MARYLAND STATE ADVISORY COUNCIL ON PAIN MANAGEMENT

FINAL REPORT TO THE GENERAL ASSEMBLY
SEPTEMBER 2004

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FINAL REPORT

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EXECUTIVE SUMMARY

Background. In 2002, the Maryland General Assembly, recognizing that chronic intractable pain is a debilitating condition and acknowledging that many individuals with pain may receive inadequate pain management, enacted House Bill 423, entitled "Health Care – Programs and Facilities – Pain Management." This bill established the Maryland State Advisory Council on Pain Management and charged it with the responsibility to provide advice and recommendations on statewide pain management policy issues.

To prepare the report, the Advisory Council consulted with over 40 different professional groups, advocacy organizations, and government officials. It created four workgroups (Current Acute and Chronic Pain Practices in Maryland, Financial and Oversight Environments, Education and Access, and Assessment and Management) to focus its activities. Each of the Workgroups was given a charge with defined areas to address. All of the Advisory Council meetings were open to the public and the public was encouraged to comment at all stages of its deliberations.

Recommendations. The Advisory Council makes the following recommendations with respect to Maryland's pain management policies:

(1) Health care facilities should adopt outcomes monitoring for evaluating the effectiveness of pain management plans for each patient or resident.

(2) The committees of the General Assembly with jurisdiction over the Maryland Controlled Dangerous Substances Act should designate a workgroup to update its drafting, after consultation with experts in the field of pain policy and addiction medicine.

(3) Projects that foster the development of electronic medical records (EMR) should be encouraged.

(4) The General Assembly should continue the Advisory Council as a permanent review and advisory body on pain management policy for Maryland.

(5) The Advisory Council should investigate the feasibility of creating a private, self-funded coalition of stakeholders to establish a pain management clearinghouse.

(6) The Advisory Council should examine the development of a public service campaign, in collaboration with a private, self-funded coalition of stakeholders (as noted in recommendation five), to promote public awareness and education regarding the range of approaches to effective pain management.

(7) The Advisory Council should consider the development of collaborative practice models that seek to address all of the needs of a patient.

(8) The Governor should designate each September as Maryland's Pain Awareness Month.

(9) The Advisory Council, in conjunction with the Department of Health and Mental Hygiene, should study the goals associated with the Healthy Maryland – Project 2010 and the strategies developed to eliminate health disparities to assure that pain management is effectively addressed.

(10) The Physician's Palliative Care Pain Hotline should be continued. The Maryland Board of Physicians should review the service provided to determine if continuing medical education credits can be awarded to those physicians who choose to volunteer for the program.

(11) The Advisory Council should work with the Hospice Network of Maryland, to the extent that resources are available, to develop a palliative care hotline for consumers that is available 24-hours, seven days a week.

(12) The Advisory Council should partner with the Maryland Pain Initiative, the American Pain Foundation, the American Cancer Society, the Hospice Network of Maryland, and any other interested party, to develop a website that assures responses within 48-hours in an "ask the expert" format.

(13) Third-party Pharmacy Reimbursement Programs should review their PDLs and related prescription approval practices to ensure that all patients who have a clinical need for specific medications have appropriate access to them. In the case of the generic version of controlled-release oxycodone, the programs should give prompt consideration to its inclusion in the PDL. Any pre-authorization process should operate efficiently, with minimal burden for prescribers. Given the recommendations of the American Geriatrics Society and the Revised Beers Criteria, COX-2 inhibitors for patients 65 years old or older should not require pre-authorization, since authorized traditional non-steroidal anti-inflammatory drugs elevate the health risks and ultimately are unlikely to save money in the older portion of the State's population.

(14) Third-party Pharmacy Reimbursement Programs should review their PDL to remove any drugs that, although inexpensive, have little clinical value for effective pain management.

(15) The Maryland Health Care Commission, in conjunction with the Maryland Insurance Administration, should assess patterns and shortfalls in coverage for pain management under private insurance contracts, employer self-insurance plans, and workers' compensation and report its findings, together with any recommendations to the General Assembly.

(16) The Office of Health Care Quality (OHCQ) should continue to give priority attention in its surveys to issues of pain assessment and management.

(17) OHCQ should, through its clinical alerts and in presentations at conferences and other forums, emphasize the importance it places on appropriate pain assessment and management.

(18) The Secretary of Health and Mental Hygiene should evaluate the survey process to ensure that adequate surveyors are available so that the survey process, including its focus on pain assessment and management, can be timely and effective.

(19) OHCQ and the Maryland Department of Aging should provide regular in-service training for surveyors and ombudsmen on the criteria for identifying inadequate pain assessment and management.

(20) The OHCQ should fund, to the extent that resources are available, through the Civil Monetary Penalty Account (e.g., monies collected from fines assessed to nursing homes for noncompliance with standards) demonstration projects on pain relief in long-term care.

(21) The Board of Physicians should update its policy and strongly consider adopting the key elements of the newly revised *Model Policy for the Use of Controlled Substances for the Treatment of Pain* of the Federation of State Medical Boards.

(22) The Board of Physicians should revise its educational strategy for new licensees, including development of a web-based format to communicate its revised policy.

(23) The Boards of Dentistry, Nursing, Pharmacy, and Physicians should adopt a joint policy statement on pain management affirming their recognition of the importance of pain management and their shared commitment to applying appropriate standards and procedures for disciplinary action related to the prescribing and dispensing of controlled substances.

(24) Continuing education (CE) on pain management should not be mandated at this time, but the Board of Physicians should monitor efficacy data about mandated CE in other states.

(25) All of the health occupation boards that license prescribers or dispensers of pain medication should encourage their licensees to take skill-based continuing education courses in pain management and should explore whether such courses might be offered through the boards at low- or no-cost.

(26) All of the health occupation boards which have licensees directly involved with aspects of pain assessment and management (for example, the Boards of Physicians, Physical Therapy, Dentistry, Nursing, Pharmacy, and Social Work Examiners) should encourage those licensees to take skill-based continuing education courses in pain management.

(27) All of the health occupation boards which have licensees directly involved with aspects of pain assessment and management should disseminate ongoing and updated information to its licensees about pain management that includes information about assessment and treatment.

(28) Maryland's medical, nursing, dental and pharmacy professional schools should report to the Advisory Council on their efforts to improve preparedness of their graduates in pain management. The Advisory Council <u>does not</u> recommend that the State attempt to alter the curriculum of these academic institutions.

(29) The Attorney General's Office should complete its review of criteria for a prescription monitoring program prior to the consideration of legislation mandating such a program.

(30) Any prescription monitoring program ultimately adopted should be designed to protect legitimate prescribing and dispensing while assuring patient privacy.

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LEGISLATIVE AUTHORITY

During the 2002 Maryland General Assembly Session, the Legislature, recognizing that chronic intractable pain is a debilitating condition and acknowledging that many individuals with pain may receive inadequate pain management, enacted House Bill 423, entitled "Health Care – Programs and Facilities – Pain Management." (See Appendix A.) This bill created the Maryland State Advisory Council on Pain Management and charged it with the responsibility to provide advice and recommendation to the General Assembly regarding pain management policy.

The Advisory Council, with representation from a cross-section of health care practitioners, regulators, and legislators, met throughout 2003 and 2004 for the purpose of studying and making recommendations regarding Maryland's pain management policies. Specifically, the Advisory Council reviewed acute and chronic pain practices by health care providers in Maryland; State statutes and regulations relating to pain management therapies; the sanction and use of alternative therapies; acute and chronic pain management education provided by medical, nursing, pharmacy, and dental schools; acute and chronic pain management needs of both adults and children; and, development of a pain management resource compendium and palliative care hot line. The Advisory Council's recommendations are discussed in this report.

The Department of Health and Mental Hygiene's Office of Health Care Quality (OHCQ) provided staff support to the Advisory Council. The members of the Advisory Council included:

F. Michael Gloth, III, MD, Chairman
Carol Benner, Sc.M.
John Fader, II, JD
Senator Paula C. Hollinger
Mary Patricia O'D Howard, RN
Robert Lyles, Jr., MD, PhD
Pamela Parrish, RN
Jack Schwartz, JD
Marie Thompson, RN
Rene Williamson, BS, Pharm.D.
Myron Yaster, MD

House Bill 423 also provided that the Advisory Council may consult with over 40 different professionals, organizations, industries, and advocates in developing its recommendations. (See Appendix B.) The Advisory Council invited all of these organizations to participate in its discussions and meetings.

INTRODUCTION

Appointments to the Advisory Council were finalized in early 2003 and its first meeting was held in April 2003. The Advisory Council elected Dr. Michael Gloth as chair and held regular meetings. (See Appendix C.) All of the meetings were open to the public and the public was invited to comment at all stages of the Advisory Council's deliberations. Additionally, the Advisory Council actively sought participation of the public in its activities, which included

giving special attention to organizations and individuals dedicated to pain relief. All of the Advisory Council's meetings were publicized and meeting notices were disseminated through electronic mailings, posted on the Legislative Hearing Schedule and/or listed on the Advisory Council's web site.[1]

Given the breadth of its responsibilities, the Advisory Council created four workgroups (Current Acute and Chronic Pain Practices in Maryland, Financial and Oversight Environments, Education and Access, and Assessment and Management) to focus its activities. Each of the Workgroups was given a charge with defined areas to address as referenced in the Advisory Council's Interim Report. (See Appendix D). The Workgroups called on pain professionals, organizations, and advocates, as appropriate, for assistance in reviewing materials and formulating recommendations. In order to complete this massive endeavor, the Workgroups were encouraged to meet independently of the Advisory Council and to develop recommendations that are practical.

The Advisory Council then evaluated all of the Workgroups' recommendations using a consensus building process. It became apparent when the Advisory Council came together to write its final report there were many areas of similarity and considerable overlap in the findings of the four Workgroups. This report, therefore, is a distillation of all of the findings. While interested parties provided substantial technical assistance and support to the Advisory Council, the recommendations contained within this report are those that the Council believes are important policy decisions that need to be contemplated to improve pain management in Maryland.

This report will analyze the following questions:

- Where we are today in Maryland with regard to pain management policies and practices;
- What are the barriers that exist to access, adequate assessment, and effective management of pain;
- How the disconnects in statutory terminology and medical understanding may affect pain management;
- How use of electronic medical records benefit quality of care;
- Why Maryland needs to continue statewide policy review of and develop a clearinghouse on pain management;
- How the expansion of the physicians palliative care pain hotline to consumers may be beneficial;
- How balancing health care financing issues with needs of patients in pain is important;
- Where regulatory oversight of health care professionals and health care facilities may affect pain management practices;
- What benefits of continuing education on pain management may have for health care professionals; and,
- How prescription monitoring programs that assure patient privacy are a valuable resource.

[1] Advisory Council web site address: http://www.dhmh.state.md.us/ohcq/council/home.htm.

WHERE WE ARE TODAY

Insufficient data about pain control and management are a major problem in Maryland. Although there is anecdotal evidence that pain management is a problem in the State, Maryland lacks adequate statewide statistics and data to determine overall prevalence associated with providing pain relief for patients. Moreover, Maryland does not have a statewide standard of care or comprehensive policy for pain management.

Recognizing the problem that specific data are lacking for Maryland, the Maryland Pain Initiative and the American Pain Foundation conducted a telephone survey in February of 2002 that indicates that almost half of Marylanders suffer from pain, a third of whom characterize that pain as moderate to severe.[2] Forty-percent of those who experienced pain on a monthly basis suffered almost daily with pain. Even in light of study design issues, the outcome of this survey requires more work directed toward pain relief in Maryland.

Chronic pain is among the most disabling and costly afflictions in North America. An analysis of studies looking at chronic pain in the general population identified the prevalence of severe chronic pain to be 11-percent in adults and 8-percent in children.[3] This is particularly true for seniors.[4] Data indicate that half of people over the age of 65 are not functioning at their optimal level because of interference from pain.[5,6,7] In 1997, a telephone survey was reported as indicating that more than 50-percent of older adults had taken pain medication beyond a six-month period and that 45-percent had seen at least three physicians for pain in the prior five years.[8] For certain populations, the numbers are even more disconcerting. For example, in a nursing home environment, estimates are that anywhere from half to 80-percent of residents have pain, with analgesics being used by 40-percent to 50-percent of residents.[9,10] Further analysis indicates that almost a quarter of patients with daily pain did not receive any analgesics.[11] Additionally, long-term care data indicate that over 40-percent of patients, who were known to have pain at an initial assessment, had worsening or severe pain at the time of the second assessment two to six months later.[12]

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[2] http://www.painfoundation.org/downloads/md_survey_facts.pdf accessed 7/12/2004

[3] Harstall, C. & Ospina, M. (2003). How prevalent is chronic pain? Pain Clinical Updates, 11(2):1-4.

[4] Davis GC. Chronic pain management of older adults in residential settings. J Geront Nursing. 1997; 23:16-22.

[5] Crook J, Rideout E, Browne G. The prevalence of pain complaints among a general population. *Pain*. 1984;18:299-314.

[6] Anderson S, Worm-Pederson J. The prevalence of persistent pain in a Danish population. In: Proc. 5th World Congress on Pain. *Pain Suppl.* 1987;4:s332.

[7] Magni G, Marchetti M, Moreschi C, et al. Chronic musculoskeletal pain and depressive symptoms in the National Health and Nutrition Examination. I. Epidemiologic follow-up study. Pain. 1993; 53:163-8.

[8] Cooner E Amorosi S. The study of pain and older Americans. New York City, Louis Harris and Associates. 1997.

[9] Ferrell BA, Ferrell BR, Osterweil D. Pain in the nursing home. J Am Geriatr Soc. 1990; 38: 409-14.

[10] Sengstaken EA, King SA. The problems of pain and its detection among geriatric nursing home residents. J Am Geriatr Soc. 1993; 41: 541-4.

[11] Won A, Lapane K, Gambassi G, et al. Correlates and management of nonmalignant pain in the nursing home. J Am Geriatr Soc. 1999; 47:936-42.

[12] Teno JM, Weitzen S, Wetle T, Mor V. Persistent pain in nursing home residents. JAMA (Res Ltr). 2001; 285: 2081.

Individuals suffering from chronic pain are subject to significant health, quality of life and economic issues. They may be unable work, participate in physical activity, or simply enjoy social activities or time with their family. There are also serious physical and psychological consequences of inadequately managed pain that may include decreased organ system function, impaired immune function, sleeplessness, loss of appetite, and impaired movement just.

Chronic pain is also very costly. It is estimated that the cost of lost productivity due to pain is approximately $61.2 billion annually[13] and annualized medical costs associated with pain are well over $120 billion.[14] Unfortunately, effective pain management receives little attention in healthcare educational programs, yet it is a major health care issue that needs to be addressed.

It is well documented that unrelieved pain continues to be a serious public health problem affecting the general population in the United States. This issue is particularly relevant for children, the elderly, minorities, and people suffering from serious disease. Clinical experience has demonstrated that adequate pain management leads to increased functioning and improved quality of life, while uncontrolled pain leads to disability and despair.[15]

A cursory review of existing literature reveals that the majority of individuals nationally who experience pain do not receive adequate pain management. Therefore, in Maryland we can assume that this holds true as well. Inadequately treated pain is a serious public health problem, with high human and economic costs. Consequently, the objectives underlying State public policy should be to both remove barriers to quality pain management and take affirmative steps to promote access.

Everyone in Maryland should have access to adequate pain relief. Attaining this goal, however, depends on a variety of factors, such as adequate reimbursement, a supportive regulatory climate, and the availability of skilled providers and sufficient resources, including access to alternative therapies and appropriate medication.

ACCESS, ASSESSMENT AND MANAGEMENT

Many obstacles to pain relief can be overcome by educating patients. Patients need to recognize their rights and responsibilities regarding effective pain relief including awareness of health care facility policies. It is also important that patients who suffer from pain understand the goals and timeframes of a plan of care. All of these must be part of the discussion a practitioner has with his or her patient. Patients and caregivers need to take an active role in monitoring progress and be aware that they need to speak up and become their own best advocates.

[13] Stewart, W.F., Ricci, J.A., Chee, E., Morganstein, D., & Lipton, R. (2003). Lost productivity time and cost due common pain conditions in the US workforce. Journal of the American Medical Association, 290:2443-54.
[14] Griffin, R.M. (2003). The Price Tag on Pain. http://mywebmd.com/content/Article/57/66051.htm. Retrieved 3/20/04.
[15] Pain and Policy Studies: University of Maryland Comprehensive Cancer Center, February 2004.

Many observers believe that hospice provides the "gold standard" of care in pain management. In Maryland hospice care is available in every county. Nonetheless only one in about five non-traumatic deaths includes hospice care.[16] Of those deaths that involve hospice half are associated with cancer. Given that the majority of non-traumatic deaths are now associated with malignancy, efforts to improve awareness of hospice among the general public are necessary.

Table One.	*BARRIERS TO EFFECTIVE PAIN MANAGEMENT*
Problems related to health care professionals:	Inadequate knowledge of pain management; Poor assessment of pain; Concern about regulation of controlled substances; Fear of patient addiction; Apprehension of side effects; and, Anxiety over patients becoming tolerant to analgesics.
Problems related to patients:	Reluctance to report pain; • Concern about distracting physicians from treatment of underlying disease; • Fear that pain means the disease is worse; • Anxiety about not being a "good" patient. Reluctance to take pain medications. • Fear of addiction or being thought of as an addict. • Worries over unmanageable side effects • Concerns about becoming tolerant to pain medications.

Various means are available to educate patients about topics such as misconceptions about opioids and addiction, adverse events, pain experts, compliance to care plans and alternative therapies. Educational efforts could include public service announcements, public symposia, articles, radio talk show appearances, and the development of a pain management clearinghouse. These activities could be accomplished through public-private partnerships with non-profit advocacy organizations.

Little research-based information is available on the prevalence or effectiveness of pain assessment and management in Maryland. A 1999 survey of Maryland nursing homes indicated that 38-percent of all nursing home residents have persistent, severe pain.[17] In 1998, the Pain and Policy Studies Group, World Health Organization Collaborating Center for Policy and Communications in Cancer Care studied state related barriers to effective pain management. The barriers can be broken into two major categories – problems related to health care professionals and problems related to patients. (See Table One above.)

Assessment of pain is difficult because it cannot be measured objectively. "Assessment seems simple, just asking how much it hurts," says Daniel Carr, MD, a professor of pain research at the New England Medical Center in Boston, Massachusetts. "But, it's not simple because there is no direct relationship between physical pathology and the intensity of pain. It is a subjective phenomenon with a number of dimensions, including intensity, quality, duration, and impact on functionality. There are marked differences in severity, quality, and impact of pain reported by patients who appear to suffer from the same phenomenon."[18] Pain assessment tools must meet the needs of specialty populations, such as pediatrics, geriatrics, acute, chronic, cognitively impaired, and terminally ill.

[16] Testimony by Stephen Buckingham, Executive Director, The Hospice Network of Maryland on Senate Bill 177, entitled "Maryland Office of Minority Health and Health Disparities" before the Senate Education, Health and Environmental Affairs Committee on February 18, 2004. Data sources: Mortality Data from the Department of Health and Mental Hygiene's Vital Statistics Administration and the Hospice Network of Maryland.
[17] (Teno, 1999)
[18] Managed Care, October 2003.

Several different types of basic pain assessment instruments, as noted in Table Two, are currently available. Criteria for selecting a scale should include standardization (validity, reliability and responsiveness) in populations similar to the individuals for whom the scale will be used to assess pain.[19,20,21,22,23,24,25]

Table Two.	*TYPES OF PAIN SCALES (Listed in Alphabetical Order)*
Faces Rating Scale	A visually administered scale showing facial expressions suggesting various pain intensities. Faces scales are used primarily with young children but may also be used by adults who have difficulty using the numbers on the visual analog scale. (See reference below.)
Functional Pain Scale	An assessment equating responses from a patient regarding tolerability of pain and the impact on function to a score from "0" to "5." The scale has been standardized with reliability, validity, and responsiveness testing in older patients with Mini-Mental State Examination scores down to 17.
Graphic Rating Scale	This instrument builds on the visual analog scale by adding to the measurement line either words or numbers between the extremes of the scale.
Numerical Rating Scale	A verbally or visually administered 0-to-10 (or 0-to-5) scale with words and numbers along a vertical or horizontal line. The patient is asked to rate pain from 0 to 10, with 0 equaling "no pain" and 10 equaling "the worst possible pain."
Simple Descriptor Scale	A list of adjectives describing different levels of pain intensity. A simple and clinically useful example is no pain, mild pain, moderate, and severe pain.
Visual Analog Scale	A horizontal 10 cm line with word anchors at the extremes such as "no pain" and "pain as bad as it could be." The patient is asked to make a mark along the line to represent pain intensity. A number is obtained by measuring in millimeters up to the point the patient has indicated.

However, regardless of the pain assessment instrument used, basic principles of pain control and analgesic therapy should be incorporated into the assessment process. The American Pain Society suggests that pharmacotherapy[26] is the mainstay of both acute and cancer pain management. It is the obligation of all clinicians to provide comfort and effective symptom control whenever possible.

Basic principles of pain control and analgesic therapy may include:

- Integrating analgesia into a comprehensive patient evaluation and management plan;
- Recognizing and treating the emotional and cognitive aspects of pain;
- Understanding that pain is individualized;
- Identifying and treating the source of pain;
- Selecting the simplest approach to pain management;
- Considering a multi-modality approach that applies both pharmacologic and non-pharmacologic therapies;
- Choosing, if drug therapy is used, an appropriate drug and route to optimize administration;
- Anticipating and managing side effects;
- Addressing patient concerns if opioids are indicated;

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[19]Joint Commission on Accreditation of Healthcare Organizations. Pain assessment and management: An organizational approach. Oakbrook Terrace, IL. 2000. p. 15.

[20]The AGS Panel on Persistent Pain in Older Persons. The management of persistent pain in older adults. J. Am. Geriatr. Soc 2002; 50 (6 Suppl):S209.

[21] Gloth III, FM. Sheve AA, Stober CV, Chow S., Prosser J. The functional pain scale (FPS): Reliability, validity, and responsiveness in a senior population. J Am Med Dir Assoc. 2001; 2(3): 110-114.

[22] Herr KA, Mobily PR, Kohout FJ, Wagenaar D. Evaluation of the faces pain scale for use with the elderly. Clin J Pain 1998;14:29-38

[23] Briggs M. Closs JS. A descriptive study of the use of visual analogue scales and verbal rating scales for the assessment of postoperative pain in orthopedic patients. J Pain Symptom Management 1999; 18:438-446.

[24] Gloth III, FM. Handbook of Pain Relief in Older Adults: An evidence-based approach. Gloth III, FM. Ed. Humana Press, Totowa, NHJ, 2003.

[25] Melzack R. The McGill Pain Questionnaire: Major properties and scoring methods. Pain. 1975; 1:277-299.

[26] Pharmacotherapy is defined as the treatment of disease through the use of drugs. . *The American Heritage® Stedman's Medical Dictionary.* http://dictionary.reference.com

- Distinguishing the differences among tolerance, dependence, and addition; and,
- Avoiding the use of placebos to treat pain. [27]

Outcome monitoring for the evaluation of processes pertaining to effective pain management is very important and should be implemented by health care facilities to ensure that their patients or residents receive appropriate care. Health care facilities can be cited by the State's regulatory agency for state and federal deficiencies for ineffective or inappropriate pain management. In addition, accrediting organizations have also established standards for pain management. Those facilities that elect to be accredited have to adhere to the accrediting body's standards for pain management, as well as to state and federal regulations, and can be cited for a deficiency by the accrediting organization which may affect their standing with the accrediting body.

RECOMMENDATION 1. Health care facilities should adopt outcomes monitoring for evaluating the effectiveness of pain management plans for each patient or resident.

The Advisory Council suggests that any outcomes monitoring program adopted by a facility should recognize the right of patients to appropriate assessment and management of pain. Facilities should screen for the presence and assess the nature and intensity of pain in all patients. Records of the results of the assessment should be kept in a way that makes it possible for regular reassessment and follow-up. Staff competency in pain assessment and management should be promoted through ongoing in-service education and via orientation programs for new clinical staff. Policies and procedures that support the appropriate prescribing and ordering of pain medications should be implemented. It is also important to ensure that pain does not interfere with a patient's or resident's participation in rehabilitation. Therefore, educating patients and their families about the importance of effective pain management and addressing patient needs for symptom management in the discharge planning process is also critical. Additionally, facilities should incorporate pain management into performance review activities.[28]

STATUTORY TERMINOLOGY

The Maryland Controlled Dangerous Substances Act, Title 5 of the Criminal Law Article, departs from contemporary medical understanding and terminology. For example, the definition of "drug dependent person" in § 5-101(n) incorrectly confuses physical dependence or analgesic tolerance with addiction.

RECOMMENDATION 2. The committees of the General Assembly with jurisdiction over the Maryland Controlled Dangerous Substances Act should designate a work group to update its drafting, after consultation with experts in the field of pain policy and addiction medicine.

[27] American Medical Association. Pain Management: Part I, Overview of Physiology, Assessment, and Treatment. April 2003.
[28] Joint Commission on Accreditation of Health Care Organizations. Pain: Current Understanding of Assessment, Management, and Treatments. 2001.

ELECTRONIC MEDICAL RECORDS

Electronic Medical Record (EMR) systems that provide pain treatment guidance and prescription capability should be encouraged. Funding for demonstration products and outcomes based research of such systems is needed. Physicians should be encouraged to use EMR systems in their practice settings. These systems have the ability to reduce drug-drug interactions, facilitate communication, provide instant data retrieval, ease in the acquisition of information to reduce adverse events, etc. EMR are likely to improve quality of care and enhance quality improvement within individual practice settings.[29,30,31] Consideration should be given to reducing medical malpractice insurance rates, medical society dues, or improving reimbursement as an incentive for transitioning busy office practices to EMR.

RECOMMENDATION 3. Projects that foster the development of EMR should be encouraged.

OHCQ should, to the extent that resources are available, fund EMR demonstration projects in long-term care facilities through its Civil Monetary Penalty account.

ONGOING STATE POLICY REVIEW AND CLEARINGHOUSE

The problem of inadequate pain assessment and management affects tens of thousands of Marylanders and is not susceptible of a quick or definitive solution. The problem will continue to present important public policy issues for the foreseeable future, issues that involve the responsibilities of a variety of State agencies. Yet, after the termination date for this Advisory Council, no entity will be responsible for conducting ongoing review of pain management.

Substantially more work needs to be done in Maryland to improve pain management policy. Currently, Maryland does not have a statewide policy on pain management. It also does not have a single-source site for information on pain management. Individuals suffering with pain spend inordinate amounts of time conducting internet searches, and health care practitioners review multiple periodicals and research many issues that could be easily contained within a clearinghouse.

It has been noted that collaborative practice models may be beneficial in developing effective pain management care plans. The most effective patient care stems from a multidisciplinary approach. There appears to be active interest in the health care practitioner community to developing collaborative practice models to serve as best practice model for pain management in Maryland.

The **Healthy Maryland – Project 2010**, which is an ongoing initiative carried out by the Maryland Department of Health and Mental Hygiene to identify and track statewide health

[29] Safran C, Rind DM, Davis RB, et al. Guidelines for the management of HIV infection in a computer-based medical record. Lancet. 195;246:341-6.
[30] Safran C. Sands DZ, Rind DM. Online medical records: a decade of experience. Method Inf Med. 1999;38:308-12.
[31] Committee on Quality of Health Care in America, Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. National Academies Press, Washington, DC 2001:p 164-71.

objectives, is a project that involves many partners including Maryland's local health departments, hospitals, and community groups involved in tracking our State's progress toward meeting the Healthy People 2010 Objectives established by the U.S. Department of Health and Human Services. Healthy People 2010 is the prevention agenda for the Nation. It is a statement of national health objectives designed to identify the most significant preventable threats to health and to establish national goals to reduce these threats. The agenda has two overarching goals: to help individuals of all ages increase life expectancy and improve their quality of life and to eliminate health disparities among different segments of the population. The importance of pain management should be included in the development of statewide health objectives to achieve the agenda's overarching goals.

RECOMMENDATION 4. The General Assembly should continue the Advisory Council as a permanent review and advisory body on pain management policy for Maryland.

RECOMMENDATION 5. The Advisory Council should investigate the feasibility of creating a private, self-funded coalition of stakeholders to establish a pain management clearinghouse. The clearinghouse could maintain evidence based practice guidelines; pain management standards; provider listings; adjuvant therapies, etc.

RECOMMENDATION 6. The Advisory Council should examine the development of a public service campaign, in collaboration with a private, self-funded coalition of stakeholders (as noted in recommendation five), to promote public awareness and education regarding the range of approaches to effective pain management.

RECOMMENDATION 7. The Advisory Council should consider the development of collaborative practice models that seek to address all of the needs of the patient.

There appears to be active interest in the health care community to develop models to serve as best practices.

RECOMMENDATION 8. The Governor should designate each September as Maryland's Pain Awareness Month.

RECOMMENDATION 9. The Advisory Council, in conjunction with the Department of Health and Mental Hygiene, should study the goals associated with the Healthy Maryland – Project 2010 and the strategies developed to eliminate health disparities to assure that pain management is effectively included in the goals and strategies.

PAIN HOTLINE

Currently in Maryland, a Physicians Palliative Care Pain Hotline is available to health care providers. A similar type of hotline for consumers may well be beneficial. The challenge in developing the Physicians Palliative Care Pain Hotline included establishing a 24-hour answering service to handle calls, identifying, recruiting and scheduling professional volunteers

to provide information and advertising the existence of the service.[32] To create such a service for patients and caregivers is likely to present even more challenges and obstacles. A hotline for consumers would surely receive a much greater volume of calls; it is unlikely that the anticipated volume could be handled purely through volunteer efforts and donated time and equipment.

RECOMMENDATION 10. The Physician's Palliative Care Pain Hotline should be continued. The Maryland Board of Physicians should review the service provided to determine if continuing medical education credits can be awarded to those physicians who choose to volunteer for the program.

RECOMMENDATION 11. The Advisory Council should work with the Hospice Network of Maryland, to the extent that resources are available, to develop a palliative care hotline for consumers that is available 24-hours, seven days a week.

The hotline should be staffed by various levels of volunteer respondents, including nurses, pharmacists, physician assistants, nurse practitioners, and physicians. Respondents will participate in an on-call schedule and receive inquiries based on a predetermined set of criteria. Most calls of a non-urgent nature will be directed to an "ask the expert" section (see below) of the recommended website. The responses will be generated by the on-call grouping based on the nature of the call, in order to assure that none are involved in the practice of medicine unless authorized to do so.

Participation in this process should fall under the "Good Samaritan" legislation and receive exemption from liability with direction not to provide specific recommendations without a concurrent history and examination. Volunteers should come from the private sector with appropriate recognition for their individual and organizational contributions. The advisory body to be created can establish logistics for other details.

RECOMMENDATION 12. The Advisory Council should partner with the Maryland Pain Initiative, the American Pain Foundation, the American Cancer Society, the Hospice Network of Maryland, and any other interested party, to develop a website that assures responses with 48-hours in an "ask the expert" format.

Appropriate licensing boards should review the service provided to determine if continuing medical education credits can be awarded to those licensed professionals who choose to volunteer for this type of program.

HEALTH CARE FINANCING ISSUES

Even if clinicians offer appropriate pain management interventions, patients who cannot afford them will remain in pain. Hence, another objective of State policy should be to remove financial barriers that prevent access to needed pain management.

[32] Gloth FM3rd, Schwartz J. Developing a physicians' palliative care pain hotline in Maryland. Am J Hosp Palliat Care 2000 Jan-Feb;17(1):24-8.

In recent years, Third-party Pharmacy Reimbursement Programs have adopted Preferred Drug Lists (PDLs) and formularies to control costs while ensuring access to a broad range of prescription drugs. Although PDLs and formularies are intended to promote cost-effective care, advocates have argued that, if PDLs and formularies result in inadequate pain management for sizeable numbers of Medicaid patients, short-term savings will be more than offset by longer-term costs from, for example, increased emergency room visits.

Maryland Medicaid Program

To help contain costs, in late-2003 the Medicaid Program adopted a PDL. Medicaid's Pharmacy and Therapeutics (P&T) Committee, which is made up of physicians, pharmacists and two consumer members, select appropriate medications based on medical review to be included on the PDL. Physicians must obtain prior authorization to prescribe a drug that is not on the PDL.

According to officials at the Department of Health and Mental Hygiene, the prior authorization process under Medicaid's PDL is minimally burdensome. Physicians have only to state that they want their patient to have the non-preferred drug. All prior authorization requests are processed within 24-hours. The PDL has been in place for over six months and the Department reports that there have been few, if any, complaints about obtaining prior authorization for non-preferred drugs.

The PDL, for example, contains several narcotic analgesics, including oxycodone. However, OxyContin, a controlled-release form of oxycodone, which has superior clinical effectiveness in some situations, is not on the PDL and requires preauthorization. In addition, certain non-steroidal anti-inflammatory drugs known as COX-2 inhibitors, including celecoxib (Celebrex) and rofecoxib (Vioxx), non-narcotic analgesics of established value to many patients, require preauthorization as well.

The Food and Drug Administration has recently approved a generic version of controlled-release oxycodone. The new generic, however, will not be automatically placed on the PDL. Any new generic drugs that have been approved for use by the Food and Drug Administration and have been on the market for six-months are given consideration for inclusion on the PDL by the P&T Committee at its next scheduled meeting.

Private Health Insurance

There are limited data about the extent to which pain management therapies are covered by private health insurance. The sparse information available suggests a wide variation in reimbursement practices with regard to non-drug interventions.[33] In addition, the use of formularies by prescription drug plans suggests similar variation for reimbursement of pain medications.

Acting on the view that "a full range of pain management modalities … should be available to individuals regardless of the illness trajectory [or] health insurance …," the framers of the

[33] Hoffmann DE. Pain management and palliative care in the era of managed care: issues for health insurers. J Law Med Ethics 1998. 26:267-89.

Maryland Comprehensive Cancer Control Plan recommended a uniform, mandated benefit for pain assessment and management. [34]

RECOMMENDATION 13. Third-party Pharmacy Reimbursement Programs should review their PDLs and related prescription approval practices to ensure that all patients who have a clinical need for specific medications have appropriate access to them. In the case of the generic version of controlled-release oxycodone, the programs should give prompt consideration to its inclusion in the PDL. Any pre-authorization process should operate efficiently, with minimal burden for prescribers.

Given the recommendations of the American Geriatrics Society and the Revised Beers Criteria, COX-2 inhibitors for patients 65 years old or older should not require pre-authorization, since authorized traditional non-steroidal anti-inflammatory drugs elevate the health risks and ultimately are unlikely to save money in the older portion of the State's population.[35,36,37]

RECOMMENDATION 14. Third-party Pharmacy Reimbursement Programs should review their PDLs to remove any drugs that, although inexpensive, have little clinical value for effective pain management (e.g., Propoxyphene (Darvocet®, etc) and Meperidine (Demerol).[3839]

RECOMMENDATION 15. The Maryland Health Care Commission, in conjunction with the Maryland Insurance Administration, should assess patterns and shortfalls in coverage for pain management under private insurance contracts, employer self-insurance plans, and workers' compensation and report its findings, together with any recommendations to the General Assembly.

REGULATION OF HEALTH CARE FACILITIES

A variety of studies have shown an unacceptable prevalence of pain in hospital patients and nursing home residents. These studies led the Institute of Medicine, in its 1997 report on end-of-life care, to conclude that "a significant proportion of dying patients and patients with advanced disease experience serious pain, despite the availability of effective pharmacological and other options for relieving most pain."[40]

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[34] Maryland Comprehensive Cancer Control Plan 2004 – 2008: Our Call to Action. Chapter 14: Pain Management.
[35] Maetzel A, Krahn M., Naglie G. The cost effectiveness of rofecoxib and celecoxib in patients with osteoarthritis or rheumatoid arthritis. Arthritis Rheum. 2003 Jun 15:49(3):283-92.
[36] Hochberg, MC. Treatment of rheumatoid arthritis and osteoarthritis with COX-2-selective inhibitors: a managed care perspective. Am J Manag Care. 2002 Nov;8(17 Suppl):S502-17.
[37] Fendrich M. Developing an economic rationale for the use of selective COX-2 inhibitors for patients at risk for NSAID gastropathy. Cleve Clin J Med. 2002;69 Suppl 1:S159-64.
[38] The AGS Panel on Persistent Pain in Older Persons. The Management of Persistent Pain in Older Adults. J. Am. Geriatr. Soc 2002; 50 (6 Suppl):S209.
[39] Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts. Arch Intern Med. 2003 Dec 8-22;163(22):2716-24.

[40] Field MJ and Cassel CK eds. Approaching death: improving care at the end of life. Washington: National Academy Press 1997.

This demonstrated problem cannot be solved by regulatory fiat, but regulatory oversight, especially coupled with education, can be a force for positive systemic change. That is the underlying objective of the State survey process under the auspices of the OHCQ and standards established by accrediting organizations. Patients have a right to appropriate assessment and management of pain and health care facilities have a corresponding duty to make that right meaningful in practice.[41]

The staff of the OHCQ is hard working and diligent; however, it is a concern to the Advisory Council that even the best regulatory framework becomes meaningless if qualified staff are not available to carry out survey activity. The OHCQ has lost over 50 full-time equivalent positions through the past several fiscal years. The Advisory Council believes that this loss of staff may adversely affect the OHCQ's responsiveness to complaints and ultimately affect its ability to conduct annual surveys.

RECOMMENDATION 16. OHCQ should continue to give priority attention in its surveys to issues of pain assessment and management.

RECOMMENDATION 17. OHCQ should, through its clinical alerts and in presentations at conferences and other forums, emphasize the importance it places on appropriate pain assessment and management.

RECOMMENDATION 18. The Secretary of Health and Mental Hygiene should evaluate the survey process to ensure that adequate surveyors are available so that the survey process, including its focus on pain assessment and management, can be timely and effective.

RECOMMENDATION 19. OHCQ and the Maryland Department of Aging should provide regular in-service training for surveyors and ombudsmen on the criteria for identifying inadequate pain assessment and management.

RECOMMENDATION 20. The OHCQ should fund, to the extent that resources are available, through the Civil Monetary Penalties Account (e.g., monies collected through fines assessed to nursing homes for non-compliance with standards) demonstration projects on pain relief in long-term care.

PROFESSIONAL REGULATION

The removal of barriers and promoting access to quality pain management should be the objectives pursued by the agencies of the State responsible for upholding basic professional standards for clinicians, protecting the rights of residents and patients in acute and long-term care facilities, and enforcing the criminal laws. Disciplinary and criminal cases involving improper use of controlled substances should be pursued vigorously, but in a balanced manner that does not discourage clinically justified prescribing and dispensing of controlled substances.
In the words of the joint statement adopted in 2001 by 21 health organizations and the Drug Enforcement Administration, "Preventing drug abuse is an important societal goal, but there is

[41] Joint Commission on Accreditation of Healthcare Organizations. Comprehensive Accreditation Manual for Hospitals 2001.

consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care that they need and deserve." Oversight of licensees and facilities should also attend to the direct harm to patients from the demonstrably inadequate treatment of pain.

While specific data are not available, there is mounting concern of a perception among Maryland clinicians that a willingness to prescribe controlled substances puts them at heightened risk of becoming a target of investigation and discipline. In unpublished data concerning end-of-life pain management practices, derived from the survey responses of approximately 1,800 Maryland physicians and nurses in 1998, 36-percent of these clinicians reported that "legal concerns" had "often" (8-percent) or "sometimes" (28-percent) influenced their practices. Of the group noting legal concerns, 48-percent identified "disciplinary actions by medical or professional boards" as one such concern. These data are consistent with comparable surveys nationally and in other states.[42]

It is thought that this chilling effect on legitimate pain management practices can be substantially reduced by effective communication of policy that supports quality pain management. Of the licensing and disciplinary boards, the Maryland Board of Physicians (MBP) has been most explicit in this regard. In its December 1997 newsletter, the MBP, or the Board of Physician Quality Assurance as it was then known, published a statement "clarifying our policy on the prescribing of [controlled substances so] that physicians will feel confident that they can meet their patients' needs for pain relief without fearing Board sanction." The Board's policy stated its expectations about appropriate assessment, documentation, and care planning. The Board also requires new licensees to view a short videotape, "A Sense of Balance – Treating Chronic Pain," that reiterates the elements of the Board's policy. This videotape has been cited as a positive example of a regulatory board's work to "effectively communicate a positive attitude and policy toward pain management."[43]

The Board's policy, however, has not been updated since its issuance. The policy does not address inadequate pain management. As one expert observed, "it is axiomatic that if pain management is to be an expected part of quality medical practice, then substandard pain management practice must be subject to review and corrective action as in any other area of medical practice."[44]

RECOMMENDATION 21. The Board of Physicians should update its policy and strongly consider adopting the key elements of the newly revised *Model Policy for the Use of Controlled Substances for the Treatment of Pain* of the Federation of State Medical Boards.

This new policy is a revision of the 1998 guidelines that have been adopted in whole or in part by 22 state boards as of January 2004. The new policy encourages boards to view under treatment of pain as a serious violation as over treatment. In particular, the Board's policy

[42] Joranson DE, Gilson AM, Dahl JL, and Haddox JD. Pain management, controlled substances, and state medical board policy: a decade of change. J Pain Symptom Manage 2002;23:138-47
[43] Gilson AM, Joranson DE, and Maurer MA. Improving state medical board policies: influence of a model. J Law, Med & Ethics 2003;31:119-29.
[44] Joranson et al. 2002.

should make clear that a failure to provide competent pain management could be a basis for corrective action, in the form of required training.[45]

RECOMMENDATION 22. The Board of Physicians should revise its educational strategy for new licensees, including development of a web-based format to communicate its revised policy.

This strategy would broaden the audience beyond new licensees. The web-based format should also incorporate an evaluation tool.

RECOMMENDATION 23. The Boards of Dentistry, Nursing, Pharmacy, and Physicians should adopt a joint policy statement on pain management affirming their recognition of the importance of pain management and their shared commitment to applying appropriate standards and procedures for disciplinary action related to the prescribing and dispensing of controlled substances.

Comparable licensing boards in other states, such as Kansas, North Carolina and West Virginia, have developed such policies. Guidelines should also be adopted by the boards that provide for consistent and appropriate sanctioning of licensees who are negligent in providing adequate pain relief interventions.

CONTINUING EDUCATION IN PAIN MANAGEMENT

Quality pain management requires clinicians with current knowledge and capable skills. Current knowledge can be obtained from professional training and continuing education (CE). Some advocates have urged that CE be mandatory.

Traditionally, CE has encompassed lectures in a variety of formats. The efficacy of such efforts in changing behavior has been debatable at best. It should be noted that California recently enacted a CE requirement on pain management. However, data are lacking on whether this CE requirement actually results in benefits to patients. As medical and scientific knowledge expands, CE after formal training continues to be of vital importance in the battle to provide adequate pain relief.

In Maryland, the health occupation licensing boards have traditionally refrained from requiring continuing education on specific topics, preferring instead simply to allow each practitioner to self-select the offerings needed to meet a minimum number of hours. Courses are available in the State on pain management, such as the Maryland End-of-Life Training (MET) Program, which incorporate a strong pain management module.[46]

RECOMMENDATION 24. Continuing education (CE) on pain management should not be mandated at this time, but the Board of Physicians should monitor efficacy data about mandated CE in other states.

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[45] Tucker KL. Medical board corrective action with physicians who fail to provide adequate pain care. J Med Licensure & Discipline 2001;87:130-31.

[46] Maryland End-of-Life Training (MET) Program. http://www.hnmd.org/met_program.htm

If the data are positive, the Board should study either the nature of an appropriate mandate for such CE or effective incentives for physicians to take this CE (for example, tied to reduced malpractice insurance premiums or license renewal fees).

RECOMMENDATION 25. All of the health occupation boards that license prescribers or dispensers of pain medication should encourage their licensees to take skill-based continuing education courses in pain management and should explore whether such courses might be offered through the boards at low- or no-cost.

RECOMMENDATION 26. All of the health occupation boards which have licensees directly involved with aspects of pain assessment and management (for example, the Boards of Physicians, Physical Therapy, Dentistry, Nursing, Pharmacy, and Social Work Examiners) should encourage those licensees to take skill-based continuing education courses in pain management.

RECOMMENDATION 27. All of the health occupation boards, which have licensees directly involved with aspects of pain assessment and management, should disseminate ongoing and updated information to its licensees about pain management that includes information about assessment and treatment.

RECOMMENDATION 28. Maryland's medical, nursing, dental and pharmacy professional schools should report to the Advisory Council on their efforts to improve preparedness of their graduates in pain management. The Advisory Council does not recommend that the State attempt to alter the curriculum of these academic institutions.

The report should include what is required and what is available in each curriculum. This will provide valuable information and draw attention to the importance of this issue in Maryland.

PRESCRIPTION MONITORING PROGRAM

Monitoring of prescription practices can be a valuable tool in detecting fraud and other criminal conduct.[47] Despite the fact that the great majority of health care professionals comply with the laws on controlled substances, law enforcement cannot ignore the minority who do not. For example, the Attorney General's Medicaid Fraud Control Unit has brought a number of cases because of information derived from a prescription monitoring program that is an established part of the Medicaid Program. Moreover, in two of the past three legislative sessions, bills to create an expanded electronic prescription monitoring program have been introduced (House Bill 60 of 2003 and Senate Bill 44 of 2002) but not enacted.

Advocates for quality pain management have expressed concern about the potential burdens and chilling effect of ill-designed prescription monitoring programs. Recent survey data suggest that the use of an electronic monitoring program does not necessarily correlate with an increased

[47] Joranson DE, Carrow GM, Ryan KM et al. Pain management and prescription monitoring. J Pain Symptom Manage 2002b;23:231-38.

level of investigatory or disciplinary activity.[48] Nevertheless, the Advisory Council believes that concerns about the unintended consequences of a monitoring program must be carefully considered before a program is implemented. All aspects of a program should be assessed for their adherence to the principle of balance.

The Attorney General's Office, which has both law enforcement responsibilities and a longstanding interest in improved pain management, has informally indicated to us its intention to review this issue in depth. In its review, the Attorney General's Office plans to examine, among other pertinent material, the Model Act that has been adopted by the Alliance of States with Prescription Monitoring Programs and the National Association of State Controlled Substances Authorities, the position statements on prescription monitoring of advocacy and professional groups, and the recommendations of expert commentators.[49]

RECOMMENDATION 29. The Attorney General's Office should complete its review of criteria for a prescription monitoring program prior to the consideration of legislation mandating such a program.

RECOMMENDATION 30. Any prescription monitoring program ultimately adopted should be designed to protect legitimate prescribing and dispensing while assuring patient privacy.

CONCLUSION

The creation of State Advisory Council on Pain Management has led to 30 recommendations to bring some relief to individuals in Maryland suffering with pain and to improve pain management best practices.

The recommendations in this report focus on practicable solutions to the relatively easiest issues surrounding pain management policy in Maryland. Yet, many difficult issues remain to be explored and addressed. The continuation of the State Advisory Council on Pain Management is very important and will ensure that those areas are reviewed.

This report must launch new efforts along the areas of education, oversight, assessment, intervention, and reimbursement if we are to finally reign in the pain that is so pervasive and destructive throughout the population. For citizens of the "Free State" this marks the beginning of an opportunity to be pain-free as well.

[48] Hoffmann DE and Tarzian AJ. Achieving the right balance in oversight of physician opioid prescribing for pain: the role of state medical boards. J Law, Med & Ethics 2003;31:21-40.
[49] Brushwood DB. Maximizing the value of electronic prescription monitoring programs. J Law, Med & Ethics 2003;31:41-54.

APPENDIX A:

HOUSE BILL 423 – "HEALTH CARE – PROGRAMS AND FACILITIES – PAIN MANAGEMENT

APPENDIX B:

LIST OF CONSULTING ORGANIZATIONS

APPENDIX C:

MARYLAND STATE AVISORY COUNCIL
ON PAIN MANAGEMENT - MEETING NOTES

APPENDIX D:

MARYLAND STATE ADVISORY COUNCIL
ON PAIN MANAGEMENT – INTERIM REPORT