

STATE OF MICHIGAN
MICHIGAN DEPARTMENT OF CONSUMER and INDUSTRY SERVICES
BUREAU OF HEALTH SERVICES

**PAIN and SYMPTOM MANAGEMENT
ADVISORY COMMITTEE REPORT**



NOVEMBER 2002

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I. ADVISORY COMMITTEE MEMBERS

MEMBER

REPRESENTING

Julie A. Golembiewski, Pharm.D.	Board of Pharmacy
Dennis W. Dobritt, D.O.	Board of Osteopathic Medicine and Surgery
Susan Rose, D.O	Board of Osteopathic Medicine and Surgery
Henry E. Beckmeyer*, III, D.O	College of Osteopathic Medicine/MSU
Philip J. Lanzissera, Ph.D, A.B.P.P	Board of Psychology
Ada Jacox, R.N., M.S.N, Ph.D.	Board of Nursing
Sr. Mary Giovanni Monge*, R.N.	Representative of Hospice Organizations
Robert Hamel, M.M., PA-C	Task Force on Physician's Assistants
Valerie Kinsora*	Public Member
Gary E. Jeffers, D.M.D., M.S	Board of Dentistry
Gregg K. VandeKieft*, M.D.	College of Human Medicine/MSU
Steven M. Wiener*, M.D	Wayne State School of Medicine
Karen Ogle, M.D	Board of Medicine
Vildan Mullin*, M.D.	University Of Michigan School of Medicine
Maury R. Ellenberg M.D.	Board of Medicine
J. Kay Felt*	Public Member
Thomas C. Lindsay, II, Director,	Bureau of Health Services, DCIS
James K. Haveman, Jr., Director,	Department of Community Health

Please see Appendix F for the meeting dates.

* Appointed by the Governor

II. EXECUTIVE SUMMARY

The Pain and Symptom Management Advisory Committee consisting of representatives from nearly every health professional licensing board, was established under the Occupational regulation sections of the Michigan Public Health Code, P.A. 421 of 1998, which took effect April 1, 1999. The first interdisciplinary advisory committee was established in 1995 under P.A. 232 of 1994.

The committee was charged to deal with issues pertaining to pain and symptom management, hold a public hearing to gather information from the general public and make recommendations.

Three subcommittees were formed to deal with issues concerning:

1. Public Education
2. Professional Education
3. Public Policy

A public hearing was held on June 20, 2000.

Based on the public hearing testimony the advisory committee identified the following issues related to pain and symptom management to be of utmost concern to the public:

- Lack of education and training in pain and symptom management for health care professionals
- Lack of 'Pain and symptom management' curriculum in medical, dental, pharmacy, psychology and nursing programs in Michigan health professions educational institutions
- Lack of awareness of pain and symptom management among patients, family members, insurers and state agencies
- Lack of access and coverage for treatment for pain and symptom management
- Fear of addiction and misinformation regarding Schedule II drugs
- Lack of availability of Schedule II drugs in pharmacies
- Doctors' reluctance to prescribe Schedule II drugs for fear of disciplinary action (Michigan official prescription program)
- Patients' difficulty in proving disability to insurers

The following recommendations were made by the Sub-committees:

1. Michigan Department of Consumer and Industry Services (MDCIS) should develop and implement a website on pain and symptom management for the following (See Appendix A):

A. Healthcare professionals:

The website should address the issues of state law and related administrative rules, education and continuing education, provider issues, pharmacy issues and links to professional associations and other resources on pain and symptom management.

MDCIS should publish information about the website and access to the website in "Health Alert." MDCIS staff should be responsible for updating the website with information received from the advisory committee, from professional associations and newsletters.

B. General public:

To increase the public awareness regarding pain management, the website should cover topics such as the definition of pain, causes of pain, frequently asked questions, current news concerning pain issues in Michigan and across the country, policy statements, bibliography and topics of interest. The website should be linked to other user-friendly pain and symptom management websites such as the American Pain Society, the International Association for the Study of Pain, the American Pain Foundation etc. The website should also have a "contact us" feature where the public can express their concerns related to pain and symptom management to the committee, department and legislature.

2. The legislature should amend all statutes to eliminate the use of the term "intractable pain." The term "intractable pain" should either be eliminated in these statutes or amended to read "pain," as appropriate.
3. MDCIS in consultation with the Department of Community Health shall develop, publish, and distribute an informational booklet on pain including acute pain, chronic pain and malignant pain, and the use of pharmaceuticals (including opioids and other controlled substances) as well as non-pharmacologic modalities for the control of pain and symptoms.
4. MDCIS should develop and publish brochures and prepare videos in consultation with the pain and symptom management advisory committee members for the benefit of patients/patient families and care givers regarding pain, the causes of pain, the emotional needs of the patients and their families, and treatment and health care coverage.
5. MDCIS should develop and disseminate guidelines similar to the Joint Commission on Accreditation of Healthcare Organizations requirements for "pain standards" as the standard of care for all health providers, in collaboration with the licensing boards and their respective professional associations.
6. MDCIS should disseminate curricula developed by or similar to the International Association for the Study of Pain (IASP) model core curricula regarding pain and symptom management to the Michigan institutions that provide health care education and continuing education, and should integrate pain and symptom management into the customary practice of health care.
7. The State legislature should establish a grant program to facilitate the integration and implementation of the model curricula into appropriate educational programs in Michigan institutions so as to encourage Michigan institutions educating health professionals to implement the model core curricula. The impact of implementing model core curricula in pain management can be further evaluated and reassessed to determine the effectiveness.
8. MDCIS should formulate the language for an administrative rule through the respective boards to address continuing education as a condition for license renewal of health professionals in support of the existing statute (333.16204) regarding pain and symptom management. Continuing medical education in pain and symptom management for health care professionals shall be for a minimum of 1 hour per licensing cycle and include materials on indications and use of controlled substances.
9. MDCIS should encourage the hospitals to increase the medical and nursing staff's knowledge by providing the guidelines for the required curricula in pain and symptom management to be covered through their organized educational programs.

10. MDCIS should encourage professional associations to address education and training in pain and symptom management for those health professionals who are not required by the statute to have continuing education to assure that all health professionals maintain a current understanding of pain and symptom management.
11. MDCIS should establish guidelines similar to the "Model guidelines for the use of controlled substances for the treatment of pain" (See Appendix B) published by the Federation of State Medical Boards of the United States (FSMB), in collaboration with the licensing boards and their respective professional associations.
12. The state legislature should replace the current Official Prescription Program with a simplified electronic monitoring system to balance availability of safe and effective drugs for pain and symptom management and deter the diversion of prescription drugs for illegitimate use. The new system should be an on-line interactive system that will be able to provide data sets for providers.

Until such a system is in place, MDCIS should educate health professionals about Michigan's Official Prescription Program with an emphasis on the intent to facilitate appropriate care and give providers access to information regarding patient drug use patterns.
13. The Public Policy Subcommittee supports the Commission on End of Life Care's recommendation that the State Legislature should amend the Policy on Patient and Resident Rights and Responsibilities (MCL 333.20201(2)) to add a new subsection to the effect that patients have the right to adequate pain and symptom management as an essential element of medical treatment, and to be informed of that right.
14. MDCIS should promote Health Maintenance Organizations, Medicaid, Medicare and other insurers to provide access to and coverage for the care provided or recommended by a multidisciplinary team including alternative therapies and procedures such as acupuncture, behavioral management, therapeutic massage and musculoskeletal manipulation/treatment.
15. MDCIS should encourage pharmacies within communities or among pharmacy chains to share information and carry an adequate supply of Schedule II medications to meet the needs of the patients/communities by ensuring that pharmacies are aware of supply and demand issues.
16. MDCIS should promulgate rules that require pharmacies to assist patients in finding adequate supplies of medications within a reasonable time when the pharmacy is unable to fill a valid prescription as presented.
17. The state legislature, MDCIS and MDCH should work to minimize the state regulatory impediments to access to effective pain medications under Schedule II to assure appropriate care in pain management. These include:
 - a. Lengthening the time limit for filling prescriptions from five (5) days to 90 days
 - b. Lengthening the period from 72 hours to 14 days for completely filling a prescription that is only partially filled
18. MDCIS and the practice boards should adopt and publicize statements of principle that under-treatment is as serious an offense as any other form of inappropriate treatment of pain under the practice acts applicable to physicians, dentists, nurses, and pharmacists. This is consistent with the grounds for violation under the Michigan Public Health Code 333.16221.

III. BACKGROUND

A. **Establishment of the first interdisciplinary advisory committee:**

In the early 1990s the area of pain and symptom management became an issue of concern. To address this issue, the first interdisciplinary advisory committee on pain and symptom management was created pursuant to P.A. 232 of 1994, which was enacted June 30, 1994. The committee consisted of 18 members, appointed from each health professional licensing board, the board of examiners in Social Work and the Task Force on Physician's Assistants. Excluded were the boards of Veterinary Medicine and Sanitarians. The committee also included a representative of the Department of Community Health and was chaired by a designee of the director of the Department of Consumer and Industry Services.

The committee was charged with several legislative mandates. Those mandates were as follows:

- Provide a forum open to all health care professions and hospices in developing an integrated approach to pain and symptom management.
- Hold a public hearing to gather information from the general public on the issue of pain and symptom management.
- Develop and encourage the implementation of model core curricula on pain and symptom management.
- Develop recommendations for the boards on integrating pain and symptom management into the customary practice of health care professionals and identify the roles and responsibilities of the various health care professionals in pain and symptom management.
- Develop written materials explaining pain and symptom management and hospice care for distribution to health care professionals, health care payment and benefits plans and the public.
- Advise the licensing boards on the duration and content of continuing education requirements for pain and symptom management.
- Report activities and recommendations to the legislature.

A public hearing was held on January 17, 1995 pursuant to the legislative mandate. Upon review of the hearing transcript, the committee/subcommittees made the following recommendations:

Health Care Integration Subcommittee

- ❑ Any physician treating a patient suffering from intractable pain in Michigan should feel free to prescribe Schedule 2 controlled substances where such treatment is medically necessary to control the patient's pain. No physician licensed in this state need fear administrative action for rendering medically necessary pain control treatment through use of Schedule 2 controlled substances as long as such necessity is properly diagnosed and documented.
- ❑ Physicians should be educated about the scope and purpose of the Official Prescription program as a tool to enforce drug control laws and prevent diversion.
- ❑ An integral part of pain management is ensuring that patients with intractable pain are able to obtain the prescription drugs necessary to manage and control their pain. Community pharmacies are encouraged to do their part to serve this segment of the population. Communication between physician, patient and pharmacist will assist the pharmacist in identifying the need for particular controlled substances. Pharmacies must be held accountable for controlled

substances they stock, however this accountability should not be used as a barrier to stocking controlled substances.

- ❑ Primary care physicians should be educated in the treatment of intractable pain in patients and the maintenance of patients on pain management programs designed by pain specialists upon referral. This education should stress the importance of referral back to the primary care physician from the pain management specialist for patient pain management maintenance.
- ❑ Primary care physicians should be educated in the non-medical treatment modalities of intractable pain in patients and the referral of patients to specialists in these disciplines. This education should stress when to refer and the appropriate discipline for the referral.
- ❑ Because the development of a pain management drug regimen can vary significantly for each patient, third party payers who reimburse on a DRG (diagnostic related group) should allow longer lengths of stay in hospitals for acute pain control. DRG reimbursement practices should recognize the need for variable lengths of stay for patients receiving pain management services.
- ❑ Third party payers, including Medicaid, should recognize the importance of non-drug therapies, such as occupational therapy and social services, as adjuncts for pain management that improve the patient's quality of life. Third party payers and Medicaid should authorize payment of these services as necessary for appropriate pain management.
- ❑ Third party payers should authorize direct payment for pain management services provided in a setting other than a home health agency or other licensed or certified health care facility by non-physician providers.

Continuing Education Subcommittee

- ❑ Group I: Medical, Osteopathic, Podiatric physicians, Physician's Assistants, Nurses and Pharmacists;
Recommended hours of course work: 2 hours per year.
Course work should address proper diagnosis including pain assessment techniques, treatment, and maintenance of intractable pain to avoid over treating and under-treating patients. Treatment course work should include pharmacological, physical, invasive and psycho/social interventions. Course work should further include an ongoing update of the role of the various, non-medical disciplines in pain and symptom management, and provide guidance as to when a referral to a specialist in one or more of these fields is appropriate.
- ❑ Group II: Dentists, Optometrists and Chiropractors;
Recommended hours of course work: 1 hour per year
Course work should address diagnosis, within the limits of the specific scope of practice of each of these professions, and referral of patients with intractable pain for medical treatment. Course work should further include an ongoing update of the role of the various, non-medical disciplines in pain and symptom management, and provide guidance as to when a referral to a specialist in one or more of these fields is appropriate.
- ❑ Group III: Counselors, Psychologists, Social Workers, and Occupational and Physical Therapists
No continuing education requirement is recommended for these disciplines, however health professionals within these categories are encouraged to voluntarily attend seminars concerning pain and symptom management.

Core Curricula Subcommittee

- ❑ Michigan educational centers for health professionals are encouraged to implement the core curriculum set forth by the IASP in its publication entitled Core Curriculum for Professional Education in Pain.
- ❑ Michigan educational centers for health professionals are encouraged to supplement the core curriculum recommended above with instruction on state law and related administrative rules, specifically with regard to the Official Prescription Program, and federal law and related regulations, specifically with regard to the role of the Drug Enforcement Agency. Students should come away from this instruction with an understanding of how these agencies work in conjunction with health professionals, and how these laws and regulations affect them as health professionals.

Publication Development Subcommittee

With so many available resources, the Subcommittee chose not to develop any new material which would do nothing more than mirror existing publications. The Subcommittee decided instead to concentrate its efforts in compiling a list or bibliography of existing resources, tailoring them to assist 1. health care professionals 2. health care payment and benefits plans, and 3. the public in obtaining this information by providing a point of reference.

Implementation of these recommendations was voluntary. No significant progress has been made in implementing the recommendations in the ensuing years (See Appendix E).

Pain and symptom management continued to be an issue in the forefront and with the physicians' reluctance to prescribe Schedule II drugs and a serious lack of understanding by the public and health professionals, P.A 421 of 1998 was enacted.

B. Establishment of the current advisory committee:

P.A. 421 of 1998 amended P.A.232 of 1994. It was established under the Occupational regulation sections of the Michigan Public Health Code, and became effective April 1, 1999.

The amendments are as follows (See Appendix C):

- Change of name from interdisciplinary advisory committee to advisory committee
- Revision in the committee's membership
- Revision in the committee's duties
- In making recommendations and developing written materials, review guidelines on pain and symptom management issued by U.S. Department of Health and Human Services (HHS)
- Defined "Intractable Pain"

!V. PURPOSE OF THE LEGISLATION

The legislation is designed to enhance the quality of care available for Michigan citizens by reducing and removing roadblocks to access to pain and symptom management. The bills include a measure that was intended to give physicians a clear legislative policy on using opiates for pain control without fear of prosecution. Specifically, the bill endorses the use of Official Prescription forms and says the Official Prescription Program was not intended to "prevent or inhibit the legitimate, medically recognized use of those controlled substances to treat patients with cases of intractable pain, especially long-term treatment."

The bills include an expansion of the state's advisory committee on pain management to include representatives from nearly every health professional licensing board, a person who has intractable pain and a member of the public. The committee oversees education and licensure dealing with pain management as well as reviews changes in pain and symptom management.

The bills also require insurance providers to inform subscribers or insureds of their rights and coverage for pain management.

A. Composition of the Advisory Committee

An advisory committee on pain and symptom management was created in the department. A member would serve for two years, or until a successor is appointed. A vacancy would have to be filled in the same manner as the original appointment.

The committee consists of the following members appointed in the following manner:

- (a) The Michigan Board of Medicine and the Michigan Board of Osteopathic Medicine and Surgery appoint 2 members, 1 of whom is a physician specializing in primary care and 1 of whom is a physician certified in the specialty of pain medicine by 1 or more national professional organizations approved by the department of Consumer and Industry Services, including, but not limited to, the American board of medical specialists or the American board of pain medicine
- (b) One psychologist who is associated with the education and training of psychology students, appointed by the Michigan Board of Psychology
- (c) One individual who is representative of the general public appointed by the governor
- (d) One registered professional nurse with training in the treatment of intractable pain who is associated with the education and training of nursing students, appointed by the Michigan Board of Nursing
- (e) One dentist with training in the treatment of intractable pain who is associated with the education and training of dental students, appointed by the Michigan Board of Dentistry
- (f) One pharmacist with training in the treatment of intractable pain who is associated with the education and training of pharmacy students appointed by the Michigan Board of Pharmacy
- (g) One individual appointed by the governor who represents Michigan hospice organizations
- (h) One representative appointed by the governor from each of the state's medical schools

- (i) One individual appointed by the governor who has been diagnosed as a chronic pain sufferer
- (j) One physician's assistant with training in the treatment of intractable pain appointed by the Michigan task force on physician's assistants
- (k) The director of the Department of Consumer and Industry Services or his or her designee, who shall serve as the chairperson
- (l) The director of the Department of Community Health or his or her designee.

Three Sub-Committees (See Appendix D) were formed based on the charges assigned to the advisory committee, after the appointments were made as follows:

Public Education Sub-Committee

The Public Education Sub-Committee is responsible for educating the public in pain and symptom management. It is important to increase the public awareness regarding pain, what causes pain, emotional needs of the patients and their families, treatment and health care coverage.

Public Policy Sub-Committee

This committee is responsible for making recommendations to the Department of Consumer and Industry Services, Department of Community Health and the legislature related to regulatory and reimbursement policy issues.

Professional Education Subcommittee

The Professional Education Sub-Committee is responsible for evaluating and recommending the need for education and continuing education, training in pain and symptom management for healthcare professionals, and to examine issues related to providers and pharmacies.

B. Committee charges pursuant to legislation

- A. Annually consult with all of the Public Health Code boards and the Board of Social Workers to develop an integrated approach to understanding and applying pain and symptom management techniques.
- B. Hold a public hearing to gather information from the general public on issues pertaining to pain and symptom management.
- C. Develop and encourage the implementation of model core curricula on pain and symptom management.

- D. Develop recommendations to the boards and task force on integrating pain and symptom management into the customary practice of health care professionals and identify the roles and responsibilities of the various health professionals in pain and symptom management.
- E. Advise the boards on the duration and content of continuing education requirements for pain and symptom management.
- F. Annually report on the activities of the advisory committee and make recommendations on the following issues to the Director of the Department of Consumer and Industry Services and the Director of the Department of Community Health:
 - a. Pain management educational curricula and continuing education requirements of institutions providing health care education
 - b. Information about the impact and effectiveness of previous recommendations, if any, that have been implemented, including, but not limited to, recommendations made under subdivision D
 - c. Activities undertaken by the advisory committee in complying with the duties imposed under subdivisions C and D
- G. Beginning in January of the first year after the effective date, annually review any changes occurring in pain and symptom management.

In making recommendations and developing written materials, review guidelines on pain and symptom management issued by the United States Department of Health and Human Services.

A public hearing was held on June 20, 2000. Three people gave oral testimonies and many individuals and organizations submitted the written testimonies. The issues raised in these testimonies are grouped under the following Sub-Committee headings:

- w Public Education
- w Professional Education
- w Public Policy

V. PUBLIC EDUCATION SUBCOMMITTEE

The Public Education Sub-Committee is responsible for educating the public in pain and symptom management. Prescription drugs can relieve a variety of pain syndromes and improve the lives of millions of Americans experiencing pain. Nonpharmacologic therapies may also provide important benefits. It is important to increase the public awareness regarding pain, the causes of pain, the emotional needs of the patients and their families, and treatment and health care coverage.

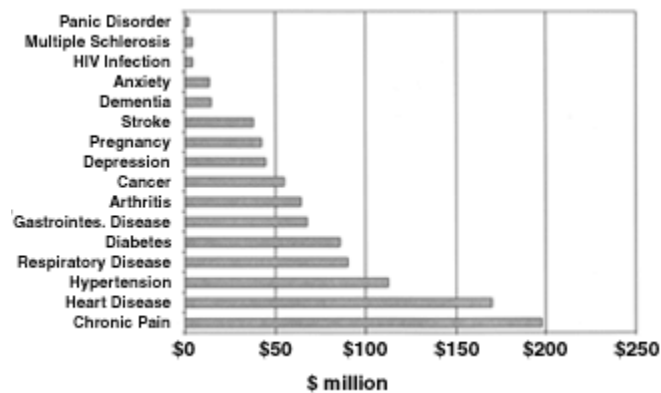
Pain - Definition

Pain is a universal problem affecting millions of people regardless of social, economic and cultural considerations. The American Academy of Pain Medicine estimates that over 75 million Americans live with serious pain. 50 million suffer from chronic pain, and each year another 25 million experience acute pain as a result of injuries or surgeries. In a 1997 survey of Michigan residents sponsored by the Pain Education Fund at Chelsea Community Hospital, one in five Michigan adults reported experiencing some form of chronic pain, and 40 percent of people with chronic pain say the pain affects their ability to live a normal life. More than 4 billion workdays are lost each year, resulting in a financial loss to the economy greater than \$79 billion per year.

Chronic pain accounts for greater total annual costs than other chronic conditions, including heart disease, hypertension, and diabetes (Figure 1) (Fishman, Von Korff, Lozano, & Hecht, 1997). Such findings indicate that chronic pain is highly prevalent and has a major impact on patients' utilization of healthcare services and on costs in managed care settings.

FIGURE 1. Total Annual Costs of Treatment by Chronic Condition at Group Health Cooperative of Puget Sound in 1992

(Costs were calculated by multiplying the number of patients by the mean cost per patient. The chronic pain category includes back and neck pain, facial pain, and headache.)



Note. Adapted from Fishman P., Von Korff M., Lozano P., Hecht, J. (1997). Chronic care costs in managed care. *Health Affairs*, 16(3), 239247.

Pain is a personal experience and unique to each individual. Pain may include a range of physical and mental sensations, such as aching, tightness, numbing and burning. These sensations may vary in severity, persistence, source and duration.

The Advisory Committee on Pain and Symptom Management agreed to adopt the definition of pain as defined by the International Association for the Study of Pain (IASP). IASP defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage or both.

Pain can be classified as either acute or chronic. Acute pain is caused by injury, surgery, illness, trauma or painful medical procedures. It generally lasts for a short period of time, and usually disappears when the underlying cause has been treated or has healed. However, unrelieved acute pain may lead to chronic pain problems that may result in long hospital stays, rehospitalizations, visits to outpatient clinics and emergency departments, and increased costs.

Chronic pain exists beyond an expected time for healing. It is a persistent pain state that may or may not be associated with a long-term medical condition or disease.

Emotion

People who suffer from chronic pain experience emotions associated with pain such as anger, anxiety and depression. Unrelieved pain is associated with a range of serious potential problems, including sleep disturbance, impaired functional capacity, sexual dysfunction, marital strife, and reduced mental capabilities.

Family members may also experience anger, depression and resentment, as well as compassion and patience. Divorce may occur, or relationships may be strengthened.

An emotional response to pain is normal. Dealing with those responses, both for the individual and the family in a productive and self-helpful manner, is necessary to good pain management.

Anyone with chronic pain that impairs one's ability to function and is associated with significant mood alteration should be able to find pain management providers who acknowledge the reality of physical pain as well as the associated emotions. Emotional state and social circumstances can contribute to the experience and patient reports of pain and can be powerful reinforcers of pain.

Education

Despite great progress in the management of pain, some people continue to experience pain unnecessarily because of inadequate treatment. Some barriers to pain management include the public's general lack of knowledge about what constitutes good pain management, understanding what dangers are inherent in untreated pain, and understanding how to access providers who have expertise in pain and symptom management.

Pain can be seriously disruptive of a person's personal, family, and employment life. Fear and misinformation pose barriers to patients with regard to reporting their pain and accessing adequate treatment. Adequate treatment requires an individualized approach that evaluates the patient's specific needs and clinical judgment that brings to bear the wide variety of interventions available to treat pain.

It is important for patients to understand their symptoms and become as educated as possible about pain management issues, as with any other medical condition. While acute pain can be more easily managed in most circumstances, treatment of chronic pain can fall short of complete elimination of pain.

Evidence that pain has harmful consequences and that improved pain management is cost-effective are certainly reasons to elevate the importance of pain management. Contrary to our cultural attitude of, "No pain, no gain," pain can kill. Patients with cancer pain, and families of patients with cancer pain are willing to endure the pain rather than take "pills" for pain relief revealing strong negative attitudes about use of analgesics, especially "narcotics."

Patients Rights

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standard addresses the individual's right to involvement in all aspects of his or her care. Patients in hospitals are entitled to ask their doctor or nurse what to expect regarding pain and pain management; discuss pain relief options with their doctor or nurse; work with their doctor and nurse to develop a pain management plan; ask for pain relief when pain first begins; help the doctor or nurse to assess their pain; tell the doctor if their pain is not relieved; and tell their doctor or nurse about any worries they have about taking pain medication. The JCAHO standards now require that patients pain be assessed, treated and re-assessed to measure the extent of relief.

<p><u>The Rights of Patients with Pain</u></p>
<p><i>Bill of rights for people with pain</i></p>
<ol style="list-style-type: none">1. <i>I have the right to have my reports of pain accepted and acted on by health care professionals</i>2. <i>I have the right to have my pain controlled, no matter what its cause or how severe it may be</i>3. <i>I have the right to be treated with respect at all times. When I need medication for pain, I should not be treated like a drug abuser.</i>
<p>Iowa and Wisconsin Cancer Pain Initiatives, Cancer Care ,Inc.</p>

Patient education publications often include a list of rights for patients with pain.

Access and Treatment

There is progress in the growth of organizations and services that foster improvement of and access to pain management. Pain services for patients with acute pain related to surgery, trauma, or painful medical procedures, who are receiving IVs, epidural, or intrathecal analgesics, have become widespread in the last few years.

With the rapid growth of pain management organizations and services, it is important for the patients and their families to go to the legitimate sources/providers. The benefits of treatment outweigh the needless suffering. It was evident from the testimony that lack of treatment of pain has an impact on the patient's family members resulting in social isolation and/or divorce. Pain also prevents a patient from being a productive member of the society.

Pain can be effectively treated with early intervention and by appropriately trained specialists. Research¹ on painful disorders shows that appropriate treatment saves lives, reduces pain and suffering, decreases hospital stays, and saves money by reducing overuse of health care resources

¹ American Academy Of Pain Medicine's Website

Health Care Coverage

Individuals offering testimony at the public hearing reported their inability to afford adequate care and medication, and inability to substantiate pain as a disability in order to access benefits. Unrealistic eligibility criteria, and documentation requirements for pain related disability and bureaucratic paperwork were some of the difficulties experienced by these individuals.

Insurance policies differ widely in the scope of coverage for pain management. Patients need specific information from their insurers pertaining to coverage and participation of health care professionals in pain management care as is currently required by state statute.

VI. PROFESSIONAL EDUCATION SUBCOMMITTEE

The Professional Education Sub-Committee is responsible for evaluating and recommending the need for education and continuing education, training in pain and symptom management for healthcare professionals, and to examine issues related to providers and pharmacies.

Education and Continuing Education in Pain and Symptom Management

A significant number of patients, caregivers and professionals state that effective pain management is one of the most elusive goals in health care for Michigan residents. There is a serious lack of understanding by some professionals of the principles of pain management that are practiced by well-organized pain management services. A sustained effort to change professional values and priorities is required.

Studies of patients with acute pain conditions reveal under-treatment. Progress in improving pain management is too little and too slow. Too many patients with pain are not yet benefiting from the tremendous advances in pain management. Improving pain management requires that pain be recognized as a priority. Evidence continues to demonstrate that health care systems do not hold clinicians accountable for assessing and relieving pain. One simple strategy suggested by the American Pain Society to increase accountability for pain is for an institution to make pain intensity ratings a routine part of assessment and documentation of vital signs. This has been implemented in many hospitals, often simply by including pain on the vital sign record. This raises awareness of the problem. This assessment is now a requirement of JCAHO.

In 1997, under a grant from the Robert Wood Johnson Foundation, JCAHO began working collaboratively with institutions to create standards for pain assessment and treatment, with plans to conduct national quality improvement programs to help health care facilities meet these standards. The new pain management standards for healthcare organizations published by JCAHO are effective January 1, 2001.

Barriers to improved pain management faced by clinicians include inadequate knowledge; poor pain assessment techniques; inadequate understanding of the role of the psychosocial processes in pain problems; confusion among addiction, pseudo addiction, tolerance and physical dependence; lack of reimbursement and concerns about regulatory scrutiny.

Because pain management is a newly developed science, current recommendations for pain management need to be incorporated into the basic education provided for all health care professionals, and continuing education must provide this information for clinicians currently in practice whose basic education did not include current pain management guidelines. Educational preparation for pain management is still lacking. A survey² of nursing faculty knowledge about pain identified many weaknesses, especially knowledge about analgesics.

The study of pain is now regarded as a science and as a field of specialization in health care. The knowledge and technology now available can provide safe and effective pain relief for most people who experience pain.

Several developments have occurred that may expedite education of health care professionals. These include innovative education courses, suggestions for curriculum content for Nursing, Medicine,

² Ferrel, McGuire, Donovan: Knowledge and beliefs regarding pain in a sample of nursing faculty, J Prof Nurs 9:79-88,1993

Psychology, Dentistry, Pharmacy, Physical and Occupational Therapy by the International Association for the Study of Pain, and the publication of clinical practice guidelines.

Provider Issues

It was expressed in the written testimony that health care providers have poor communication skills when dealing with patients with pain and that they lack knowledge regarding pain management. In the oral testimony, individuals expressed that physicians prescribe medication the patient doesn't really need due to the physician's clinical assumptions, or treating the patient as a substance abuser, because a patient is using Schedule II medications at high doses. Providers may have difficulty diagnosing people with multiple symptoms, for example: fibromyalgia and cancer pain syndromes. The care given is fragmented, intermittent and disorganized. People have expressed their dissatisfaction and frustration with their providers. Some people have expressed that they have been helped by alternative treatments like acupuncture, therapeutic massage and chiropractic therapy. When these type of alternative treatments are not covered by insurance, access to pain and symptom management is still very limited.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) emphasizes a collaborative and interdisciplinary approach; individualized pain-control plans; assessment and frequent reassessment of patient, resident, or client pain; the use of both pharmacological and nonpharmacological strategies to alleviate pain; and the establishment of a formalized approach to pain management. This systemwide interdisciplinary approach has become known as "institutionalizing pain management". Ideally, it focuses on identifying and breaking down system barriers to effective pain management, while using several methods to incorporate the basic principles of pain management into patterns of daily practice.

The manuals published by JCAHO address health care organizations providing ambulatory care, behavioral health care, home care, hospice, hospital and long term care. The new "pain" standards are effective for surveys conducted after January 1, 2001.

The new standards address,

- Patient Rights and Organizational Ethics
- Assessments of Patients
- Care of Patients
- Education of Patients
- Continuum of Care
- Improving Organization Performance

Pharmacy Issues

Not all community pharmacies stock Schedule II drugs and many pharmacies do not have inventory sufficient to fill prescriptions. Patients often need to search for a pharmacy that is able to fill the prescription. Pharmacists are concerned about their licenses when dispensing controlled substances resulting in instances of refusal to fill prescriptions when they do not know the patients or providers.

For proper treatment patients must be able to obtain the prescription drugs necessary to manage and control their pain. Communication among physician, patient and pharmacist will assist the pharmacist in identifying the need for particular controlled substances. Pharmacies should be responsible for stocking adequate supplies of controlled substances or being able to redirect the patient to pharmacies within a reasonable distance to meet the needs of the communities they serve.

VII. PUBLIC POLICY SUBCOMMITTEE

This committee is responsible for making recommendations to the Department of Consumer and Industry Services, Department of Community Health and the legislature related to regulatory and reimbursement policy issues.

Making changes to a policy may or may not, by itself, result in appreciable changes in how practitioners, patients or the public perceive state policy. Policy change should be accompanied by a sustained commitment to dissemination and dialogue between healthcare professionals and policy makers.

Reimbursement Issues

It has been expressed in both the oral and written testimony that the coverage for treatment of pain is inadequate under commercial health care policies and Medicaid. The cost of medical care is high. People also feel that the providers avoid certain treatments if they know that the treatments are not covered by insurance. Insurance does not generally cover other alternative treatments like acupuncture, therapeutic massage therapy, chiropractic therapy and experimental procedures.

Public Acts 424, 425 and 426 of 1998, amended effective April 1, 1999 require insurers, health maintenance organizations and health care corporations to provide specific information to consumers pertaining to coverage and participation of health care professionals who are certified in the specialty of pain medicine and the evaluation and treatment of intractable pain.

Regulatory Issues

Some of the concerns expressed by people in their testimonies were:

Physicians prescribing less potent pain medication because of resistance to becoming licensed to prescribe under Michigan's Official Prescription Program; resistance to prescribe Schedule II drugs for fear of being tracked down by Government; 5 day rule for filling Schedule II prescriptions and the time to fill a narcotic prescription; 72 hour rule for completing partially filled prescription; requirement that for certain prescriptions the patient has to get a new prescription every 30 days making it difficult for the patients because of their physical condition at the time the prescription needs to be rewritten.

Pain cannot be proved or disproved, and health care professionals are fearful of being fooled by the patient who wishes to lie about pain. Although accepting and responding to the report of pain may result in giving analgesics to some patients who do not have pain, it is far more important that everyone who does have pain receives an attentive response. Many studies³ have shown that failure to assess pain or the existence of differences between the clinicians' pain ratings and those of patients is a major cause of unrelieved pain.

For decades the dangers of opioid analgesics have received far more attention than their benefits. Opioids have a reputation for being very dangerous drugs that have the capacity to kill or change a person into an out-of-control addict. Although these are risks associated with the use of opioids, evidence is overwhelming that clinicians' fears of these events are greatly exaggerated. An effective method of clarifying the role of opioids in chronic noncancer pain are guidelines and policies issued by the Federation of State Medical Boards. Alabama, Florida, Kansas, Nebraska, Nevada, Pennsylvania, South

³ e.g., Grossman, Sheidler, Swedeen et al., 1991; Von Roenn, Cleeland, Gonin et al; Correlation of patient and caregiver ratings of cancer pain, J Pain Symptom Manage 6:53-57, 1991

Carolina, Utah have adopted the "Model guidelines for the Use of Controlled Substances for the Treatment of Pain" in full and some states like Arizona, Louisiana, Maine, New Hampshire, New York, Oklahoma and Tennessee have adopted them in part.

Federal and State regulations for prescribing controlled substances such as opioids were not intended to interfere with the prescribing of opioids for pain. Furthermore, Michigan does not have laws or regulations that consider use of opioids for pain to be illegitimate. The recently passed chronic pain legislation is designed to enhance the quality of care for pain and symptom management for Michigan citizens while reducing and removing roadblocks.

Michigan's Official Prescription Program (OPP) was designed to address the diversion of Schedule II drugs to the streets. There were reports of problems caused by prescribers, doctor shoppers and those who were fraudulently using forged prescriptions. OPP has three major components:

1. Printing and distribution of the official prescription forms for Schedule II drugs
2. Data Collection
3. Data Analysis

The OPP is overseen by the Controlled Substance Advisory Commission (CSAC) under the auspices of the Bureau of Health Services, Michigan Department of Consumer and Industry Services. CSAC has 20 members: 13 voting members from various professions and seven ex-officio (non-voting) members from various state agencies.

Data available to the committee suggest that diversion of Schedule II drugs is less than commonly assumed. The "chilling effect" of the OPP on appropriate prescribing has been cited by some physicians as why they do not choose to write prescriptions for Schedule II drugs for pain management. Concern for diversion needs to be balanced with the need for compassionate and adequate pain management.

VII. Recommendations:

1. Michigan Department of Consumer and Industry Services (MDCIS) should develop and implement a website on pain and symptom management for the following:

- A. Healthcare professionals:

The website should address the issues of state law and related administrative rules, education and continuing education, provider issues, pharmacy issues and links to professional associations and other resources on pain and symptom management (See Appendix A).

MDCIS should publish information about the website and access to the website in "Health Alert." MDCIS staff should be responsible for updating the website with information received from the advisory committee, from professional associations and newsletters.

- C. General public:

To increase the public awareness regarding pain management, the website should cover topics such as the definition of pain, causes of pain, frequently asked questions, current news concerning pain issues in Michigan and across the country, policy statements, bibliography and topics of interest. The website should be linked to other user-friendly pain and symptom management websites such as the American Pain Society, the International Association for the Study of Pain, the American Pain Foundation etc. The website should also have a "contact us" feature where the public can express their concerns related to pain and symptom management to the committee, department and legislature.

2. The legislature should amend all statutes to eliminate the use of the term "intractable pain." The term "intractable pain" should either be eliminated in these statutes or amended to read "pain," as appropriate.
3. MDCIS in consultation with the Department of Community Health shall develop, publish, and distribute an informational booklet on pain including acute pain, chronic pain and malignant pain, and the use of pharmaceuticals (including opioids and other controlled substances) as well as non-pharmacologic modalities for the control of pain and symptoms.
4. MDCIS should develop and publish brochures and prepare videos in consultation with the pain and symptom management advisory committee members for the benefit of patients/patient families and care givers regarding pain, the causes of pain, the emotional needs of the patients and their families, and treatment and health care coverage.
5. MDCIS should develop and disseminate guidelines similar to the Joint Commission on Accreditation of Healthcare Organizations requirements for "pain standards" as the standard of care for all health providers, in collaboration with the licensing boards and their respective professional associations.
6. MDCIS should disseminate curricula developed by or similar to the International Association for the Study of Pain (IASP) model core curricula regarding pain and symptom management to the Michigan institutions that provide health care education and continuing education, and should integrate pain and symptom management into the customary practice of health care.

7. The State legislature should establish a grant program to facilitate the integration and implementation of the model curricula into appropriate educational programs in Michigan institutions so as to encourage Michigan institutions educating health professionals to implement the model core curricula. The impact of implementing model core curricula in pain management can be further evaluated and reassessed to determine the effectiveness.
8. MDCIS should formulate the language for an administrative rule through the respective boards to address continuing education as a condition for license renewal of health professionals in support of the existing statute (333.16204) regarding pain and symptom management. Continuing medical education in pain and symptom management for health care professionals shall be for a minimum of 1 hour per licensing cycle and include materials on indications and use of controlled substances.
9. MDCIS should encourage the hospitals to increase the medical and nursing staff's knowledge by providing the guidelines for the required curricula in pain and symptom management to be covered through their organized educational programs.
10. MDCIS should encourage professional associations to address education and training in pain and symptom management for those health professionals who are not required by the statute to have continuing education to assure that all health professionals maintain a current understanding of pain and symptom management.
11. MDCIS should establish guidelines similar to the "Model guidelines for the use of controlled substances for the treatment of pain" (See Appendix B) published by the Federation of State Medical Boards of the United States (FSMB), in collaboration with the licensing boards and their respective professional associations.
12. The state legislature should replace the current Official Prescription Program with a simplified electronic monitoring system to balance availability of safe and effective drugs for pain and symptom management and deter the diversion of prescription drugs for illegitimate use. The new system should be an on-line interactive system that will be able to provide data sets for providers.

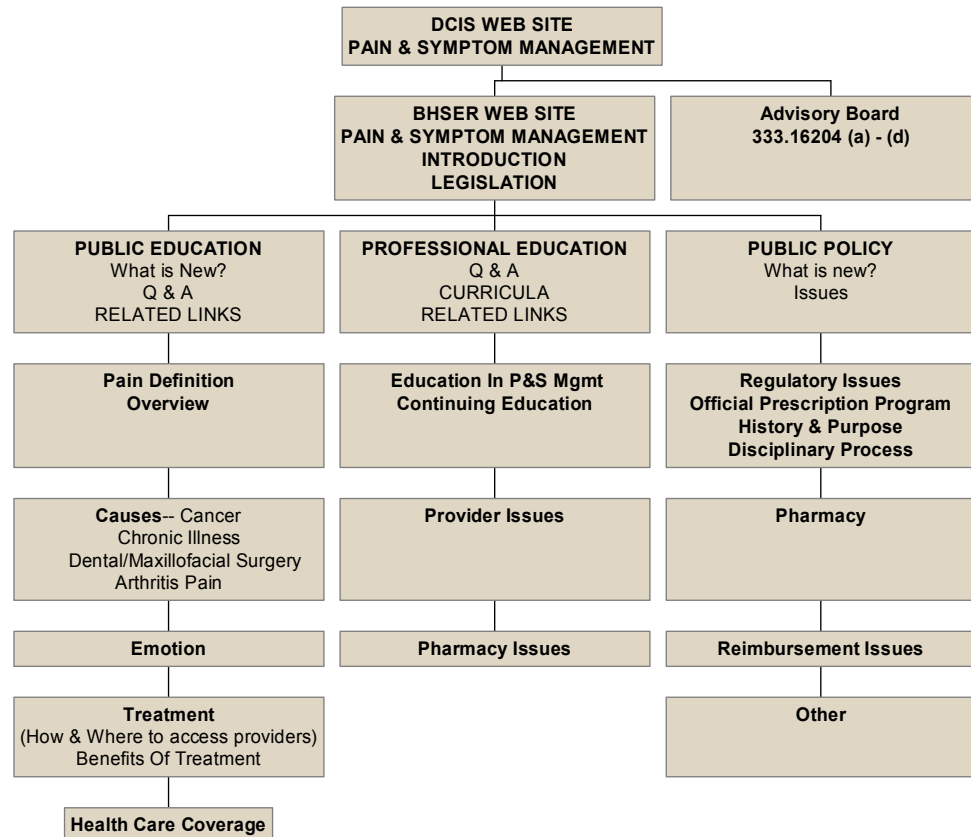
Until such a system is in place, MDCIS should educate health professionals about Michigan's Official Prescription Program with an emphasis on the intent to facilitate appropriate care and give providers access to information regarding patient drug use patterns.
13. The Public Policy Subcommittee supports the Commission on End of Life Care's recommendation that the State Legislature should amend the Policy on Patient and Resident Rights and Responsibilities (MCL 333.20201(2)) to add a new subsection to the effect that patients have the right to adequate pain and symptom management as an essential element of medical treatment, and to be informed of that right.
14. MDCIS should promote Health Maintenance Organizations, Medicaid, Medicare and other insurers to provide access to and coverage for the care provided or recommended by a multidisciplinary team including alternative therapies and procedures such as acupuncture, behavioral management, therapeutic massage and musculoskeletal manipulation/treatment.
15. MDCIS should encourage pharmacies within communities or among pharmacy chains to share information and carry an adequate supply of Schedule II medications to meet the needs of the patients/communities by ensuring that pharmacies are aware of supply and demand issues.

16. MDCIS should promulgate rules that require pharmacies to assist patients in finding adequate supplies of medications within a reasonable time when the pharmacy is unable to fill a valid prescription as presented.
17. The state legislature, MDCIS and MDCH should work to minimize the state regulatory impediments to access to effective pain medications under Schedule II to assure appropriate care in pain management. These include:
 - a. Lengthening the time limit for filling prescriptions from five (5) days to 90 days
 - b. Lengthening the period from 72 hours to 14 days for completely filling a prescription that is only partially filled
18. MDCIS and the practice boards should adopt and publicize statements of principle that undertreatment of pain is as serious an offense as any other inappropriate treatment of pain under the practice acts applicable to physicians, dentists, nurses, and pharmacists. This is consistent with the grounds for violation under the Michigan public health code 333.16221.

STATE OF MICHIGAN

MICHIGAN DEPARTMENT OF CONSUMER & INDUSTRY SERVICES

PAIN & SYMPTOM MANAGEMENT



Model Guidelines for the Use of Controlled Substances for the Treatment of
Pain
(Federation of State Medical Boards of the United States)

Position Paper on Prescribing Guidelines for the
Use of Opioids in the Management of Intractable, Non-Cancer Pain
(Michigan Osteopathic Association)

Model Guidelines for the Use of Controlled Substances for the Treatment of Pain

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 1998.

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute¹ and cancer-related pain.² The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. *Clinical Practice Guideline*. AHCPR Publication

Appendix B

No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

1. 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 Resources, Public Health Service. March 1994.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

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2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may

require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records

The physician should keep accurate and complete records to include

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction

Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

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Analgesic Tolerance

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain

A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain

An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction

Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse

Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.



**Michigan Osteopathic Association
Service Corp**

**Position Paper on Prescribing Guidelines for the Use of Opioids in the
Management of Intractable, Non-Cancer Pain**

The last several years have seen tremendous interest on the part of patients, third party providers, the federal and state governments and licensing organizations, and physicians of all specialties in the areas of pain medicine and the management of the patient with pain. Since the publication in 1992 of the Agency for Health Care Policy and Research's clinical practice guideline, Clinical Practice Guideline for Acute Pain Management: Operative or Medical Procedures and Trauma, enormous attention has been paid to an historically neglected, poorly understood, and inadequately treated area of primary importance in health care, the alleviation and attenuation of pain.

This document reflects the philosophy that physicians have an obligation to treat patients with intractable pain and to lessen suffering and that opioids may be appropriately and safely prescribed for many pain conditions as long as acceptable protocols and standards are closely followed.

The discipline of pain medicine has produced a new awareness about the necessity of proper diagnosis, history and physical examination, and treatment planning for the patient with intractable pain. Unfortunately, the paucity of specially trained physicians in the field of pain management often precludes patient access to specialized pain treatment facilities. The treatment for these patients will appropriately fall within the realm of the primary care or specialty physician. Until adequate guidelines are made for prescribers of opioids for patients with intractable non-cancer pain, episodes of undertreatment of this deserving population will continue.

In 1994, following the tremendous reception of the Acute Pain Guidelines, the second practice guidelines, The Management of Cancer Pain were published: In both acute and cancer pain, the primary treatment has historically utilized the use of opioids and other analgesic regimens, both pharmacological and procedural. The non-disputed use of opioid analgesics in these states has led to much discussion and research for their role in non-cancer pain. Many studies have shown the efficacy of opioids in intractable non-cancer pain, but because of legal, educational, social and historic reasons, their use has been less well received. As a result, many physicians have a reluctance to use opioid analgesics on a chronic

basis. This stems partly because of the paucity of proper education and training about these medications at the undergraduate and graduate medical levels: Unfortunately, associated with the adequate use of these medications are unfounded myths of addiction and abuse-conditions which, when they do occur are exceedingly rare. However, it is not only physicians, but also patients, other members of the health care team (pharmacists, nurses, et, al), and family and friends of patients who have trepidation about using these highly effective agents because of these same unfounded reservations. When physicians do attempt to overcome some of these barriers surrounding their use, there is tremendous fear about the legal and regulatory oversight issues involved in the proper documentation and prescription of these highly regulated medications.

In the last two to three years, multiple states have studied the use of these agents in the difficult intractable pain patient, hoping to develop documents that provide assistance to physician who make efforts to treat this deserving but under treated population of sufferers. Attention from the national media, the judicial system, and state/federal regulatory agencies has caused the topic of chronic opioid use in non-cancer intractable pain states to be hotly contested and debated at various levels with our health care and legal systems. Recently, there have been several bills proposed in our state's legislature defining standard of care concerning the use of opioids in intractable benign pain conditions. The establishment of practice parameters and standard of care issues should remain the responsibility of the medical profession not the legislature.

The following guidelines are not intended to be interpreted as an absolute standard of care, but are intended to provide assistance and guidance in the treatment of the intractable pain, patient when opioid analgesics are considered in the therapeutic management. Hence, these guidelines emphasize the importance of proper pain related history, past medical history, physical examination of the patient, and formulation and documentation of the differential diagnosis and treatment plan. Additionally, the guidelines stress the importance of compliance on the part of the patient and physician, as well as mechanisms whereby compliance can be observed.

The guidelines provide physicians of all specialties and backgrounds the basic information upon which confidence and protection can be provided such that, similar to the patient with cancer or acute pain, opioids can be used properly and safely, and without untoward fears of legal repercussion, in the huge population of chronic pain sufferers.

While the guidelines are fairly specific in content, the intent is to provide a fluid document which serves not as a definitive practice standard, but as a flexible, dynamic document that provides the practitioner with a template for the logical and safe medical practice when prescribing opioids to the intractable pain patient. It is anticipated that as attitudes and experience change that the guidelines will be similarly updated.

The following guidelines are proposed with the hope that they will attenuate fears about professional discipline, encourage adequate and proper treatment of intractable pain with all

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appropriate therapies, and educate about and protect patients as well as the general public from unsafe or inappropriate prescribing patterns or abuses.



**Michigan Osteopathic Association
Service Corp**

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**Prescribing Guidelines for the Use of Opioids in the
Management of Intractable, Non-Cancer Pain**

Definitions: For the purpose of this document the following terms shall have the following definitions:

Acute pain is the normal, predicted physiological response to an adverse (noxious) chemical, thermal, or mechanical stimulus. Acute pain is generally time limited and is historically responsive to opioid therapy, among other therapies.

Addiction is a disease process involving use of opioid(s) wherein there is a loss of control, compulsive use, an continued use despite adverse social, physical, psychological, occupational; or economic consequences.

Intractable pain *is a state of pain in which the cause: could not be removed or otherwise treated; and which, in the generally accepted practice of allopathic or osteopathic medicine, no relief or cure of the cause of the pain was possible, or had been found after reasonable efforts including, but not limited to, evaluation by an attending physician and one or more other physicians who specialized in the treatment of the area, system, or organ of the body that was perceived to be the source of pain. *(As defined under House Bill 4681)

Physical dependence is a physiologic state of adaptation to a specific opioid(s) characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is a predictable sequel of regular, legitimate opioid or benzodiazepine use, and does not equate with addiction.

Substance abuse is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

Tolerance is a state resulting from regular use of opioid(s) in which an increased dose of the substance is needed to produce the desired effect.. Tolerance may be a predictable sequelae of opiate use and does not imply addiction.

Withdrawal syndrome is a specific constellation of signs and symptoms due to the abrupt cessation of, or reduction in, a regularly administered dose of opioid(s). Opioid withdrawal is characterized by three or more of the following symptoms that develop within hours to several days after abrupt cessation of the substance: (a) dysphoric mood, (b) nausea and vomiting, (c) muscle aches and abdominal cramps, (d) Lacrimation or rhinorrhea, (e) pupillary dilation, piloerection, or sweating, (f) diarrhea, (g) yawning, (h) fever, (I) insomnia.

I. Assessment, Documentation, and Treatment

A. **Pain History:** The physician must have on record a complete pain history of the patient prior to the initiation of opioids. At a minimum the medical record must contain legible documentation of the following history from the chronic pain patient:

- 1a. Current and past medical, surgical, and pain history including any past interventions and treatments for the particular pain condition being treated.
- 2a. Psychiatric history and current treatment.
- 3a. History of substance abuse and treatment.
- 4a. Social/work history
- 5a. Documentation of current and prior medication management for the pain condition, including types of pain medications, frequency with which medications are/were taken, history of prescribers (if possible), reactions to medications and reasons for failure of medications.
- 6a. Review of appropriate diagnostic testing.

B. Pertinent Examination

- 1b. Limited regional exam pertinent to chief complaint

C. Diagnosis

- 1c. A justification for initiation and maintenance of opioid therapy.

D. Treatment Plan

1d. Types of medication(s) prescribed, dose, schedule administered and quantity.

II. **Informed Consent and Written Agreement for Opioid Treatment:** There shall be written documentation of both physician and patient responsibilities *documentation may include but not limited to:***

A. Risks and complications associated with treatment using opioids

B. Use of a single prescriber or clinic for all opioid pain related medications

C. Use of a single pharmacy, if possible

D. Monitoring compliance of treatment:

1d. Urine/serum medication screening (including checks for nonprescribed medications/substances) when requested.

2d. Number and frequency of opioid prescription refills.

3d. Reason(s) for which opioid therapy may be discontinued .(e.g. violation of written agreement item(s)).

III. **Periodic Review:** These reviews may include but are not limited to:

A. Efficacy of Treatment

1a. Social functioning and changes therein due to opioid therapy.

2a. Activities of daily living and changes therein due to opioid therapy.

3a. Adequacy of pain control using a pain rating scale(s) or statements of the patient's satisfaction with the degree of pain control.

B. Pertinent physical exam

C. Medication side effects.

D. Review of the diagnosis and treatment plan

E. Assessment of compliance (e.g. counting pills, keeping, record of number of medication refills, frequency of refills, and disposal of unused medication/prescriptions, indicated laboratory testing)

III. Consultation as needed

Consultation with a specialist in pain medicine or with a psychologist may be warranted, depending on the expertise of the practitioner and the complexity of the presenting problem. The management of pain in patients with a history of addiction or a co-morbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids. Consultations should be documented.

**Examples are attached for your review.

Amendments made to P.A. 421 of 1998 from P.A. 232 of 1994:

Committee's name: From **interdisciplinary advisory committee to advisory committee**

Committee's membership:

Old: The committee consisted on 18 members, appointed from each health professional licensing board, the board of examiners in Social Work and the Task Force on Physician's Assistants. Excluded were the boards of Veterinary Medicine and Sanitarians. The committee also included a representative of the Department of Community Health and was chaired by the designee of the director of the Department of Consumer & Industry Services.

New:

- (a) The committee consists of The Michigan Board of Medicine and the Michigan Board of Osteopathic Medicine & Surgery appoint 2 members, 1 of whom is a physician specializing in primary care and 1 of whom is a physician certified in the specialty of pain medicine by 1 or more national professional organizations approved by the department of Consumer & Industry Services, including, but not limited to, the American board of medical specialists or the American board of pain medicine
- (b) One psychologist who is association with the education and training of psychology students, appointed by the Michigan Board of Psychology
- (c) One individual appointed by the governor who is representative of the general public
- (d) One registered professional nurse with training in the treatment of intractable pain who is associated with the education and training of nursing students, appointed by the Michigan Board of Nursing
- (e) One dentist with training in the treatment of intractable pain who is associated with the education and training of dental students, appointed by the Michigan Board of Dentistry
- (f) One pharmacist with training in the treatment of intractable pain who is associated with the education and training of pharmacy students appointed by the Michigan Board of Pharmacy
- (g) One individual appointed by the governor who represents Michigan hospice organization
- (h) One representative from each of the state's medical schools, appointed by the governor
- (i) One individual appointed by the governor who has been diagnosed a chronic pain sufferer
- (j) One physician's assistant with training in the treatment of intractable pain appointed by the Michigan task force on physician's assistants
- (k) The director of the Department of Consumer & Industry Services or his or her designee, who shall serve as the chairperson
- (l) The director of the Department of Community Health or his or her designee.

Revision of committee's duties:

Note: Most of the duties have remained the same.

Appendix C

Deleted from old:

Develop written materials explaining pain and symptom management and hospice care for distribution to health care professionals, health care payment and benefits plans and the public.

Replaced from old:

1. **Old:** Provide a forum open to all health care professions and hospices in developing an integrated approach to pain and symptom management.

New: Annually consult with all of the Public Health Code boards and the board of Social Workers to develop an integrated approach to understanding and applying pain and symptom management techniques.

2. **Old:** Report activities and recommendations to the legislature.

New: Annually report on the activities of the advisory committee and make recommendations on the following issues to the Director of the Department of Consumer & Industry Services and the Director of the Department of Community Health

- a. Pain management educational curricula & CE requirements of institutions providing health care education
- b. Information about the impact and effectiveness of previous recommendations, if any, that have been implemented, but not limited to, recommendations made under recommendation.. integrating pain and symptom management into the customary practice of health care professionals and identifying the role and responsibilities of the various health professionals in pain and symptom management.
- c. Activities undertaken by the advisory committee in complying with the duties imposed under model core curriculum development and implementation; integrating pain and symptom management into the customary practice of health care professionals and identifying the role and responsibilities of the various health professionals in pain and symptom management.

New duties added:

1. Beginning in January of the first year after the effective date, annually review any changes occurring in pain and symptom management.

Review of Guidelines

In making recommendations and developing written materials, the advisory committee shall review guidelines on pain and symptom management issued by the United States Department of Health and Human Services.

Appendix C

Definition of "Intractable Pain"

Intractable pain means a pain state in which the cause of the pain cannot be removed or otherwise treated and which, in the generally accepted practice of allopathic or osteopathic medicine, no relief of the cause of the pain or cure of the cause of the pain is possible or none has been found after reasonable efforts, including, but not limited to, evaluation by the attending physician and by 1 or more other physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

Advisory Committee on Pain and Symptom Management

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A Listing of Recommendations from the first legislative report of the interdisciplinary advisory committee 1994-95 and the current advisory committee on Pain and Symptom Management (P&SM), 1999-2001.

Recommendations regarding	Interdisciplinary advisory committee (1994-95)	Advisory Committee (June 2001)
The Official Prescription Program	<p>1. Any physician treating a patient suffering from intractable pain in Michigan should feel free to prescribe Schedule 2 controlled substances where such treatment is medically necessary to control the patient's pain. No physician licensed in this state need fear administrative action for rendering medically necessary pain control treatment through use of Schedule 2 controlled substances as long as such necessity is properly diagnosed and documented.</p> <p>2. Physician should be educated about the scope and purpose of the Official Prescription program as a tool to enforce drug control laws and prevent diversion.</p>	<p>1. The state legislature should replace the current Official Prescription Program (OPP) with a simplified electronic monitoring system to balance availability of safe and effective drugs for Pain and Symptom Management and deter the diversion of prescription drugs for illegitimate use. The new system should be an on-line interactive system that will be able to provide data sets for providers.</p> <p>Until such a system is in place, MDCIS should educate health professionals about Michigan's Official Prescription Program (OPP) with an emphasis on the intent to facilitate appropriate care and give providers access to information regarding patient drug use patterns.</p> <p>2. MDCIS should establish guidelines similar to the "Model guidelines for the use of controlled substances for the treatment of pain" published by the Federation of State Medical Boards of the United States (FSMB), in collaboration with the licensing boards and their respective professional associations.</p>
Prescription Filling in Community Pharmacies.	<p>An integral part of pain management is ensuring that patients with intractable pain are able to obtain the prescription drugs necessary to manage and control their pain. Community pharmacies are encouraged to do their part to serve this segment of the population. Communications between physician, patient and pharmacist will assist the pharmacist in identifying the need for particular controlled substances. Pharmacies must be held accountable for controlled substances they stock, however this accountability should not be used as a barrier to stocking controlled substances.</p>	<p>1. MDCIS should encourage pharmacies within communities or among pharmacy chains to share information and carry an adequate supply of Schedule II medications to meet the needs of the patients/communities by ensuring that pharmacies are aware of supply and demand issues.</p> <p>2. MDCIS should promulgate rules that require pharmacies to assist patients in finding adequate supplies of medications within a reasonable time when the pharmacy is unable to fill a valid prescription as presented.</p> <p>3. The state legislature, MDCIS and MDCH should work to minimize the state regulatory impediments to access to effective pain medications under Schedule II to assure appropriate care in pain management. These include:</p> <ul style="list-style-type: none"> a. Lengthening the time limit for filling prescriptions from five (5) days to ninety (90) days b. Lengthening the period from 72 hours to 14 days for completely filling a prescription that is only partially filled
The Primary Care Physician - Specialist Relationship	<p>Primary care physicians should be educated in the treatment of intractable pain in patients and the maintenance of patients on pain management programs designed by pain specialists upon referral. This education should stress the importance of referral back to the primary care physician from the pain management specialist for patient pain management maintenance.</p>	

A Listing of Recommendations from the first legislative report of the interdisciplinary advisory committee 1994-95 and the current advisory committee on Pain and Symptom Management (P&SM), 1999-2001.

Recommendations regarding	Interdisciplinary advisory committee (1994-95)	Advisory Committee (June 2001)
Role of Non-Drug Related Therapies in Pain Management	Primary care physicians should be educated in the non-medical treatment modalities of intractable pain in patients and the referral of patients to specialists in these disciplines. This education should stress when to refer and the appropriate discipline for the referral.	
Reimbursement for Pain management services	<p>1. Because the development of a pain management drug regimen can vary significantly for each patient, third party payers who reimburse on a DRG (diagnostic related group) system should allow longer lengths of stay in hospitals for acute pain control. DRG reimbursement practices should recognize the need for variable lengths of stay for patients receiving pain management services.</p> <p>2. Third party payers, including Medicaid, should recognize the importance of non-drug therapies, such as occupational therapy and social services, as adjuncts for pain management that improve the patient's quality of life. Third party payers and Medicaid should authorize payment of these services as necessary for appropriate pain management.</p> <p>3. Third party payers should authorize direct payment for pain management services provided in a setting other than a home health agency or other licensed or certified health care facility by non-physician providers.</p>	1. MDCIS should promote Health Maintenance Organizations, Medicaid, Medicare and other insurers to provide access to and coverage for the care provided or recommended by a multidisciplinary team including alternative therapies and procedures such as acupuncture, behavioral management, therapeutic massage and musculoskeletal manipulation/treatment.
Core Curricula	<p>1. Michigan educational centers for health professionals are encouraged to implement the core curriculum set forth by the International Association for the Study of Pain in its publication entitled Core Curriculum for Professional Education in Pain.</p> <p>2. Michigan educational centers for health professionals are encouraged to supplement the core curriculum recommended above with instruction on state law and related administrative rules, specifically with regard to the OPP, and federal law and related regulations, specifically with regard to the role of the Drug Enforcement Agency. Students should come away from this instruction with an understanding of how these agencies work in conjunction with</p>	<p>1. MDCIS should disseminate curricula developed by or similar to the International Association for the Study of Pain (IASP) model core curricula regarding pain and symptom management to the Michigan institutions that provide health care education and continuing education, and should integrate pain and symptom management into the customary practice of health care.</p> <p>2. The State legislature should establish a grant program to facilitate the integration and implementation of the model curricula into appropriate educational programs in Michigan institutions so as to encourage Michigan institutions educating health professionals to implement the model core curricula. The impact of implementing model core curricula in pain management can be further evaluated and reassessed to determine the effectiveness.</p>

A Listing of Recommendations from the first legislative report of the interdisciplinary advisory committee 1994-95 and the current advisory committee on Pain and Symptom Management (P&SM), 1999-2001.

Recommendations regarding	Interdisciplinary advisory committee (1994-95)	Advisory Committee (June 2001)
	health professionals, and how these laws and regulations affect them as health professionals.	
Continuing Education	<p>1. Group I: Medical, Osteopathic, Podiatric physicians, Physician’s Assistants, Nurses and Pharmacists; Recommended hours of course work: 2 hours per year. Course work should address proper diagnosis including pain assessment techniques, treatment, and maintenance of intractable pain to avoid over treating and under-treating patients. Treatment course work should include pharmacological, physical, invasive and psycho/social interventions. Course work should further include an ongoing update of the role of the various, non medical disciplines in pain and symptom management, and provide guidance as to when a referral to a specialist in one or more of these fields is appropriate.</p> <p>2. Group II: Dentists, Optometrists and Chiropractors: Recommended hours of course work: 1 hour per year Course work should address diagnosis, within the limits of the specific scope of practice of each of these professions, and referral of patients with intractable pain for medical treatment. Course work should further include an ongoing update of the role of the various, non-medical disciplines in pain and symptom management, and provide guidance as to when a referral to a specialist in one or more of these fields is appropriate.</p> <p>3. Group III: Counselors, Psychologists, Social Workers, and Occupational and Physical Therapists No continuing education requirement is recommended for these disciplines, however health professionals within these categories are encouraged to voluntarily attend seminars concerning pain and symptom management.</p>	<p>1. MDCIS should formulate the language for an administrative rule through the respective boards to address continuing education as a condition for license renewal of health professionals in support of the existing statute (333.16204) regarding pain and symptom management. Continuing medical education in pain and symptom management for health care professionals shall be for a minimum of 1 hour per licensing cycle and include materials on indications and use of controlled substances.</p> <p>2. MDCIS should encourage the hospitals to increase the medical and nursing staff’s knowledge by providing the guidelines for the required curricula in pain and symptom management to be covered through their organized educational programs.</p> <p>3. MDCIS should encourage professional associations to address education and training in pain and symptom management for those health professionals who are not required by the statute to have continuing education to assure that all health professionals maintain a current understanding of pain and symptom management.</p>
Patient Rights		1. Supports the Commission on End of Life Care’s recommendation that the State legislature should amend the policy on Patient and Resident Rights and Responsibilities (MCL333.20201(2)) to add a new subsection to the effect that patients have the right to adequate P&SM as an essential element of medical treatment, and to be informed of that right.

A Listing of Recommendations from the first legislative report of the interdisciplinary advisory committee 1994-95 and the current advisory committee on Pain and Symptom Management (P&SM), 1999-2001.

Recommendations regarding	Interdisciplinary advisory committee (1994-95)	Advisory Committee (June 2001)
General Policy Issues		<p>1. The legislature should amend all statutes to eliminate the use of the term "intractable pain." The term "intractable pain" should either be eliminated in these statutes or amended to read "pain," as appropriate.</p> <p>2. MDCIS and the practice boards should adopt and publicize statements of principle that under-treatment of pain is as serious an offense as any other inappropriate treatment of pain under the practice acts applicable to physicians, dentists, nurses, and pharmacists. This is consistent with the grounds for violation under the Michigan public health code 333.16221.</p>

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