide care to an aging population.

All of these factors - regulatory burden, cost, paperwork, and their impact on the practice of medicine, including physician burnout - should be considered by CSI when reviewing these specific rules (and future rules for that matter). Those of us on the front lines of medicine are overwhelmed and sinking under the weight of the regulatory system around us.

Thanks again for your willingness to listen to our concerns. We urge the State Board of Pharmacy to withdraw these rules that unnecessarily restrict physicians in the practice of medicine. Please don't hesitate to call me, if you have questions.

Sincerely,



Thomas P. Houston, MD  
President

Copy to:

The Honorable Shannon Jones, Chair  
Senate Health and Human Services Committee

The Honorable Anne Gonzales, Chair  
House Health and Aging Committee

Cameron McNamee  
Director of Policy and Communications  
State of Ohio Board of Pharmacy