



To: Joseph F. Vallario, Jr., Chairman, House of Delegates Judiciary Committee  
Members, House of Delegates Judiciary Committee

From: Karen Kaiser, RN, MS, AOCN  
Maryland Pain Initiative, Board Member  
American Pain Foundation, Volunteer

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Topic: Strong Opposition to House Bill 60, Controlled Dangerous Substances – Dispensing  
Monitoring Program

The Maryland Pain Initiative (MPI) is an independent, voluntary, statewide, interdisciplinary organization dedicated to the improvement of the quality of life of all Marylanders affected by pain through the promotion of pain management education, research, clinical practice and advocacy. Similarly, on a national level, the American Pain Foundation (APF), whose national headquarters are located in Baltimore, is an independent nonprofit 501(c)3 organization serving people with pain through information, advocacy, and support. APF's mission is to improve the quality of life for people with pain by raising public awareness, providing practical information, promoting research, and advocating to remove barriers and to increase access to effective pain management. I am a registered nurse with over 15 years of experience in the field of acute, chronic, and cancer pain that spans the life trajectory from a tiny premature baby to the old-old at various stages of a variety of illnesses and disease, including the management of pain at the end-of-life. I have worked with patients, their families, and health care providers (HCP) in acute care settings, long-term care, outpatient environments, as well as hospice and palliative care settings. I am a Board member of MPI, a supporter of APF, a doctoral student at the University of Maryland with a dissertation focus on barriers to effective pain management, a non-paid faculty at the University of Maryland School of Nursing, and a person who experiences daily pain that is controlled by medication. Similar to myself, MPI and APF are committed to addressing the public health care crisis of uncontrolled pain and to improving pain management in the State of Maryland. Personally, I have spent half of my career actively working to improve the management of patients' pain by addressing health care professional and patient/family fears related to the management of pain. One of the greatest fears and impediments to effective pain control is the fear of regulatory and legal sanctions.

We are concerned about the potential negative impact on the public health care crisis of uncontrolled pain associated with House Bill 60. This bill requires the Department of Health and Mental Hygiene (DHMH) to establish an electronic monitoring system for controlled substances. Effective pain medications such as opioids already draw the attention of law enforcement and regulatory officials.<sup>1</sup> While federal law permits the appropriate use of opioids for pain

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<sup>1</sup> Von Roenn JH, Cleeland CS, Gonin R, Hatfield AK, Pandya KJ. Physician attitudes and practice in cancer pain management: A survey from the Eastern Cooperative Oncology Group. *Ann Intern Med* 1993;119:121-6.

management in patients, fear of controlled substances and agencies that enforce associated laws and regulate the health care professions contribute to inadequate treatment.<sup>2</sup>

Increased numbers of media reports describing abuse and diversion of opioid pain medications have heightened patient and provider awareness of the regulatory scrutiny surrounding prescription of these medications. Stigma associated with prescribing these medications increase patient fear of addiction, as well as cause providers to choose a lower profile and select potentially less effective medications. Policies such as the proposed PMP may inadvertently inhibit access to appropriate and effective pain management by increasing fears and placing further requirements on providers.<sup>3,4,5</sup>

While the proposed bill is intended to control fraud, abuse, and diversion of controlled substances, regulations focusing solely on the abuse potential of a drug lead to the erroneous belief that such drugs should be avoided<sup>6</sup>. Unfortunately, no studies have analyzed the impact of electronic PMP on fraud, abuse and diversion or quality of care for patients. However states that have implemented other types of PMP have reported the inadvertent consequence of decreasing the number of opioid prescriptions written and causing needless pain and suffering.

Two of Maryland's health care professional regulatory agencies have recognized provider fears and the health care crisis associated with inadequate pain control and taken proactive steps to curb this fear. They have utilized recommendations from numerous national organizations, federal agencies, and accrediting bodies which encourage or require health care agencies to improve the management of pain<sup>7,8,9,10,11,12</sup>. Maryland's Board of Physician Quality Assurance

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<sup>2</sup> Joranson DE, Gilson AM. Controlled substances, medical practice, and the law. In: Schwartz, HI. *Psychiatric practice under fire: The influence of government, the media and special interests on somatic therapies*. Washington, DC: American Psychiatric Press, Inc.; 1994. p 173-94.

<sup>3</sup> Joranson DE, Gilson AM, Ryan KM, Maurer MA, Nischik JA, Nelson JM. *Achieving balance in state pain policy: A guide to evaluation*. Madison, Wisconsin: The Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center; 2000.

<sup>4</sup> Joranson DE, Gilson AM. Controlled substances, medical practice, and the law. In: Schwartz, HI. *Psychiatric practice under fire: The influence of government, the media and special interests on somatic therapies*. Washington, DC: American Psychiatric Press, Inc.; 1994. p 173-94.

<sup>5</sup> Joranson DE, Gilson AM, Ryan KM, Maurer MA, Nischik JA, Nelson JM. *Achieving balance in state pain policy: A guide to evaluation*. Madison, Wisconsin: The Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center; 2000.

<sup>6</sup> "Promoting pain relief and preventing abuse of pain medications: A critical balancing act." A joint statement between 21 health organizations and the Drug Enforcement Administration. Available via the Internet: <http://www.medsch.wisc.edu/painpolicy/Consensus2.pdf>.

<sup>7</sup> American Pain Society Subcommittee on Quality Assurance Standards (1991). American Pain Society quality assurance standards for relief of acute pain and cancer pain. In M.R.Bond, J. E. Charlton, & C. J. Woolf (Eds.), *Proceedings of the VI World Congress on Pain* (pp. 185-189). NY: Elsevier Science Publishers

<sup>8</sup> Acute Pain Management Guideline Panel (1992). *Acute pain management: Operative or medical procedures and trauma. Clinical practice guideline*. Publ No. 92-0032. Rockville, Md: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services.

<sup>9</sup> Jacox, A. Carr, DB, Payne, R., et al. *Management of Cancer Pain. Clinical Practice Guideline No. 9*. AHCPR Publication No. 94-0592. Rockville, MD. Agency for Health Care Policy and Research, U.S. Department of Health and Human Services, Public Health Service, March, 1994.

<sup>10</sup> Joint Commission on Accreditation of Healthcare Organizations (2000). *Comprehensive accreditation manual for hospitals: The official handbook*. (Update 1, February 2002 ed.) Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations.

has adopted in part the U.S. Federation of State Medical Boards “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain”, which is formally endorsed by the Drug Enforcement Agency and the National Association of State Controlled Substance Authorities. The Maryland Board of Nursing has developed “Pain Management: Nursing Role/Core Competency a Guide for Nurses”.<sup>13</sup> One of the objectives of these documents is to address provider fear of regulatory scrutiny.<sup>9,14,15</sup> While these documents represent laudable efforts in the State of Maryland, they have been accompanied by inadequate educational efforts. Hence health care provider’s concerns over use of opioid medications persist<sup>16</sup>. Additional and sustained efforts are needed to ensure that new barriers are not erected and that adequate pain relief for patients in pain is assured.

A recent survey of Maryland residents by the Maryland Pain Initiative and the American Pain Foundation found that 66% of people surveyed reported they or someone in their household suffers from pain on a monthly basis.<sup>17</sup> Of those people, 46% reported pain occurs daily or several times per week and 68% report the pain is moderate to severe. Pain interferes with day-to-day activities and diminishes a person’s physical, psychological, and interpersonal well-being and reduces quality of life. Over 50 to 70 percent of cancer patients experience uncontrolled pain at some point during their illness.<sup>18,19</sup> The treatment and management of pain must be improved significantly.

While we support efforts to reduce the abuse and diversion of pain medication, providers, pharmacists, patients and regulatory officials must work together to develop policies that minimize abuse and diversion while maintaining appropriate access for pain patients. We encourage members of the legislature to consider a recently issued joint statement from numerous health organizations in concert with the Drug Enforcement Administration – “Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act”. This statement recognizes the need for collaboration between health care organizations and the law enforcement community in order to achieve an appropriate balance between regulation and access to appropriate pain medication for patients in need.<sup>20</sup>

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<sup>11</sup> Kang, J. (2002). personal communication. February 14, 2001.

<sup>12</sup> Lewin-VHI, I. F. (1993). Nursing Report Card for acute care settings: Nursing quality indicator definitions and implications. Washington, DC: American Nurses Publishing.

<sup>13</sup> “Pain Management: Nursing Role/Core Competency a Guide for Nurses“ Available via the Internet:

<http://www.mbon.org> Nursing Practice Section.

<sup>14</sup> National Association of State Controlled Substance Authorities. Organ. 99-01: NASCSA RESOLUTION 99-01

October, 29, 1999. Available via the Internet: <http://www.medsch.wisc.edu/painpolicy/domestic/NASCSA.htm>

<sup>15</sup> Good PM. “The Drug Enforcement Administration and Proposed Model Guidelines for the Use of Controlled Substances in Pain Management.” Federation of State Medical Boards Symposium on Pain Management and State Regulatory Policy. Dallas, Texas. 17 Mar. 1998. Available via the Internet:

<http://www.medsch.wisc.edu/painpolicy/domestic/dea98.htm>

<sup>16</sup> The American Alliance of Cancer Pain Initiatives Statement on State Prescription Monitoring Programs June 2002

<sup>17</sup> American Pain Foundation, “Pain in Maryland: Key Survey Findings” Available via the Internet:

[www.painfoundation.org/downloads/md\\_survey\\_release.pdf](http://www.painfoundation.org/downloads/md_survey_release.pdf)

<sup>18</sup> Foley KM. The treatment of cancer pain. *New Engl J Med* 1985;313:84-95.

<sup>19</sup> Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *New Engl J Med* 1994;330:592-6.

<sup>20</sup> “Promoting pain relief and preventing abuse of pain medications: A critical balancing act.” A joint statement between 21 health organizations and the Drug Enforcement Administration. Available via the Internet:

<http://www.medsch.wisc.edu/painpolicy/Consensus2.pdf>

Prior to implementing a PMP in the State of Maryland, a multidisciplinary group consisting of health care professionals specializing in pain management, regulators, patients, legislators, and law enforcement should be convened to study the problem and recommend a solution that achieves a balance between regulation and access for people with legitimate pain problems. PMP implemented in other states should be evaluated for intended outcomes and unintended consequences. Prior to implementing new, potentially expensive programs, the group should consider utilizing already existing information to study and curb diversion and drug abuse. For example, the Medicaid Drug Utilization Review Program required for state use by the federal government does not target specific drugs for regulation, but rather monitors all drugs prescribed to Medicaid recipients. This approach does not increase HCP fears and impact prescribing by targeting controlled substances. Information that is currently available from regulatory groups and offices related to controlled substances diversion and control should also be scrutinized. A carefully orchestrated, proactive assessment is more likely to ensure that any proposed PMP legislation does not impair the delivery of effective, appropriate pain management.

The group should consider a well-controlled study to thoroughly evaluate both benefits and harms of any PMP implemented in the state of Maryland so that the effects of this program on legitimate pain patients can be adequately assessed. This requires planning and baseline data collection. Joint efforts between law enforcement, regulatory agencies and health care professionals to strike a balance between regulation and the provision of effective pain management should be assessed. We believe additional statewide educational initiatives are needed that address patient and provider fears of regulatory action in order to reduce regulatory barriers to appropriate pain medication. We support efforts designed to ensure that physicians and other medical practitioners are aware of appropriate guidelines for pain control and dissemination of the knowledge that they will not be prosecuted for appropriately treating their patients' pain.

We believe it is imperative for all patients to have access to appropriate effective pain management and oppose efforts that result in increased barriers to receiving proper pain care, even if the effect is unintentional. Effects of PMP on quality of care for patients, have not been adequately analyzed and are therefore poorly understood.<sup>21</sup> We are concerned that the proposed PMP may create an additional barrier for pain patients and may increase fear of prescribing the appropriate and most effective medications for pain patients. If so, then any benefits associated with PMP may be realized at a high price.

We place a great deal of importance on the provider/patient relationship for clinical decisions about appropriate care, and oppose efforts that might have an adverse effect on health care providers' willingness and ability to provide pain medication and pain management when treating patients in pain. We believe the bill as written lacks a number of important features that are outlined below.

- A multidisciplinary review group with pain expertise to assure protection of legitimate prescribing and dispensing
- Jointly developed education programs to address HCP concerns about PMP

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<sup>21</sup> The American Alliance of Cancer Pain Initiatives Statement on State Prescription Monitoring Programs June 2002.

- A well advertised mechanism for the HCP to communicate with PMP administrators
- Research about the impact of PMP on individuals needing controlled substances for legitimate medical reasons and the prevalence and incidence of drug diversion
- An interagency diversion prevention and control program

In addition some items in the bill that should be considered for revision or inclusion are listed below.

- Reconsider the exclusion for reporting time, which may encourage HCP to limit prescriptions to an inadequate time period.
- Provide consultation from a member of a multi-disciplinary review group when the review group receives requests for information from regulatory and law enforcement agencies.
- Allow for HCP who work together to provide care for a patient to share information outlined in this bill and requested of DHMH without facing penalties. Without this provision, patient care cannot be coordinated between or among health care disciplines.

While the sponsors of this bill have put in a lot of hard work and effort, it is our position that considerable additional work is needed on the bill to make sure that the people in the State of Maryland have access to effective, appropriate pain management. We strongly urge you to consider charging an advisory group as outlined in this document to take on this task and that a bill be resubmitted that addresses the concerns outlined in this document.

We thank you for consideration of our views. Please feel free to contact me if you have questions.

Respectfully submitted,

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Attachments:

- The American Alliance of Cancer Pain Initiatives Statement on State Prescription Monitoring Programs June 2002.
- “Promoting pain relief and preventing abuse of pain medications: A critical balancing act.” A joint statement between 21 health organizations and the Drug Enforcement Administration. Available via the Internet:  
<http://www.medsch.wisc.edu/painpolicy/Consensus2.pdf>

*Adapted with permission from the American Cancer Society’s position statement on Prescription Monitoring and Drug Utilization Review Programs and The American Alliance on Cancer Pain Initiatives Statement on State Prescription Monitoring Programs.*