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COMMENTS ON PROPOSED DEPARTMENT OF HEALTH RULES AND REGULATIONS FOR PAIN MANAGEMENT

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The following comments are submitted on behalf of the American Civil Liberties Union of Rhode Island and the Rhode Island Disability Law Center.

We want to begin by acknowledging and strongly supporting the Introduction to the regulations, which recognizes the importance of pain management in improving the quality of life of patients who suffer from pain, and the role that controlled substances can play in treating pain. A practitioner's unwillingness to provide appropriate pain treatment to patients – whether out of unwarranted concerns about addiction, fear of unduly strict DOH surveillance, or other reasons – is poor medical policy and cause for needless suffering.

We also applaud the Department for the many emergency steps it has recently taken to deal with the tragic sweep of opioid overdose deaths that Rhode Island has been experiencing, many of them apparently the result of questionable street drugs, and especially fentanyl-laced heroin.

Having said that, we are very concerned about this proposal, and particularly the punitive nature of the written treatment agreement that the regulations would require physicians to adopt in treating patients for pain. Our concerns are further heightened by the model “Sample Prescriber-Patient Agreement” appearing on the Department’s website. We believe that these detailed agreements may have the unintended but dangerous effect of exacerbating the ongoing

epidemic that the Department is working so hard to control. For the reasons that follow below, we therefore ask the Department to revisit this proposal and to instead adopt regulations that set limits on the types of pain management agreements that physicians may require their patients to enter into.

Section 3.4 establishes the minimum standards for patient-prescriber agreements. Among other things, the agreement requires the patient to agree “to provide biological samples for urine/serum medical level screening when requested by the practitioner.” Sec. 3.4(a)(1). It is important to note that this requirement is not limited to patients who have a history of illicit drug abuse.

We oppose the imposition of such an intrusive mandate on patients merely because they are in legitimate need of pain medication. Demanding that patients essentially be available 24/7 to take drug tests at the beck and call of their physician or staff undermines notions of trust and respect that should underlie the doctor-patient relationship. A requirement that a urine sample be provided on command is best left to people in prison or similar settings.

This intrusive mandate may also encourage those with addiction problems – and not necessarily with opioids – to seek their medication underground, which is an outcome that these regulations should be seeking to avoid.

In fact, an earlier draft of these regulations had gone even further, confirming the “surveillance model” of treatment that the urine testing provision implies. That draft required the patient-prescriber agreement to include a “written authorization that the practitioner may notify the proper authorities if he or she has reason to believe the patient has engaged in illegal activity.”

While this warning no longer appears in these proposed regulations, it remains in the sample “Patient-Prescriber Agreement” that appears on the Department’s website as a model policy. That agreement requires the patient to agree to allow the physician to “contact any healthcare professional, family member, pharmacy, legal authority, or regulatory agency to obtain or provide information about my care or actions *if the [sic] he or she feels it is necessary.*” (emphasis in original)

This threatening warning and waiver of confidentiality would appear to violate basic laws and standards governing the confidentiality of substance abuse treatment records. Further, as noted earlier, any good doctor-patient relationship must be based on trust, respect, and open communication among the patient, doctor and staff. That trust cannot exist if practitioners are demanding authorization to contact “legal” or other authorities any time they feel it “necessary,” especially since it may often be based on information provided candidly by the patient.

One can easily foresee some patients foregoing pain relief (or foregoing it through legal channels) and others refusing to be open with their practitioners about addiction or other problems they have, if they must agree to such a relinquishment of their privacy.

It is also worth noting that the DOH model agreement’s waiver of confidentiality is not, on its face, limited to addressing opioid prescription abuse. A patient who candidly reveals an addiction to other drugs, the use of marijuana, an acknowledgement of an alcohol problem that includes driving after drinking, or other problems that may be important for a physician to know, does so only upon risk of being reported to the police or family members if the physician deems it “necessary.” Encouraging practitioners to engage in this sort of disclosure inappropriately turns health care providers into law enforcement operatives, and takes their emphasis away from patient care.

In short, the Department's model agreement not only raises potentially serious legal issues, but also amounts to a disturbing erosion of the physician-patient relationship. We fear its expanded use has the potential unintended effect of driving individuals with addictions underground where they are more likely to obtain lethal drugs. It could lead others in need of medical attention to forego care altogether, or limit the care they need by not telling their physician everything he or she should know in order to properly treat them.

Unfortunately, greater use of this model agreement by physicians seems inevitable if these regulations are adopted. In being required to adopt a pain management agreement for patients, the first stop for many physicians will likely be whatever the Department is recommending.

In fact, we know that some medical providers have already taken the Department's model agreement to heart. In the past year, we have received complaints from patients about doctors who are requiring them to sign a "controlled substance agreement" as a condition of being prescribed pain medication. Like the Department's model, these agreements authorize the physician to share the patient's confidential health care information with police under broadly defined circumstances.

Attached as an appendix are redacted copies of two of those agreements. In both instances, the patients claimed they had never been accused of abusing the medication they had been prescribed. Rather, all patients receiving these medications from their doctor were being told to sign the agreements.

One agreement states: "[Medical practice] works with police. If police think I am breaking drug laws, I lose my right to privacy. [Medical practice] may share my records of prescribed controlled substance use." The second agreement requires the patient to "waive any

applicable privilege or right of privacy or confidentiality with respect to the prescribing of my pain medications” and authorizes the medical staff to “cooperate fully with any city, state, or federal law enforcement agency... in the investigation of any possible misuse ... of my pain medications.”

We have trouble reconciling these agreements with fundamental notions of the doctor-patient relationship. There is no small amount of irony in the fact that one agreement professes that “honest relationships are based on respect and open communication between patient, doctor, and all staff,” and that the other one claims that signing the agreement is “an essential factor in maintaining the trust and confidence necessary” in a physician-patient relationship. It would seem difficult to establish a patient’s “trust” or encourage “open communication” with doctors who seem so willing, even eager, to share information about their patients with the police any time they “think” the patient may be violating any drug laws.

Indeed, the punitive and patronizing tone of the actual agreements we have seen, as well as the content of the Department’s model agreement and the one envisioned by these regulations, is extremely jarring. But they are the logical outcome of the implementation of the Department’s proposed regulations.

In light of these problems, we also have concerns about Section 3.4(a)(6)’s acknowledgement that any violation of the agreement could result in “a tapering or discontinuation of the prescription.” In some instances, of course, this may very well be an appropriate response. But it is at tension with the Introduction’s sentiments about the importance of pain medication as a medical tool. It is somewhat cruel to require a patient to sign an agreement acknowledging the potential discontinuation of needed medical care solely because of a violation, no matter how small, of any of the numerous provisions that may be contained in it.

Rather than mandate such intrusive pain prescription agreements, as these regulations propose, we instead urge the Department to adopt regulations that bar medical providers from requiring patients to sign broadly worded agreements that have such punitive requirements as unbridled drug testing and broad confidentiality waivers.

In support of our concerns, we would be curious to learn if, in proposing this “written agreement” requirement, the Department is relying on any studies that have documented the efficacy of such a mandate in reducing prescription drug abuse. If not, that provides yet another reason for a revamp of these regulations.

In any event, it is difficult for us to think of a less productive way to promote an open doctor-patient relationship than by adopting this problematic “terms of agreement” requirement. While it may often be appropriate for a physician to set parameters for their patients in prescribing potentially addictive medications, doing so in the form of a detailed formal agreement strikes us as overkill. In fact, we are concerned that a patient’s violation of any such required agreement could potentially subject him or her to felony penalties pursuant to R.I.G.L. 21-28-4.05.

Finally, we wish to raise a concern about one other provision in these regulations. Section 3.2(b) requires a person picking up an opioid medication prescription to provide photo identification. We have learned in a completely unrelated context – in objecting to the implementation of a photo identification requirement in order for residents to vote – that a fair number of people simply do not have photo ID. The groups most likely not to have such ID are the poor, the elderly, and racial minorities. Section 3.2(b) could be a real impediment for some individuals seeking to obtain prescriptions for pain medication.

In conclusion, we recognize the difficult balancing act that physicians face. They certainly should not be in the position of knowingly facilitating the prescription of unnecessary pain relief medication. On the other hand, they should not be discouraging contact and threatening patients with police intervention, especially when the potential consequences, as demonstrated by the current epidemic, are so deadly. Yet the mistrust underlying these agreements is almost certain to encourage some patients to look for illegal drugs instead or, at the very least, deter some patients from seeking the legal pain medication they need. We believe the Department, through its introductory comments to the regulations, recognizes this. And the Department has acted in a much more positive and non-punitive manner in many other ways, such as through its new program to provide phone consultations for doctors who want expert assistance to help a patient they believe needs addiction treatment. These regulations, however, send a very different, and less constructive, message.

Since we have now heard from three patients attending three separate health facilities about this issue, the counter-productive nature of agreements such as those envisioned by these proposed rules cannot be shrugged off or easily ignored. In light of its serious nature, we hope that, particularly in light of the epidemic, DOH will review this matter, concur that these agreements are problematic, and revise the regulations substantially along the lines of our recommendations. As we have indicated, we believe they should bar physician agreements that subject patients to random drug screening at any time or require broad waivers of their privacy rights.

If the suggestions we have made are not adopted, we request, pursuant to R.I.G.L. §42-35-3(a)(2), a statement of the principal reasons for and against adoption of these rules,

incorporating therein your reasons for overruling the suggestions urged by us. Thank you for your time and attention to these concerns.

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