



MAINE MEDICAL ASSOCIATION

Jo E. Linder, MD *President* • Nancy M. Cummings, MD *President-Elect* • Kenneth Christian, MD *Chair, Executive Committee*
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November 1, 2010

Daniel Eccher
Program Manager
Controlled Substances Prescription Monitoring Program
Department of Health & Human Services
Office of Substance Abuse
State House
Augusta, Me 04333

RE: Proposed Amendments to Chapter 11 Rules Governing the Controlled Substances Prescription Monitoring Program

Dear Daniel:

Please accept the following written testimony as the Maine Medical Association's formal comments on the proposed rule amendments referenced above. These comments will be enhanced by my oral testimony at the rule-making hearing. After hearing the testimony of other interested parties, we may provide further written testimony prior to the expiration of the comment period.

In the way of background and context, from 2001 to 2003, the Association was very active in support of the important legislation that enabled the establishment of the Controlled Substances Prescription Monitoring Act. (Title 22, Chapter 1603). The proposal, advanced by Rep. Ann Perry and other legislators concerned about the growing problem of the abuse of prescription drugs, was no "slam dunk". To the contrary, the Maine Civil Liberties Union and many other opponents justifiably were concerned that the creation of a database in Maine of all patients prescribed controlled substances would be a gross violation of privacy and that its security could not be ensured.

Nonetheless, the law was enacted after two years of discussions and compromises. And part of its passage was based upon the understanding that the primary purpose of the law was to provide health professionals – prescribers with a powerful tool to prevent prescription drug abuse. Law enforcement personnel were not provided access and access to the health professions licensing boards was restricted to “for cause” investigations. In 2008, the law was amended to permit access to the Office of the Chief Medical Examiner and MaineCare, changes that MMA supported.

And in addition to supporting the original bill and the amendments, the Association has partnered with the Office of Substance Abuse and the Board of Licensure in Medicine to educate prescribers about the law and to encourage its use. We have participated in over thirty education programs presented in venues from York to Fort Kent in the last seven years, with financial support from OSA and the Board. The PMP has become the most important tool for prescribers in controlling diversion and we are proud of our role in assisting over one thousand prescribers enrolling in the program.

I present this background, as I do not want our comments this morning to be construed as the Association opposing the Program or being anything other than supportive of its staff. We have significant discomfort with portions of the proposed rule, and even the process by which it is presented here this morning, but remain strongly supportive of the program and its potential to assist prescribers in preventing diversion of legitimately prescribed medication.

As to the proposed amendments, I will start on a positive note.

The proposed change to Section 3. subsection 6., defining the term, “Data requester”, is a change we support. Adding the ability of non-licensed office staff to access the database will greatly assist busy physicians in accessing the available information. As much as we might wish otherwise, the existing portal is not very user friendly and it is not easy in the middle of a shift in the emergency room or in the middle of office visits to go to a computer terminal and log in. Currently, only a licensed health professional in the office can access the database on behalf of a prescriber preventing a capable medical

assistant or other office non-licensed personnel from performing this task. For those persons concerned that increasing access to the database may lead to violation of patient privacy or unauthorized access, note that section 7251 of the underlying statute subjects a person who intentionally misuses the dataset to a Class C crime. I am pleased to say that I am not aware of any improper access to the database over these past five or six years.

We are also supportive of the proposed amendments in Section 5, which require dispensers (pharmacies) to correct their own records and submit corrective copies of these records to the Program whenever they become aware of errors or omissions. We are also supportive of the proposed changes to Section 8 (Confidentiality), which allow the office to make aggregate information based on prescription monitoring information available to the public. It is important for the public to be aware of this information and this change is consistent with the underlying purpose of the law, which is to promote the public health and welfare.

It is the proposed new Section of the rule, Section 9 (Review of Information) that the Association opposes. While subsection 2 regarding review of patients does not appear to change the existing practice of informing prescribers and dispensers of certain thresholds being exceeded, subsection 3 regarding review of prescribers to a referral to their licensing board, threatens to upset the delicate balance between adequately treating pain and preventing diversion. In other words the proposal may have a “chilling effect” on the willingness of licensed health professionals to prescribe controlled substances to their patients.

Our problems with this section are both content-related and process-related, as follows:

- a. The proposed rule has not been reviewed by the PMP Advisory Committee, a group that was established for the very purpose of considering amendments to the law. We recommend setting aside Section 9, subsection 3 regarding prescriber review until the Advisory Committee, which meets in two weeks time, can review the proposal.

- b. It is not clear where the medical input would come from when the data calls for a review. We are very much opposed to any referrals to licensing boards without a thorough vetting of the data by one or more physicians who are specialists in that field. Even then, we would remain concerned about its impact. It is important to remember that the Program was intended by the legislature to be a tool for prescribers, not to be a route to punishment and discipline.
- c. We are very much opposed to PMP staff contacting patients, as provided for in Section 9, subsection 3B. Such contact by the state is likely to alarm patients and in some cases could lead to unnecessary anxiety or even to frivolous claims of medical negligence against the prescriber.
- d. There are parts of the rule which make no sense, particularly the threshold of 1000 patients receiving scripts in the previous six months. Historical data shows that we currently have no prescribers in the state who exceed this threshold.
- e. While we concur that self-prescribing is a red-flag for abuse, we are not certain that every instance of self-prescribing in Schedule II-IV should lead to a review. We are in the process of receiving input from the staff of the Medical Professionals Health Program on this provision and will share this with you prior to the expiration of the comment period.
- f. The referral of prescribers to the licensing board is currently authorized by 22MRSA§7250 subsection 2, entitled review of information, so this portion of the rule is not necessary and the PMP could notify a licensing board now if data from the PMP showed a particularly egregious pattern.

The development of appropriate thresholds is a critical piece of all of this. The requirement that a prescriber has to meet all of the four thresholds in 3.A. needs to be reviewed by professionals in the field, based upon current data. As we do not believe such a review has occurred, we recommend deferring action on this part of the proposal. Given that any final rule needs to be reviewed by the committee of jurisdiction of the Legislature, and given that legislation impacting on the PMP is expected in any case, setting aside this portion of the rule, will not prevent a timely resolution of these issues.

Thank you for the opportunity to make these comments. We continue to value the program, its capable and dedicated staff and look forward to working collaboratively with OSA, law enforcement, and other health-related organizations in addressing the significant problem of prescription drug diversion and abuse in the state.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gordon H. Smith", with a long, sweeping horizontal flourish extending to the right.

Gordon H. Smith, Esq.
Executive Vice President
Maine Medical Association

GHS:dm