

**House Bill 1570**  
Revising Hospital Regulations

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To  
The Pennsylvania House of Representatives  
Health Committee

By  
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Pennsylvania  
**MEDICAL SOCIETY**<sup>®</sup>  
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Good morning Chairman Baker and members of the House Health Committee. My name is Marilyn Heine and I am president of the Pennsylvania Medical Society (PAMED). My tenure as president began five days ago, so suffice it to say, I'm a little new at this. So please bear with me. For background purposes, I practice emergency medicine in Montgomery County and hematology/oncology in Bucks County.

I sincerely appreciate the opportunity to appear before this committee today to discuss House Bill 1570, legislation intended to update our state's hospital regulations. As we all know, the practice of medicine and the delivery of health care services is in a continual state of change. Physicians are accustomed to change. Advances in clinical medicine change rapidly...sometimes overnight, as new approaches in treatment protocols and surgical techniques are often refined with each patient encounter. While medicine is based in science, the "practice" of medicine is an art form that must remain flexible to appropriately treat the uniqueness of each and every patient.

It is no surprise that the current hospital regulations, whose sole purpose is to govern the practice of medicine within the hospital setting, are in need of a major overhaul. Representative Reichley, House Bill 1570's prime sponsor, is to be commended for undertaking such a daunting task. We agree that improvements to these regulations, whose last major overhaul took place some 30 years ago, are long overdue. However, we have serious concerns that elements of House Bill 1570 stray far afield from ensuring the safe delivery of hospital based healthcare services. Our focus is solely on improving and protecting the quality of care in Pennsylvania, and we are concerned that this bill—while well-intended—will not accomplish this.

Our first concern is a hospital's medical staff. As we all know, a "hospital" is simply a building, bricks and mortar, where physicians both provide and direct the delivery of medical care to patients. We believe that it is critically important that a hospital's medical staff function independently of a hospital's administrative staff. The decision to proceed with a particular treatment be it surgical, diagnostic or otherwise must rest with the physician and the patient for whom he or she is caring—if quality care and appropriateness of that care is our ultimate goal.

I believe that it is very important for this committee to be aware that this proposal, as currently drafted, fundamentally changes the way licensing standards for hospitals will be established, which could indirectly affect a medical staff's independence. Currently, hospitals must comply with the standards established in regulation by the Department of Health. In establishing its standards, the department must "take into consideration Federal certification standards and the standards of other third party payers for health care services and such nationally recognized accrediting agencies as the department may find appropriate." However, the department remains the ultimate authority in establishing these licensing standards (with the exception of fire and safety standards).

In stark contrast to this oversight, House Bill 1570 will, for all practical purposes, make meaningless any Department of Health regulations for licensure of hospitals. It exempts from "department-established standards" any hospital that is accredited by a national accrediting organization approved by Medicare or that participates in Medicare and is subject to the Medicare conditions of participation. Virtually all hospitals in Pennsylvania are accredited by a qualified accrediting organization – the most common being the Joint Commission. The few hospitals who are not accredited would be exempt by virtue of their participation in Medicare.

We believe that this "deemed licensure" of hospitals, while appearing benign is a slippery slope that is fraught with potential problems...several of which may not be readily apparent. Hospital

regulations do not only address what many of us might consider hospital infrastructure and operating guidelines, they also set important standards for matters such as hospital medical staff eligibility, as I mentioned earlier.

These regulations govern critical areas of patient safety such as physician oversight and supervision of certified registered nurse anesthetists, CRNA's, as one example. Interestingly, since the Joint Commission does not specifically address medical staff eligibility and physician supervisory requirements, these issues would become "unregulated" for any hospital licensed through the "deemed status" process. This is of great concern to physicians who provide or direct care in hospitals since it is ultimately their responsibility to ensure that patients receive care that is appropriate and of the highest quality possible.

Hospital regulations are a complex set of rules and guidelines that govern nearly every aspect of patient care by physicians, and non-physicians alike, taking place within the hospital setting. Yes, the current regulations are in desperate need of revision. Yes, much has changed with medical technology and the way in which we deliver care in hospitals since these regulations were last updated. But we should not take the path of least resistance by in essence handing over regulatory authority of our hospitals to national accrediting organizations. More importantly, we must not permit hospital medical staffs to be influenced by forces that may not be focused solely on "clinical" medicine.

House Bill 1570 does not simply adopt the "current standards" of a private accrediting organization. In essence it "deems" the accredited hospital exempt from any state licensure oversight regardless of how the national accrediting organization's standards may change in the future. It is certainly appropriate for the legislature to incorporate by reference, for example, the current Joint Commission standards. However, carte blanche acceptance of future Joint Commission standards is a completely different path.

Does the legislature really want to cede control over the licensure of its hospitals to a private entity located outside the Commonwealth?

Another potential concern is whether the "deemed license" provision restricts the Department of Health's authority to survey or inspect accredited facilities and limits the department's authority to enforce compliance. Under current law, the department may rely on a Joint Commission survey. House Bill 1570, however, appears to mandate the department to accept the Joint Commission's findings, arguably even in the face of a complaint that the hospital is not in compliance with those standards. Importantly, there are no provisions authorizing the department to survey or inspect an accredited institution as a result of a complaint or a random audit or to proceed with a licensure action against a hospital who continues to be accredited.

In addition to the "deemed status" issue, we have concerns with language in the bill that would potentially lead to the regulation of private physician offices by the Department of Health. Currently, private physician offices are neither required to be licensed nor regulated by the Department of Health (except to the extent that they are operating an ambulatory surgery facility on the premises) The Health Care Facilities Act gives the Department of Health the authority to license and regulate health care facilities. Under this law, health care facilities are not permitted to include an office used primarily for private practice by a health care practitioner. As you know, private practice physicians are already regulated by their applicable licensing boards. So, depending on how House Bill 1570 is interpreted, it could create a situation where a physician's private office is regulated by two separate state entities.

House Bill 1570 also seeks to redefine a "health care facility" to include "specialized health services" and "outpatient health care facilities". Though the bill retains the exclusionary provision relating to physician offices, our concern is that the redefinition could be interpreted as restricting that exclusion. Language referencing "Specialized health services" is another area of the legislation that merits careful scrutiny. The bill broadly and vaguely defines this term to include "certain diagnostic, treatment or rehabilitative services which involve highly technical medical procedures and require extraordinary expertise and resources to be effective and safe as determined by the Department of Health." Under that definition the Department of Health has *carte blanche* in determining what is covered. I believe that the care I provide to my cancer patients requires "extraordinary expertise". Would that result in the Department of Health mandating that my office be "licensed" and regulated similar to a hospital? I would hope not.

House Bill 1570 gives the Department of Health great latitude in defining "outpatient health care facilities", which is of particular concern to us. While we applaud the recognition that departmental oversight of mobile facilities such as cataract surgery vans is warranted, language permitting the Department of Health to capture any other clinical service it deems appropriate to fall under the purview of an "outpatient health care facility" is very troubling.

As an example, physicians "admit" patients to hospitals for medical treatment because their illness is either acute or complex in nature. That is why you typically find the "sickest" patients in hospitals. When you consider the general health of patients being treated in facilities such as ambulatory surgical centers, the complexity of their treatment and their general health status is vastly different. While we certainly agree that ASC's must meet strict standards, those standards will, by the very nature of the care being provided, be different than acute care hospitals. This "sweeping authority", provided to the department under House Bill 1570, should rest with the legislature and not the regulators.

Again, we applaud the spirit in which Representative Reichley is working to review our current hospital regulations and to modernize them. However, as with any legislative proposal, care must be taken to avoid unforeseen problems. The PAMED has met with representatives of the hospital association to "work through" many of our concerns. We will continue to work with them and the members of this committee, specifically Representative Reichley, to achieve a set of regulations that protect Pennsylvanians while at the same time are grounded in sound clinical judgment.

Thank you again for the opportunity to share our concerns. To the best of my ability, I will be happy to answer any questions you may have regarding my comments here today.