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May 21, 2014

James McDonald, MD, MPH
Chief Administrative Officer, Board of Medical Licensure & Discipline
RI Department of Health
3 Capitol Hill
Providence, RI 02908

Re: Community review draft of *Rules and Regulations for Pain Management, Controlled Substance Prescribing and the Registration of Distributors of Controlled Substances in Rhode Island,* published by the Department of Health April 2, 2014

Dear Dr. McDonald:

The Department of Health is to be commended for actively seeking new and effective ways to stem the current epidemic of prescription and illegal drug overdosing in the state. It is well known that the impact of this deadly nationwide problem has been especially tragic in Rhode Island. In response, as you know, the Rhode Island Medical Society has been a leading proponent of the establishment and use of the state's prescription drug monitoring program (PMP). We also introduced and championed successful legislation to establish drug "drop boxes" at police stations. In addition, we have sponsored a number of continuing medical education events in pain management for physicians, most recently on May 17, 2014; we have treated the topic in our newsletter and established a safe opioid prescribing link on our website. We agree with you that more must be done.

Over the years we have sincerely appreciated the accessibility of the leadership of the Rhode Island Department of Health for frequent consultation and discussion about this entire complex of issues. We also appreciate the present opportunity to comment on the newly proposed amendments to the regulations affecting controlled substances.

As we wrote in response to the original iteration of these regulations, we have strong reservations about the approach outlined in the draft *Rules and Regulations* ("the Draft"). Our objections are based on the principle that every patient deserves to be treated and cared for as an individual, with sensitivity and respect for that patient's own best interest. We must hold fast to that principle and to its corollary, which is that physicians must have discretion to exercise medical judgment in providing care, based on their unique knowledge of the patient. To put it another way, the patient-doctor relationship must be recognized as primary; all else in health care, including many activities of government, are best regarded as support systems to the patient-doctor encounter. Physicians may draw upon scientific research, sound data, "best practices," the wisdom and experience of peers, and other resources for "decision support" of all kinds; but the intrusion of government into the actual practice of medicine and the management of patients, however well-intentioned it may be, is to be scrupulously avoided in any form.

We find that the Draft oversteps these bounds. In particular, we note that Sections 3.1 and 3.2 set forth highly detailed lists of mandatory steps that are unlikely to be relevant to every patient care situation and, in any case, whether relevant or not, would require extensive documentation, simply because the requirement is set in regulation. In addition, we note that 3.4 ("Written Agreement for Treatment") would require that all "(c)hronic noncancer pain patients who receive opioid medication(s) for greater than twenty-nine (29) continuous days *shall* [emphasis added] have a written signed agreement between at a minimum the practitioner and the patient (or their proxy)," and, further, that this written agreement must include at least eleven elements specified in the Draft.

This level of prescriptiveness in patient care is highly inappropriate in any governmental document, especially one that has the force of law, (and even in ones that may be promulgated as government-issued "guidelines"). Not only would such regulations impermissibly constrain medical judgment and homogenize large numbers of individual patients; they would also create acres of new minefields for physicians and extensive new playgrounds for certain attorneys -- all with no compensating benefit for patients. Indeed, for every patient for whom the Draft's straitjacketed approach to written agreements may be appropriate, there will be many others whose important relationship of trust and collaboration with their physicians will be damaged by it. We are not suggesting that patient-physician agreements are not useful; on the contrary. However, it is not appropriate that government mandate their use in any situation. We believe that our perspective is consonant with the feedback provided to you in person by the Primary Care Physician Advisory Committee on Wednesday morning, January 15. We also remind you that we, along with the Hospital Association of Rhode Island and the RI Academy of Physician Assistants, presented these same concerns to you in a meeting that took place at your offices on December 31, 2013.

In this regard, the observed voluntary responses of our professional community to public health emergencies are instructive. For example, the advent of the AIDS epidemic in the 1980s prompted the development and dissemination of new practices and protocols; these were supported by a modest new CME requirement (universal precautions), new confidentiality and testing safeguards, decriminalization of syringes and the implementation of a needle exchange program; at no time did government attempt to dictate how the emerging new at-risk population would be identified and cared for.

In the present opioid emergency, not only has RIMS sought to provide continuing education, but the AMA has responded with a new series of twelve CME offerings on pain management, all of which are available online (a total of 14.5 Category 1 Credits). For their part, the various emergency departments of Lifespan have voluntarily instituted their own policy of providing no more than three-day scripts for Schedule II drugs.

State government can still complement and support voluntary initiatives. The Medical Society is advancing legislation that will require registration with the Prescription Drug Monitoring Program as a condition of holding a license to prescribe schedule drugs. The Medical Society will also promote legislation in the current General Assembly session, as the Department suggested, to enable medical office personnel other than physicians to use the PMP. We believe the PMP could also be made more effective by enabling it to monitor and flag duplicative prescribing and dispensing.

We consider this kind of complementary and supportive government action to be fundamentally different from prescribing how physicians care for patients. We note that the overuse of antibiotics, promoting the evolution of "superbugs," represents an imminent public health threat that poses a far more serious danger to the general population than the current opioid epidemic. We would hope government authorities will resist any temptation to meet that threat with regulations that would either stay or force any doctor's hand in the care of any particular patient.

We thank you again for your diligent work in this and other areas and look forward to further collaboration in the interest of maintaining and promoting safe, high quality medical care for patients in Rhode Island.

Sincerely,

Elaine C. Jones, MD
President

c: Governor Chafee
Chief Judge Healy
Chairman Miller
Chairman McNamara
Senator Ottiano
Director Fine
Hospital Association of Rhode Island
Rhode Island Academy of Physician Assistants
Rhode Island State Nurses Association