STATE OF CALIFORNIA

Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing

Summit Report

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July 29, 1994

To: All Participants of the Summit on Effective Pain Management

Re: Summit Report from the Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing

We are pleased to share with you the final Summit Report from the Summit on Effective Pain Management. This report was produced through the joint efforts of many summit participants, sponsors, and the summit planning committee. Although the report process took longer than we anticipated, we felt it was necessary and important to include input from all participants who provided excellent, thoughtful and feasible recommendations to address the issues and concerns brought to the table at the Summit.

Two important outcomes resulted from the Summit:

1) A productive, positive coalition has been created to focus attention and to direct actions to pain management problems and issues. This coalition of health care practitioners, professional and public educators, academicians, professional association representatives, pharmaceutical manufacturer representatives, health care consumers, pain patients, regulators and legislators is unique and unprecedented. The group now has an open communication channel with each other and critical sectors such as regulators, which can make the necessary changes to improve pain management.

2) Due tlo the Summit, many pain management activities have been undertaken and that is a major achievement. The Medical Board of California and the Board of Registered Nursing have adopted policies on pain management. The Board of Pharmacy is in the process of establishing a similar policy and has agreed to underwrite a feasibility study to implement an electronic monitoring system of controlled substances prescriptions by December 1, 1994.

The Summit has been an effective forum to exchange ideas and information, share solutions and take action. We thank all of you who took the time to give us your comments and input for the draft report. This Summit Report reflects the energy, interest and dedication that the participants demonstrated throughout the entire summit process.

Please feel free to contact Lowayne Shieh at 91 6-324-0794 or other members of the Summit Planning Committee (roster included in report) if you have questions or comments. For additional copies of the Summit Report, please call 916-445-7450 or fax your request to 916-322-2951.

With warm regards,

C Barnett interim Director

California Department of Consumer Affairs

Enclosure

SUMMIT ON EFFECTIVE PAIN MANAGEMENT:

REMOVING IMPEDIMENTS To APPROPRIATE PRESCRIBING

On March 18, 1994, the State of California sponsored a virtually unprecedented event-The Summit on Effective Pain Management: Removing impediments to Appropriate Prescribing.

More than 120 health care practitioners, professional and public educators, representatives of professional schools and associations, and health care consumers met to identify and recommend solutions to legal, professional, and educational barriers to effective pain management.

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EXECUTIVE SUMMARY

Many Californians suffer from acute pain associated with injury, illness, and surgery, as well as from chronic pain due to cancer, degenerative diseases and other conditions.. Unrelieved pain impedes recovery from surgery, injury, or illness; interferes with physical functioning and productivity; destroys the quality of life; and increases the use and cost of health care services.

However, the reality is that many effective treatments are available. Drug treatments include the opioid analgesics and other controlled substances that are the cornerstone of acute and cancer pain management and are also useful for carefully selected patients with chronic, noncancer pain. There are also nondrug treatments, including physical and psychological approaches, that are effective in pain management.

Many patients do not receive effective treatment. Pain is undertreated in our society for many reasons: the low priority given to pain management by our health care system; failure to diagnose pain properly; lack of awareness that much pain can be relieved; incomplete application of existing knowledge; exaggerated fears of addiction; and problems with government and private sector attitudes toward controlled substances, health care, and reimbursement. Pain is also more likely to be undertreated if the patient is minority, female, elderly, or a child.

Significant and widespread concern about the undertreatment of pain in California has united many diverse groups in the last several years. The Legislature, state agencies, associations of professionals, and concerned health care professionals have taken major steps toward effective pain management. The Governor, through the State and Consumer Services Agency, convened this Summit to examine why pain is undertreated in California and to initiate collaborative efforts to remove the impediments to appropriate pain management.

On March 18, 1994, more than 120 representatives from the health, education, legislative, regulatory, and public sectors examined the barriers to effective pain management. Participants made a number of recommendations that are detailed later in this report, including:

Inform patients that they are entitled to quality pain management and should have informed consent on the choice of treatment plans for their pain.

Establish accountability in the health care system for the assessment and management of pain. Examine the extent to which inadequately or improperly managed pain leads to additional health care costs, including lack of recovery, slower recovery, and unnecessary and extended hospitalization.

Have regulatory boards adopt policies that foster appropriate use of controlled substances in pain management. Include questions about pain on licensing examinations for health care professionals.

Revise laws and regulations that: impede timely access to pain medications by patients; contain confusing standards such as "excessive prescribing;' and appear to ban prescribing controlled substances to patients in pain with a history of drug abuse.

Replace the triplicate prescription system with an electronic prescription monitoring system as soon as possible.

Develop clear standards for evaluating and investigating inappropriate prescribing methods.

Promote ongoing communication among regulators, health care practitioners, and law enforcement agencies involved in monitoring or investigating prescription medication.

Improve peer review of pain management and general prescribing practices.

Ensure that all patients-receive adequate pain treatment regardless of age, race, gender, ethnicity, or medical condition.

Assure that health care coverage includes pain 'management services and medications. Work with California's Insurance Commissioner and others, including third party payors, Medi-Cal, and MediCare, to examine and remove impediments to: reimbursement for pain medications; pain assessment; and appropriate consultation and treatment, including exclusion or limitation on conditions covered or amount of medication covered.

Develop a more active role for pain medication manufacturers, including better, more readable drug information, consumer bulletins, and telephone services.

Accelerate the education of the public, patients, regulators, and health care professionals about pain management.

OVERVIEW OF PUBLIC POLICY ISSUES

The Summit helped to identify public policy issues relating to the management and treatment of chronic pain within California's health care, regulatory, and law enforcement environment:

1. California citizens experience significant undertreatment of acute,cancer-related pain, postoperative pain or other pain, including chronic, nonmalignant pain.

2. There are many important nonpharmacologic methods for treating pain, but controlled substances, including opioids, play a critical role in pain management. Regulatory mechanisms must strike a balance between providing timely access to morphine and other Schedule 11 controlled medications that relieve chronic intractable pain, while preventing diversion of those medications for nontherapeutic uses.

Currently, there are both government and private sector impediments to patients receiving sufficient, timely, and appropriate treatment. There is also a persistent problem with diversion of some controlled substances from legitimate channels. And at least some current regulatory practices are not achieving their purposes.

3. A coalition has emerged that believes that all patients have a right to adequate pain management and should participate in decisions regarding the treatment and management of their pain. However, it is not yet current practice for all health care providers, in all health care settings within the State, to actively involve patients and their caregivers in deciding the course of pain management treatment, whether by medication or nonmedication techniques.

4. Patients and their caregivers, health care professionals, and government agencies lack up-to-date knowledge regarding pain management and appropriate use of controlled.substances.

IMPEDIMENTS To APPROPRIATE PRESCRIBING

Pain Assessment

Lack of recognition of patient rights and professional responsibilities.

Lack of interdisciplinary assessment.

Failure to use simple, standard assessment techniques already available.

Development of Treatment Plans

Low priority of pain management in the health care system.

Financial disincentives by payors.

Fear of regulatory intrusion.

Prescribing Pain Medication

Outdated triplicate prescription system.

Unwarranted fears of addiction and side effects.

Inadequate use of allied health professionals in long-term care and hospice settings.

Failure to serve the underserved population adequately, such as rural or inner city patients.

Administration of Pain Treatment to the Patient

· Regulatory delays in the delivery of medication to patients.

· Payor restrictions on payment for pain-related services.

· Limited patient and professional knowledge about pain management techniques.

· Incomplete planning for discharging patients.

Ongoing Evaluation

Infrequent dialogue between patients and their health care providers.

Diversion of Pain Medication to Nontherapeutic Uses

Inability to analyze and use information captured by regulatory and investigative agencies.

IMPEDIMENTS To APPROPRIATE PRESCRIBING

Summit participants addressed the significant undertreatment of acute, cancer related and other pain, including chronic, nonmalignant pain. Participants recognized that every person or entity that is involved in providing care or that regulates health care practitioners must acknowledge that patients have the right to receive and participate in appropriate pain management.

A variety of regulatory and nonregulatory factors may impede effective pain management. These factors are arranged in sections that roughly parallel the delivery of pain care to patients.

Impediments to Pain Assessment

Patients, their family members, and allied health care professionals assess and report pain. However, patients are often unaware of their rights and responsibilities regarding pain management, including that pain can usually be treated and doesn't have to be the "price" of illness or disease.

Many chronic-pain patients believe that health care providers often presume to know how much pain their patients experience, don't really believe what their patients say, or are not as interested in treating the pain as they are in treating the disease. Patients report pain but often are not provided with universal tools such as pain assessment questionnaires or methodologies that provide physicians with feedback to appropriately manage treatment.

Nurses, pharmacists, and others in the patient-care chain are critical to the management of pain, including proper administration of pain medication, reporting changes in the tolerance to medication, and triggering timely followup assessment. This interdisciplinary, ongoing pain assessment is critical but is often weakened by caregivers, professionals, and nonprofessionals alike, who are not familiar with their role in pain management.

Impediments to Development of Treatment Plans

Pain management is a low priority in the health care system. Medication and nonmedication approaches to managing pain and its side effects are often afterthoughts in developing a patient's treatment plan because of outdated knowledge of and attitudes toward pain management, as well as an antiquated approach to prescribing controlled substances.

Financial disincentives by payors can needlessly limit and bias pain treatment. Insurance company managers and other personnel lack an understanding and acceptance of pain management which can result in: denial of coverage; lack of access to certain pain management procedures and medication; or use of more expensive and often less effective treatments.

Additionally, as long as physicians are fearful of regulatory intrusion, they will continue to undertreat pain. Fear of reprisal often overrides appropriate, aggressive use of drugs.

Impediments to Prescribing Pain Medication

The triplicate prescription system-which must be used when Schedule 11 controlled substances are prescribed-is outdated, impractical for many modern health care settings (especially long-term care), and generally ineffective for monitoring and controlling diversion of medications for nontherapeutic purposes. Because of the administrative complexities of and implied intimidation by the triplicate system, almost half of California's physicians have chosen not to seek prescribing privileges for Schedule 11 medications. This system of oversight is often viewed as persecution by physicians and pharmacists, and the result is that patients in pain suffer.

Unwarranted fears of opioid addiction and side effects still exist among practitioners, and especially among the public, patients, and their caregivers. As the Medical Board of California, in its statement 'Prescribing Controlled Substances for Pain,' concluded, minorities, women, children, the elderly, and people with HIV/AIDS are at particular risk for undertreatment of their pain.

State law implies that drug addicts should be treated differently for pain or not treated for pain at all. Laws and regulations are inflexible in addressing this population of patients.

Impediments to Administration of Pain Treatment

Summit participants gave many examples of how the triplicate prescription system also delays the delivery of medication to patients. First, over half of California physicians do not write triplicate prescriptions. Both prescribers and pharmacists find the triplicate form cumbersome and time-consuming to use and process. Even minor errors can invalidate the triplicate, requiring that the entire process be repeated.

Pharmacies experience a delay in the receipt of Schedule 11 opioids due to minor, inadvertent discrepancies on DEA form 222 that can compromise patient care. In emergency circumstances, the requirement that the distributors and manufacturers receive DEA Form 222 prior to the shipment of Schedule 11 drugs can result in patient hardship.

Third-party payors often restrict payment for pain-related services, especially for Medicare and Medi-Cal patients.

Patients' and caregivers' knowledge of pain management and the appropriate use of controlled substances and other pain management techniques is limited. Educational materials available to prescribing physicians for distribution to their patients are equally limited. This intensifies patient and caregiver misgivings and misunderstandings and complicates compliance and education issues.

When patients leave hospitals and are transported to other facilities, continuity of pain treatment is frequently ignored. Patients frequently do not receive an adequate supply of medication for effective pain management.

Impediments to Ongoing Evaluation

Pain management, whether drug or nondrug-based treatment, requires that patients and their health care providers discuss with each other the effectiveness of various treatment methods and dosage levels. Payors are often unwilling to reimburse health professionals for sufficient ongoing pain evaluation, and in some instances set artificial limits on the amount of drug and nondrug treatments, services, or both.

Diversion of Pain Medication to Nontherapeutic Uses

Participants recognized that drug diversion is a problem in California that must be controlled. Participants. validated the need for vigilance and oversight but stressed the importance of balancing that need with relieving the suffering of people in pain.

Regulators, health care professionals, and patients agree that the current regulatory structure fails to provide good data that can identify and reduce diversion.

There is limited ability to analyze information captured by the regulatory system in a timely manner and use it to control diversion.

SUMMIT RECOMMENDATIONS

Participants recognized that any solution to the problem of inadequate pain management requires the cooperative efforts of regulators, practitioners, patients, payors, and the public to educate themselves regarding the nature of pain, the extent of pain, and pain management itself.

Participants acknowledged that drug diversion is a problem in California which must be controlled. Participants discussed the nature and extent of statutes and regulation, and the regulatory and law enforcement activity that is necessary to control the problem without hampering medical care.

The following sections categorize the recommendations according to the groups that the summit participants believe are the best, most effective agents for change. Each section includes consensus recommendations, as well as other input that was received but to which not everyone agreed.

Recommendations for Legislators to Consider

Our legislators should provide continuing leadership for pain management by assessing the value of laws, regulations, and policies concerning the prescribing, dispensing, or administering of controlled substances. Legislators should strike a balance between the efficacy of identifying and controlling abuses, the scope of the problem, and interfering with legitimate medical care. The following legislative changes were recommended:

Replace the requirement for a special, state-issued prescription form (triplicate system) with electronic monitoring of controlled substances prescriptions that can foster better, more effective pain management and better diversion detection. Ensure that any such system is based on sound principles, such as those set out in the model Uniform Controlled Substances Act and in the report of the Controlled Substances Prescription Advisory Council. The Board of Pharmacy has agreed to underwrite the feasibility study to implement this recommendation, and the report will be due December 1, 1994.

Electronic monitoring must be able to track diversion of controlled substances by prescribers, pharmacists, and patients.

Until the triplicate system is replaced, reduce the burden on physicians, pharmacists and patients to avoid disrupting good pain control. For example, no triplicate should be needed if there is a written order in medical records of a licensed health care agency. Similarly telephone or faxed prescriptions should be accepted under certain circumstances.

Revise laws and regulations to reflect the current practices of those involved in pain management, especially in emerging health care settings. (increased costs of hospitalization have encouraged the use of nonhospital settings. Today we see greater reliance on skilled nursing facilities, long-term care facilities, and earlier release to home settings.)

Eliminate the apparent prohibition on prescribing controlled substances to those with a history of drug abuse. People in pain should receive effective treatment regardless of whether they have a dependency problem.

Clarify or eliminate confusing or outdated statutory provisions, including "clearly excessive prescribing or dispensing" of controlled substances and the use of the terms "addict" and "habitual user."

Evaluate mail-order restrictions on drugs, including limitations on the number of doses, and the impact of such restrictions on patient well-being.

Identify funding sources for the Food and Drug Section of the California Department of Health Services to eliminate delays in the evaluation of new drugs and devices.

Other Input for Legislators to Consider

Oklahoma and several other states have approved coordinated legislation and regulations that streamline the regulatory mechanism, yet provide good data with which to control possible diversion of medications. California can and should use these models as a starting point for improving the effectiveness of its regulatory mechanisms.

In long-term care, hospice care, and certain other health care settings, other health professionals are closer to patients than physicians. These health professionals should be considered for privileges to legally prescribe or regulate the dosage of controlled substances in response to a patient's daily medical condition.

Address issues of personal liability and prosecution for prescribing a Schedule II opioid for treatment of acute pain (i.e., postoperative), chronic intractable pain, or cancer pain to a patient with a known substance abuse history.

Ensure that individuals who are prescribed opioids for chronic pain are not denied employment or discharged solely based on drug screening that is used increasingly. as an employment screening tool.

Create, by statute, a positive legal duty to effectively treat pain and suffering, such as: Doctors (e.g., MD, DO, DIVID, DPM) have a duty to effectively treat the pain and suffering of a patient. Effective pain and suffering treatment is that provided by current clinical practice guidelines on pain management issued by the US Department of Health and Human Services, or that followed by clinicians who specialize in pain management. Doctors have a duty to effectively treat pain, including appropriate referral to and periodic review by clinicians who specialize in pain management.

Create a controlled substances credential for physicians that requires ongoing education in pain management and appropriate prescribing.

Legislate pain management education as a requirement for licensure.

Be careful what we legislate. Develop a standard that is issued and administered by boards, but one that is not too legislatively detailed that we might regret it later.

Incorporate the White House model on Electronic Data Transfer (EDT) programs.

Health care facilities should demonstrate a minimum standard of pain management by the end of 1996, using federal guidelines as reference standards.

Recommendations for Regulators to Consider

Develop and promote positive statements on pain management and the appropriate use of controlled substances by the medical, nursing, pharmacy, dental, podiatry, physician assistant and osteopathic boards, and the Department of Consumer Affairs. An example of such a statement is the draft policy statement circulated to Summit participants by the Medical Board of California on May 6, 1994 (see attachment). The Board of Registered Nursing has also adopted a pain management policy (see attachment).

When electronic monitoring is implemented, take into consideration the unique needs of specialty practices and pain patients. Some patients need high doses of opioids for extended periods.

Take into consideration that unusual prescribing practices are sometimes necessary to take care of patients in pain.

Develop and communicate to licensees clear standards for evaluation and investigation of inappropriate prescribing and dispensing. Avoid standards that rely on volume or duration of prescribing without taking into account the nature of the prescriber's practice and the condition for which a particular controlled substance is prescribed.

Ensure that government uses consultants and experts who are currently involved in either pain management or the licensee's field of practice.

Promote ongoing communication among regulators, practitioners, and legislators, so that all are sensitized to the impact of pain management laws and regulations. Likewise, maintain communication and cooperation among the various regulatory and law enforcement agencies involved in monitoring or investigating prescription controlled substances practices.

Ensure that neither laws and regulations nor health care facility policies interfere with the ability of patients, especially cancer patients who are discharged from one facility to another or from a facility to home care, to have an uninterrupted supply of adequate analgesics.

Include questions on pain management in health care professional licensure examinations and encourage revision of professional school curricula to include adequate coverage of pain management in Undergraduate and postgraduate training.

Simplify and clarify federal policy regarding the use of federal controlled substance order forms, including emergency transfer of controlled substances from a manufacturer or distributor to pharmacies which have run out of a controlled substance. Examine other federal provisions which govern emergency supplies of controlled substances. Clarify federal enforcement policy governing minor, inadvertent errors on controlled substance order forms.

There was a clear consensus at the Summit that professional education in pain management techniques and appropriate prescribing is a critical component of addressing these issues. There was not, however, consensus on whether this continuing education should be mandated by regulation or legislation. Other input on this topic included:

Legislation requiring physician education or competence in pain management will likely breed resentment and reduced effectiveness. A better strategy would be to encourage educational attempts to improve the skills of training and practicing physicians by engaging the profession in a positive program to find a solution that will improve the care of their patients.

This summit is a landmark for pain education and treatment. However, until state boards put their licensed members on notice that a lack of basic knowledge about pain, pain assessment, drugs, and treatment is not the standard of practice for patient care, little will change. Even federal guidelines have not had an impact. The state should mandate that all licensed members must demonstrate updated basic pain management skills by a set date - say 1996. There would be a vertical learning curve - which would result in less patient suffering, less pain related medical costs, less time spent time away from work, and savings for private and government payors.

Currently, medical professionals must acquire extensive, additional education to learn the multitude of regulatory statutes. This is a real disincentive to learn or change practice if that change increases liability. A teacher at an academic medical center can teach the clinical issues to students and practitioners, but they are 're-educated' by regulatory issues and concerns shared by practicing colleagues.

Just as real estate brokers and lawyers are required to have a course in ethics as part of their mandatory continuing education requirements, licensed health care professionals should have a mandatory course in effective pain management or a self-assessment test on pain management as part of their licensing requirements.

Other input on the triplicate system included:

Until the triplicate program is replaced, could the Bureau of Narcotic Enforcement send the triplicates preseparated and in larger quantities to prevent the need for monthly, half-yearly, or yearly prescriptions orders, which are not in a patient's best interest?

It is interesting that the only members of the participating panel who are in favor of triplicates are the lay members. It is difficult enough to obtain a sufficient supply of triplicates that are received in a timely manner and are reliable and reproducible. It takes more than four minutes to properly fill out a triplicate and most MDs cannot allow a patient to talk while the triplicate is being written for tear of making an error.

Other Input for Regulators to Consider

Phone authorization is not a solution in many cases. As a pharmacist who has worked in a community pharmacy, you do not know all the MDs who may call your pharmacy. As a pharmacist, you and your staff's safety is always in the back of your mind. If someone you do not know calls asking it you carry triplicate drugs, you say 'no.' It only takes looking down one shotgun barrel for you to tell a white lie. For phone authorization to work, it is imperative to educate MDs to talk with pharmacists in their area and let them know their prescribing patterns. If communication between MDs and pharmacists occurs, obtaining these medications in California will be much easier.

Long-term care, home health and hospice practitioners need authorization for an emergency controlled substances kit. A 72-hour supply of Schedule 11 drugs should be available for hospice, long-term care, and home health settings.

Nurse practitioners often serve as the most accessible primary care providers for people in California's rural communities. Eight states currently allow prescribing of controlled substances by nurse practitioners. Can California follow their lead?

I practice medicine in a large group, and my patients' records are typed and quite complete. When I am away, some of the patients for whom I care run out of medication and call one of my partners for a refill. The rule that there must be a "good faith' exam if more than 72 hours of pain medication are to be prescribed is a great imposition on my patients, who, by law must: 1) make an unnecessary and expensive trip to the physician; or 2) try to get by for however long it is until I return. This rule should be revised to at least encompass situations in which adequate records are available.

Reviews should be performed by those who have knowledge of and are sensitive to the practice setting being investigated. Reviewers should be practicing in the same medical area.

Require health care facilities to demonstrate minimum standards of pain management for licensure after 1996. U.S. Department of Health and Human Services Guidelines for Acute and Cancer Pain Management can be used as reference standards.

Recommendations for Consumers and Their Caregivers to Consider

Summit participants agreed that consumers will get changes in pain management when they demand them. They can't wait for physicians to provide those changes. For example, detection of breast and prostate cancer are areas where consumers have demanded and received changes in standard practice from their physicians.

Ensure that patients are informed of their rights, including the alternatives for pain management and treatment, and that they exercise informed consent. Ensure that every patient knows he or she is entitled to receive adequate treatment for pain and to have his or her reports of pain believed. Ensure that patients or their caregivers receive adequate consultation about drug therapy from the prescriber, dispenser, or other qualified health care professional.

Make use of the many consumer publications and groups, including those which target special groups such as minorities, women, children, and the elderly, to communicate rights to patients, their caregivers and the public.

Distribute the Agency for Health Care Policy and Research (AHCPR) patient guidelines to pharmacies and to other appropriate health care settings, including all cancer care facilities.

Ensure that misinformation based on race, ethnicity, gender, and age factors does not affect the treatment of pain.

Educate members of the media, including television, print, and radio about the importance of pain management as a part of the health care reform agenda.

The public and private sectors must work together to use consumer research to develop a campaign the public will accept.

Other Input for Consumers and Their Caregivers to Consider

The message of the war on drugs is adversely affecting public attitudes toward medical use of controlled substances. We need to recognize that substance abuse is primarily a medical, not a criminal, problem.

Recommendations for Health Care Professionals to Consider

Increase and improve the education of health care professionals, including: current standards of pain management, available tools to assess the nature and severity of pain, and patients as the best source of information about their pain.

Recognize that proper management of pain often includes both drug and nondrug therapy, and proper initial and ongoing assessments, including: (1) more individualized pain treatment that is based on a patient's report, presenting condition, and current and past physical, social, and psychological condition and treatment; (2) standardized questionnaires assessing the physical, psychological, social, and cultural factors affecting pain, administered by appropriately trained health care personnel; and (3) interdisciplinary involvement by doctors, nurses, pharmacists, psychotherapists, and others.

Better professional and ongoing education on adequate pain management is critical and must include:

· Education on patient rights to pain management and medication;

· Revision of professional school curricula to include adequate coverage of pain management issues in undergraduate and postgraduate training;

· Offering enough continuing education programs that address the issues of physicians whose knowledge is dated; and

· Education on nondrug pain management techniques beyond medication.

A number of comments argued for mandating pain management education, but Summit participants did not come to a consensus on whether mandates were the most appropriate way to motivate physicians and other health care professionals.

Recommendations for Payors to Consider

Summit participants generally agreed that pain management is given a very low priority by payors. The comment that best reflects the discussion is "they think they [payors] are saving money, but they're not."

Payors should assess the total cost of leaving their patients in pain. They should update their policies, standards, and guidelines for reimbursement to reflect that effectively managed pain can return patients to active, productive lives. Such assessment and change can result in lower total health care costs.

Work with California's Insurance Commissioner and others, including both public and private third party payors, to examine ways to remove impediments to reimbursement for pain medications, pain assessment, appropriate consultation, and treatment, including exclusions of or limitations on conditions covered or amounts of drugs covered.

Examine the extent to which inadequately or improperly managed pain leads to additional health care costs, including lack of recovery, slower recovery, unnecessary hospitalization and extended hospitalization.

The State Insurance Commissioner should begin a dialogue with payors who do business in California to initiate the studies recommended above to assess whether payors' pain management practices require regulation.

Other Input for Payors to Consider

Payors impose more prior approval requirements for pain management than for other procedures.

Measure the outcome of patients treated for intractable pain through the increased use of Health Assessment Questionnaires (HAOs). Many authorities (e.g., J.F. Fries, T. Pincus, etc.) have shown that these instruments are accurate, reproducible and statistically superior to many more commonly used medical tests. Unfortunately the insurance industry, which will pay for Magnetic Resonance Imaging (MRI), will not pay for the administering and grading HAQs.

Many comments mentioned unreasonable and clinically counterproductive Medicare guidelines for reimbursement of pain management visits and medications. One example is:

Medi-Cal patients are subject to limited reimbursement of narcotics, and these limits must be addressed. I have had limited income Medi-Cal patients who are forced to choose between buying pain agents and other necessities. For example, reimbursement is limited to acetaminophen and aspirin with codeine.

Recommendations for Law Enforcement Agencies, including the Enforcement Divisions of Regulatory Bodies, to Consider

Publish and circulate the enforcement philosophy and state board guidelines (such as those recently issued by the Medical Board of California) to reduce fear of inappropriate punishment among ethical members of the medical community and to increase fear of discipline or arrest among those diverting narcotics for nontherapeutic uses.

Other Input for Law Enforcement Agencies, Including the Enforcement Divisions of Regulatory Bodies, to Consider

Punish only those who really need punishment. Read and enforce the spirit of the law, rather than fostering fear of the letter of the law.

Experts in pain management must communicate with regulators and law enforcement professionals to curb abuses.

Diversion may not be as big a problem as many think. A pharmacist in a San Diego hospital once estimated that the legal supplies of all opioids in the pharmacies in San Diego would not supply San Diego street addicts for twenty four hours.

Ongoing, mandatory interagency cooperation is essential.

Recommendations for Manufacturers to Consider

Participants felt drug manufacturers should be full members of any coalition interested in finding more effective treatments for people in pain. Participants recommended that manufacturers should be more proactive in educating patients, including developing better, more readable drug information, consumer bulletins, and telephone services.

These recommendations included:

Have health care providers and consumer advocacy groups provide manufacturers with input on what types of consumer information to develop. For example: print inserts in large type, develop simpler language, include benefits not just potential complications, and sponsor consumer bulletins.

Provide telephone assistance numbers so that patients can contact knowledgeable health professionals in addition to their primary health care provider, or give patients the names of advisory groups and consumer advocacy groups.

Expedite delivery of pain medication to the patient, which will require improved efficiency of tracking mechanisms with federal and state regulators, especially for emergency supplies of medication. One participant noted a patient w as

denied emergency supplies of medication that were legally prescribed because of a typographical error on the IDEA form 222. DEA's enforcement penalties are overly punitive for minor record keeping discrepancies.

Broaden the manufacturers' role in professional education, from specific use of medication to basic pain management skills.

Note that manufacturers can and do support legislative efforts as well as outcomes research.

PRIOR AND ONGOING PAIN MANAGEMENT ACTIVITIES

1990

Senator Leroy Greene sponsored the Intractable Pain Treatment Act in 1990, making California the second state to specifically recognize by statute the importance of the use of controlled substances in the treatment of intractable pain.

1992

In December 1992, a professional symposium on pain management, including regulatory impediments, was held at the University of California at San Francisco.

Senator Robert Presley sponsored a resolution that established the Controlled Substances Prescription Advisory Council (Council) to examine the triplicate prescription program, alternative methods of monitoring and enforcing the laws, and regulations governing drug diversion.

1993

Senator Leroy Greene sponsored legislation in 1993 that requires the Medical Board of California to ensure that its licensees are made aware of the Intractable Pain Treatment Act and federal clinical practice guidelines for the treatment of acute, post-surgical, and cancer pain.

Assembly Member Jack O'Connell sponsored Assembly Concurrent Resolution (ACR) 34 in 1993. The resolution directs the Medical Board of California to conduct and complete a survey of medical school curricula to determine whether medical students receive adequate training in pain management and palliative care of the terminally ill. The resolution also directs the Board to determine whether physicians and surgeons adequately understand pain management and palliative care for the terminally ill and to report their recommendations to the Legislature for modifications in medical school curricula to ensure physicians and surgeons have adequate training this area.

In December 1993, the Council issued a landmark report, recommending the implementation of electronic monitoring of controlled substances prescriptions in place of the triplicate prescription program and numerous reforms of laws, regulations, and practices governing drug diversion monitoring, investigation, and enforcement. It recognized the importance of using controlled substances for medical purposes and the problem of undertreating pain as well as the problem of abuse of controlled substances.

In early 1993, a forum on pain management and regulatory issues was proposed and was in initial planning stages at the Department of Consumer Affairs, when the Medical Board of California's task force issued its report.

In February 1993, the University of California at Los Angeles held a symposium on barriers to effective health care; in October 1993, a similar program entitled "Cancer Pain, Opiates and the Law' was held at the California Cancer Center in Fresno. In November 1993, a similar program was held at Cedars-Sinai in Los Angeles, at which time the Southern California Cancer Pain Initiative was organized.

During 1993, the Medical Board of California established a task force on appropriate prescribing. Its report recommended that a pain forum be held and that the Board create a statement on the need for effective pain management. [The draft statement was circulated to Summit attendees, and the final statement -was adopted in May 1994 (see attachment); the Board is now adopting Guidelines for Pain Management; the Board of Registered Nursing has also adopted a policy and curriculum guidelines on pain management (see attachment); the Board of Pharmacy is in the process of doing so.]

Assembly Member Richard Polanco sponsored Assembly Bill (AB) 2155 in 1993 which would have established a pain management committee to, among other things, clarify standards for appropriate procedures and techniques for the management of acute, chronic, or intractable pain, study the impact of the triplicate prescription program on prescribing and dispensing for pain, and examine the adverse impact of the undertreatment of pain.

The Governor vetoed AB 2155 but agreed that the proponents of such a committee made: "...a compelling argument that the medical community and law enforcement community need to work together in a cooperative fashion to make certain patients are receiving medically necessary pain treatment.....

The Governor directed the State and Consumer Services Agency to establish a committee with representatives from various health boards to work with the Attorney General "...on appropriate pain management procedures and recommendations on how to overcome the obstacles that contribute to inadequate pain management.'

1994

The March 18, 1994 Effective Pain Management Summit is the result of the Governor's mandate, and a culmination of the many other activities and legislation described above.

The Medical Board of California, along with the California Medical Association, the Board of Pharmacy, the Board of Dental Examiners, the Board of Registered Nursing, the Department of Consumer Affairs, and the State and Consumer Services Agency became sponsors of the Summit on Effective Pain Management.

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