

REPORT 6 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-07)
Standards, Laws, and Regulations Addressing Pain Medications and Medical Practice
(Resolution 543, A-06)
(Reference Committee E)

EXECUTIVE SUMMARY

Objective: To evaluate the various factors, as well as federal and state policies or standards, that influence pain management practices, particularly the prescribing of opioid analgesics.

Methods: English-language reports on studies using human subjects were selected from a MEDLINE search of the literature from 1997 to March 2007 using the terms “analgesics, opioid*” or “opioid-related disorders” in combination with “epidemiology,” “prevention & control,*” “prescriptions, drug/statistics & numerical data,” “government agencies,” and “substance abuse detections.” Additional articles were identified by manual review of the references cited in these publications. Web sites of the American Pain Society, American Academy of Pain Medicine, National Institutes of Health, Drug Enforcement Administration (DEA), Federation of State Medical Boards, and the Wisconsin Pain & Policies Study Group also were searched for relevant articles.

Results: Although prescriptions for opioid analgesics have increased substantially over the last 15 years, undertreatment of pain continues to be a problem. Unfortunately, there are clear indications that the unauthorized use of prescription opioids has increased, although the sources of unauthorized supplies are varied. In response to increasing prescription drug diversion and misuse, law enforcement has worked to limit access to these medications in the hope of reducing their use outside of regular medical practice. Federal and state pain policies (or standards) affecting physicians have different features. Generally, the language and provisions of state pain policies are more unbalanced than federal policies. However, the actions and pronouncements of federal agencies carry substantial weight in influencing physicians’ prescribing behavior. The advent of state-based electronic prescription drug monitoring programs also appears to significantly influence physicians’ prescribing behavior.

Conclusion: Further research and policy evaluation and development, as well as better communication, cooperation, and education of all stakeholders, are needed to prevent or overcome barriers to patients receiving adequate pain management. Further research is needed to determine the reasons why pain management is not adequate or sufficiently accessible. Youth and young adults remain populations at particular risk for unauthorized opioid use, as do pain patients with comorbid psychiatric disorders. These populations should be the target of more intensive prevention initiatives for drug misuse and addiction. Further research also is needed to identify the sources of diversion of opioid analgesics so that appropriate public health or law enforcement interventions can be devised. Several additional questions need to be addressed to better inform balanced pain management policies. Improvement in state-based pain policies should be a continuing priority. A sustained cooperative effort is needed that is directed toward health professionals and law enforcement officials, and that involves the DEA and other relevant stakeholders. The goal should be to improve the regulatory environment for pain management, clarifying regulatory policies and demonstrating a mutual commitment to a balanced approach between enforcement, regulation, and supply controls on the one hand, and assurance of access to proper medical care on the other. Efforts to address diversion should not interfere with medical practice or patient care. Additionally, with the expansion of state-based prescription drug monitoring programs, the impact of such programs on medical care, including appropriate pain management, should be evaluated.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 6-A-07

Subject: Standards, Laws, and Regulations Addressing Pain Medications
and Medical Practice (Resolution 543, A-06)

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Referred to: Reference Committee E
(Paul C. Matson, MD, Chair)

1 Introduction

2
3 Resolution 543 introduced by the Arizona Delegation at the 2006 Annual Meeting and referred to
4 the Board of Trustees, asks:

5
6 That our American Medical Association (AMA) work with all agencies and government
7 bodies associated with setting pain standards, in cooperation with relevant medical
8 specialty societies, to urge coordination of pain standards.
9

10 The Council previously addressed barriers to pain management and the use of opioids in
11 persistent noncancer pain, as well as the overall management of patients with neuropathic pain.
12 The latter two reports also briefly reviewed the broader spectrum of pain care choices. A
13 comprehensive and multi-modal review of pain management is beyond the scope of this report.
14 In addition, most of the tension in the pain management community emanates from issues
15 involving the use of controlled substances, so these are the focus of this report.
16

17 Policies (or standards) affecting pain management are derived from laws, regulations, and
18 practice guidelines. Opioid analgesics are controlled substances because they have the potential
19 for misuse and the development of addiction. Thus, their manufacture, distribution, prescribing,
20 and dispensing are governed by a combination of international treaties, U.S. federal and state
21 laws, and regulations intended to balance drug control with patient access to needed pain
22 medicine.
23

24 This report evaluates different factors influencing pain management, as well as how various
25 federal and state policies influence physician behavior in providing appropriate pain management.
26 Only U.S. policies, laws, regulations, and government activities are discussed. This report does
27 not specifically address clinical practice guidelines for pain management, the risk assessment of
28 pain patients with a history of substance abuse, or interventions for patients with opioid
29 dependence or a history of prescription drug misuse and addiction.
30

31 Methods

32
33 English-language reports on studies using human subjects were selected from a MEDLINE search
34 of the literature from 1997 to March 2007 using the terms “analgesics, opioid*” or “opioid-
35 related disorders” in combination with “epidemiology,” “prevention & control,*” “prescriptions,

1 drug/statistics & numerical data,” “government agencies,” and “substance abuse detections.”
2 Additional articles were identified by manual review of the references cited in these publications.
3 Web sites of the American Pain Society (APS), American Academy of Pain Medicine (AAPM),
4 National Institutes of Health, Drug Enforcement Administration (DEA), Federation of State
5 Medical Boards (FSMB), the University of Wisconsin Pain & Policies Study Group also were
6 searched for relevant articles.

7 8 Background

9
10 A number of issues underlie physician concerns and frame the debate on pain management. Over
11 the last two decades, several important reports have established evidence-based clinical
12 approaches, and identified barriers to adequate pain management.¹⁻¹⁰ Widespread agreement
13 exists that opioid analgesics are indispensable for relieving moderate to severe pain. Because
14 opioids also are subject to diversion and misuse, their production and availability are strictly
15 regulated under federal- and state-controlled substances laws. However, these controls and their
16 enforcement should be balanced and not interfere with the availability of opioid analgesics for
17 legitimate medical purposes. Providing access to pain relief for those in need, while
18 simultaneously preventing the diversion and misuse of pain medications, requires “balance” in
19 pain policy. To foster a balanced approach, our AMA and 21 other health organizations joined
20 with the DEA in a joint statement of accountability in 2001.¹¹ This statement noted that “both
21 healthcare professionals, and law enforcement and regulatory personnel, share responsibility for
22 ensuring that prescription pain medications are available to the patients who need them and for
23 preventing these drugs from becoming a source of harm or abuse,” and that “preventing drug
24 abuse is an important societal goal, but there is consensus, by law enforcement agencies, health
25 care practitioners, and patient advocates alike, that it should not hinder patients’ ability to receive
26 the care they need and deserve.”

27
28 As noted above, this Council has previously identified barriers to the appropriate management of
29 patients with acute and persistent cancer pain, examined issues related to the use of opioids in
30 patients with persistent noncancer pain, and addressed the diagnosis and treatment of neuropathic
31 pain, including the use of opioids.¹²⁻¹⁴ The Board of Trustees (BOT) previously examined the
32 feasibility of addressing physician’s concerns about the use of opioids in the treatment of
33 intractable pain with legislative remedies.^{15,16} BOT Report 3 (A-06) “Promoting Pain Relief and
34 Preventing Abuse of Controlled Substances” addressed some of the same issues contained in this
35 report.¹⁷ Relevant AMA policies are noted in Appendix 1. Our AMA has been active on the
36 educational front as well, creating a successful 12-part Pain Management Continuing Medical
37 Education program, available in both print and online format, and updated for 2007.

38 39 Factors Relevant to Pain Management Practices

40
41 Undertreatment of Pain. As noted above, the publication of several important reports¹⁻¹⁰ and
42 clinical consensus guidelines¹⁸⁻²⁰ have led to improved pain management, yet undertreatment of
43 pain continues to be a significant problem, and persistent pain is often inadequately controlled. A
44 substantial percentage of individuals (~75 million Americans) report suffering from acute and
45 chronic noncancer pain that is not adequately relieved.^{21,22} Daily pain is prevalent among nursing
46 home residents, and is often untreated, particularly among older and minority patients.^{23,24}
47 Undertreatment is influenced by diverse factors including limited training in opioid prescribing
48 and pain management, unfounded concerns about addiction and side effects, fear of regulatory
49 oversight, and lack of access to pain specialists.

1 Some populations with pain (eg, cancer patients) should receive opioids as first-line agents for
2 moderate to severe pain. Less than 50% of patients with metastatic cancer receive adequate pain
3 relief, and ~40% suffer moderate to severe pain in the last 3 days of life.^{25,26} Remarkably, even
4 children dying of cancer often experience substantial suffering in the last months of life.²⁷ Such
5 factors contributed to requirements by the Joint Commission to document and monitor pain,
6 which have contributed to improved pain management in the hospital environment.

7
8 Opioid Prescribing Patterns. Opioid prescriptions have increased substantially over the last 15
9 years because of increased attention to better management of persistent pain, cancer pain, and
10 end-of-life care.^{28,29} The extent to which the increase in opioid prescriptions reflects more
11 aggressive and better pain management practices versus inappropriate prescribing is not known.
12 Substantial geographic variations exist, and prescriber demographics have shifted for some
13 products, with primary care physicians now responsible for a larger fraction of prescriptions for
14 certain opioid analgesic products.^{30,31} Nevertheless, a subgroup of patients with chronic
15 noncancer pain may benefit from long-term therapy with opioid analgesics. The size of this
16 subgroup and its characteristics remains controversial. Unfortunately, the increased availability
17 and clinical use of opioid analgesics has been temporally associated with indicators of increased
18 nonmedical use or abuse.^{29,32,33}

19
20 Some Indicators of Nonmedical Use, Misuse, and Addiction are Increasing. Several entities track
21 indicators of prescription drug misuse and addiction, but relatively few provide any information
22 on the sources of diversion. Various survey data indicate that the prevalence of nonmedical use
23 or unauthorized use of opioid analgesics has risen appreciably over the last 15 years, notably
24 among adolescents and young adults. The percentage of 12th-graders who report lifetime use of
25 “narcotics other than heroin” doubled from 1991 to 2004, but has since remained relatively stable
26 at ~13.5%. The percentage of 12th-graders who report annual use of such products declined
27 somewhat from a peak of 9.5% in 2004 to 9.0% in 2006.³³

28
29 In 2005, 2.5 million persons aged 12 years or older used “psychotherapeutics” nonmedically for
30 the first time according to the National Survey on Drug Use and Health (NSDUH).³² This
31 includes psychostimulants and sedatives, as well as opioid analgesics. However, NSDUH showed
32 a decline from 2002 to 2005 among youths aged 12 to 17 years for past-month nonmedical use of
33 prescription drugs. The rates of current use of illicit drugs are higher in young adults aged 18 to
34 25 years than in younger or older subjects. Past-month nonmedical use of prescription drugs in
35 this group increased from 5.4% in 2002 to 6.3% in 2005, primarily due to an increase in
36 prescription pain reliever use. In 2005, ~1.5 million persons aged 12 years and older were
37 diagnosable with opioid abuse or dependence—this includes a substance use disorder related to
38 heroin or prescription opioids. Information from the Treatment Episode Data Set (TEDS)
39 indicates a quadrupling of admissions for opioid treatment during the period 1995 to 2005.³⁴
40 TEDS is an administrative data system providing descriptive information about the national flow
41 of admissions to providers of substance abuse treatment.

42
43 Most youth who admit to nonmedical use acquire prescription drugs from peers or family
44 members; a smaller number purchase them illegally, and far fewer obtain them from a physician
45 in the course of a legitimate patient-physician encounter.^{35,36} Theft is a major contributor to the
46 diversion of prescription-type opioid drugs, and in some cases, these products can be obtained
47 illegally from Internet sources.³⁷

48
49 The actual percentage of patients who meet the criteria for opioid dependence after receiving
50 opioids for legitimate pain management is generally considered to be quite small (0.7%-2%),^{38,39}
51 but views on this continue to evolve. Patients with persistent noncancer pain who regularly use or

1 misuse opioid analgesics tend to be younger, with a previous history of substance abuse, or
2 concurrent anxiety or mood disorders.^{38,39-41} Thus, diagnosis of psychiatric disorders is important
3 when considering patients for long-term opioid therapy. Nevertheless, the relationship between
4 chronic pain and depression is highly complex. Individuals with major depression are more
5 likely to have chronic pain and vice versa, and both conditions may need to be treated separately.

6
7 Differential diagnosis of aberrant drug taking attitudes and addiction is not straightforward, as
8 many aberrant behaviors are ambiguous. Nevertheless, patients with a history of abuse or
9 addiction may still be appropriate candidates for opioid therapy, but require a special skill set on
10 the part of the treating physician.

11
12 Law Enforcement Actions. Drug law enforcement actions, and the perception of them, create
13 fear of regulatory or legal scrutiny among physicians. By their nature, law enforcement agencies
14 focus on diversion and inappropriate opioid prescribing, without considering the potential
15 detrimental effects of their actions or pronouncements on medically appropriate use. On the
16 surface, analysis of actual enforcement actions by the DEA or state medical boards suggests that
17 the number of physicians subject to prosecution or disciplinary actions is small, compared with
18 the total number of DEA registrants. Generally, these physicians have committed egregious
19 offenses, or clearly lacked documentation to support their prescribing practices.^{43,44} However, the
20 number of investigations is substantially higher, and the number of high-volume opioid
21 prescribers is small. One analysis estimated that ~15% of pain specialists may be subject to
22 investigation.⁴⁵ Thus, the actual risk of scrutiny for these physicians is substantially higher, and
23 statistics based only on enforcement actions do not measure the impact of media attention and
24 personal knowledge of other investigations on prescribing behavior.⁴⁶ In one survey, 40% of pain
25 management physicians indicated that regulatory, not medical concerns dissuaded them from
26 prescribing opioids for patients with persistent noncancer pain.⁴⁷

27
28 Development of Tolerance and Physical Dependence. Tolerance and physical dependence are
29 normal consequences of sustained use of opioid analgesics and are not the same as addiction.⁴⁸ A
30 consensus document developed by the AAPM, APS, and the American Society of Addiction
31 Medicine (ASAM) articulates the differences.⁴⁹ However, misunderstanding of these phenomena
32 continues to influence prescribing decisions and patient acceptance. Although tolerance does
33 occur, significant increases in dosage for patients suffering from cancer pain generally are
34 associated with a change in disease status. The development of tolerance does not preclude
35 clinical effectiveness; its development can be lessened by using a rotation of different opioid
36 compounds, and wide inter-individual variations exist in clinical response. Thus, overstatement
37 and misunderstanding of the risks of addiction or side effects likely contribute to undertreatment
38 of pain, even in the absence of concerns about regulatory scrutiny.

39 40 Federal Policies Impacting Pain Management

41
42 Food and Drug Administration (FDA). The FDA regulates the approval of prescription drugs for
43 marketing based on safety and efficacy, including their potential for misuse and addiction, and
44 shares responsibility with the DEA for assigning a drug to a controlled substance schedule (see
45 below). The FDA also provides oversight of risk management strategies and educational
46 activities that pharmaceutical companies may implement to address the risks associated with
47 certain prescription drugs, including opioid analgesics. To date, FDA policies and activities have
48 not generally served to restrict appropriate pain management.

49
50 Drug Enforcement Administration. Among other duties and authority, the DEA carries out the
51 mandates of the Controlled Substances Act (CSA) to prevent, detect, and investigate the diversion

1 of controlled substances by legitimate handlers, and to ensure an adequate and uninterrupted
2 supply to meet legitimate medical needs. The CSA is not intended to interfere with medical
3 practice or with the availability of controlled substances for legitimate medical purposes.
4 Physicians retain authority under the CSA to prescribe, dispense, or administer controlled
5 substances for the treatment of pain within acceptable medical standards. The CSA recognizes
6 the essential medical purpose of opioid analgesics and other controlled substances, noting that
7 these “drugs have a useful and legitimate medical purpose and are necessary to maintain the
8 health and general welfare of the American people” (21 U.S.C. § 801(1)).
9

10 Under the CSA, the requirement for a prescription for a controlled substance is that it must be
11 issued for a legitimate medical purpose by a practitioner acting in the usual course of professional
12 practice (21 C.F.R. § 1306.04(a)). However, the CSA does not define “legitimate medical
13 purpose” nor does it set forth standards of medical practice. These practices are defined by the
14 medical community in concert with the development of clinical guidelines, performance
15 measures, and standards of care. The Act also instructs manufacturers that are registered to
16 “produce an adequate and uninterrupted supply of these substances” 21 U.S.C. §823a(1). The
17 DEA has further noted that “the quantity of drug prescribed and frequency of prescriptions filled
18 are not alone indications of fraud or improper prescribing especially if the patient is being treated
19 with opioids for pain management.” Thus, language contained in the CSA contains many
20 elements essential to a balanced pain policy.
21

22 However, despite provisions for balance in the language of the CSA, other actions and
23 pronouncements by the DEA may have the opposite effect. The developments surrounding the
24 DEA’s action to issue an Interim Policy Statement (IPS) and withdraw its support of a publication
25 entitled: “Prescription Pain Medications: Frequently Asked Questions and Answers for Health
26 Care Professionals and Law Enforcement Personnel (FAQ)” were previously discussed in BOT
27 Report 3, A-06.¹⁷ The sudden withdrawal of the FAQs without notice or sufficient explanation
28 raised concern in the pain management community. The FAQs were intended, in part, to educate
29 health care practitioners, law enforcement, and regulatory personnel who might be misinformed
30 about pain management, opioid use and misuse, and addiction.
31

32 Statements contained in the IPS led to renewed concerns by physicians about the DEA’s real
33 intentions. For example, the IPS declared that it was illegal for a physician to prepare multiple
34 prescriptions on the same day with instructions to fill on different dates (serial prescriptions),⁴⁹
35 although this has been a longstanding practice for selected patients. In the IPS, the DEA also
36 admonished physicians to increase their vigilance in prescribing abusable drugs, particularly for
37 patients with known or suspected risk of abuse, implying that physicians currently have the
38 means to accurately assess all patients for abuse risk. Moreover, the DEA declared that the
39 government “can investigate merely on suspicion that the law is being violated, or even just
40 because it wants assurances that it is not.” Eventually, on September 6, 2006, the DEA took a step
41 to improve the clinical practice environment for pain management by issuing a notice of proposed
42 rulemaking that would allow an individual practitioner to issue multiple, but postdated
43 prescriptions for a 90-day supply, assuming certain criteria were fulfilled.⁵⁰ This proposal has not
44 been finalized, and other issues raised by the IPS remain in need of clarification.
45

46 Other Federal Agencies. Other federal agencies: (1) set policies, priorities, and objectives for the
47 nation’s drug control programs (Office of National Drug Control Policy); (2) administer grants,
48 and collect and evaluate data related to drug abuse (Substance Abuse and Mental Health Services
49 Administration); and (3) support research on the health aspects of drug abuse and addiction, and
50 provide information to the public on drug abuse (National Institute on Drug Abuse). These
51 activities assist in informing the public and professional debate on these issues.

1 State Policies

2
3 States are responsible for regulating medical and pharmacy practice. State medical practice laws
4 generally delegate the responsibility of regulating physicians to state medical boards, which
5 license physicians and grant them prescribing privileges. In addition to the federal requirements
6 noted above, the prescribing, dispensing, and administering of controlled substances is regulated
7 by states. In general, state pain policies are more “unbalanced” than federal policies, at least in
8 terms of their language, in focusing on law enforcement over adequate pain management.⁵²
9

10 Federation of State Medical Boards (FSMB) Model Policy. Initially released in 1998, the FSMB
11 Model Guidelines for the Use of Controlled Substances for the Treatment of Pain were updated in
12 2004 and renamed “Model Policy.” The Policy statement provides model language that may be
13 used by states to clarify their positions on the use of controlled substances to treat pain, help to
14 alleviate physician uncertainty, and encourage better pain management. The 2004 update, in part,
15 reflected continuing concerns about the undertreatment of pain.⁴⁸ The Model Policy recognizes
16 that pain management is an integral part of quality medical practice; controlled substances are an
17 essential part of pain management; tolerance and physical dependence are not synonymous with
18 addiction; and physicians should not fear regulatory sanctions for appropriately prescribing
19 controlled substances for pain. With respect to the latter, the Model Policy states...“the Board
20 will judge the validity of the physician’s treatment of the patient based on available
21 documentation, rather than solely on the quantity and duration of medication administration. The
22 goal is to control the patient’s pain...”
23

24 Many state medical boards have rewritten pain policies since the Model Guidelines were first
25 published. According to an analysis conducted by the Pain and Policies Study Group at the
26 University of Wisconsin, a total of 28 states had adopted either the FSMB’s Model Guidelines or
27 Policy in whole or in part.⁵³ At least 19 states evidenced positive policy changes between 2003
28 and 2006 based on adoption of policies encouraging pain management or palliative care or
29 adoption of pain-specific statutes (see Appendix 2 for a list of criteria identified by the study
30 group as either positive or negative influences). Despite these improvements, 21 states still have
31 policies that characterize opioids as a treatment of last resort.
32

33 Prescription Drug Monitoring Programs. Another way to address prescription drug diversion and
34 misuse at the state level is through the institution of prescription drug monitoring programs.
35 Current programs utilize electronic data transfer, either singly or in combination with special
36 government-issued prescription forms for controlled substances. A few electronic systems
37 operate proactively, routinely analyzing prescription data (trend analysis) to identify individuals,
38 physicians, or pharmacies with unusual patterns of use. Most monitoring programs are passive,
39 being used only for specific requests or searches that satisfy specific criteria.
40

41 As of February 2007, 24 states had implemented systems to monitor the prescription and sale of
42 controlled substances, and legislation was pending in another 11 states.⁵⁴ Many of these
43 programs were developed in response to the federal National All Schedules Prescription
44 Electronic Reporting Act (NASPER). NASPER created a program to offer individual states
45 federal funding for the establishment of state prescription monitoring programs that could help
46 detect individuals who “doctor shop” to obtain controlled substances. One analysis suggests that
47 these types of programs reduce overall opioid prescribing.⁵⁵
48

49 The use of special prescription forms clearly leads to a decline in prescribing for monitored drugs,
50 and sometimes substitution of a less suitable agent.⁵⁶⁻⁵⁸ Thus, current but limited evidence
51 suggests prescription drug monitoring programs reduce opioid prescribing and, therefore,

1 indirectly reduce prescription drug misuse and addiction. The extent to which such programs may
2 have the unintended effect of promoting the undertreatment of pain with opioid medications is not
3 known.

4 5 Summary and Conclusion

6
7 The actions and pronouncements of the DEA, the features of state-based pain policies, and the
8 development of state-based prescription drug monitoring programs represent the most significant
9 influences on physician prescribing of opioid analgesics and pain management. Further research
10 and policy evaluation and development, as well as better communication, cooperation, and
11 education of all stakeholders, are needed to prevent or overcome barriers to patients receiving
12 adequate pain management, and to determine why pain management is not adequate.
13 Improvement in state-based pain policies should be a continuing priority.

14
15 Although the number of prescriptions for opioid analgesics has increased substantially over the
16 last 15 years, undertreatment of pain continues to be a problem. This is suggested specifically by
17 the extant undertreatment of cancer pain. However, many physicians still lack comfort in the
18 clinical use of opioid analgesics, particularly for patients with persistent noncancer pain. This is
19 related to a number of factors, including limited training in opioid prescribing; uncertainty about
20 the long-term effectiveness of opioid analgesics in these patients; excessive concerns about the
21 side effects of opioid drugs and the potential for such drugs to lead to instances of misuse or cases
22 of addiction; lack of sufficient methods to detect diversion and misuse; and concern about
23 regulatory/criminal scrutiny by federal or state law enforcement officials.

24
25 Unfortunately, there are clear indications that the unauthorized use of prescription opioids has
26 increased, as well as cases of diagnosable opioid addiction. In response to increasing prescription
27 drug diversion and misuse, law enforcement has worked to limit access to these controlled
28 substances, including opioid medications, in the hope of reducing their diversion; however, such
29 actions can have the unintended consequence of exacerbating the problem of undertreatment of
30 pain. Clinicians have a responsibility to use sensible approaches to prescribing controlled
31 substances, and in maintaining appropriate vigilance to minimize opioid diversion and misuse.
32 Pre-teens, adolescents, and young adults remain populations at particular risk for nonmedical
33 opioid use and misuse, as are pain patients with comorbid psychiatric disorders. These
34 populations should be the target of more intensive drug abuse prevention initiatives. Research is
35 needed to identify the sources of diversion of opioid analgesics so that appropriate public health
36 or law enforcement interventions can be devised.

37
38 Several questions must be addressed to better inform balanced pain management policies,
39 including:

- 40
41 Who is involved in unauthorized/nonmedical use of opioid analgesics?
42 What are the sources of the prescription drugs that are diverted and misused?
43 What is the relationship between increased numbers of opioid prescriptions and rates of
44 opioid addiction?
45 What are the consequences of lack of adequate epidemiological or clinical knowledge
46 about prescription drug use, misuse, and addiction on physician prescribing and the
47 appropriate use of opioid analgesics for pain patients?
48

49 A sustained cooperative effort is needed that is directed toward health professionals and law
50 enforcement officials, and that involves the DEA and other relevant stakeholders. The goal
51 should be to improve the regulatory environment for pain management, clarifying regulatory

1 policies and demonstrating a mutual commitment to a balanced approach to drug diversion and
2 pain management. Additionally, with the expansion of state-based prescription drug monitoring
3 programs, the impact of such programs on medical care, including appropriate pain management,
4 should be evaluated.

5
6 RECOMMENDATIONS

7
8 The Council on Science and Public Health recommends that the following recommendations be
9 adopted in lieu of Resolution 543 (A-06) and that the remainder of this report be filed:

- 10
11 1. That states should examine their pain policies and seek to improve them, based on the
12 Federation of State Medical Boards Model Policy and/or criteria established by the
13 Wisconsin Pain & Policies Study Group. (New HOD Policy)
14
15 2. That the impact of state-based prescription drug monitoring programs on medical care,
16 including appropriate pain management, should be evaluated. (New HOD Policy)
17
18 3. That the American Medical Association (AMA) urge the Drug Enforcement Administration
19 to work with physician organizations and other relevant stakeholders to reconstruct a
20 document similar to “Prescription Pain Medications: Frequently Asked Questions and
21 Answers for Health Care Professionals and Law Enforcement Personnel” to serve as a
22 legitimate resource for physicians, regulators, and law enforcement personnel. (Directive to
23 Take Action)

Fiscal Note: No Significant Fiscal Impact

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Appendix 1.
AMA Policies on Pain Management

H-120.960 Protection for Physicians Who Prescribe Pain Medication

Our AMA supports the following: (1) the position that physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution. It is the policy of the AMA that state medical societies and boards of medicine develop or adopt mutually acceptable guidelines protecting physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain before seeking the implementation of legislation to provide that protection; (2) education of medical students and physicians to recognize addictive disorders in patients, minimize diversion of opioid preparations, and appropriately treat or refer patients with such disorders; and (3) the prevention and treatment of pain disorders through aggressive and appropriate means, including the continued education of doctors in the use of opioid preparations. Our AMA opposes harassment of physicians by agents of the Drug Enforcement Administration in response to the appropriate prescribing of controlled substances for pain management. (BOT Rep. 1, I-97; Reaffirm: Res. 237, A-99; Appended: Res. 506, A-01; Appended: Sub. Res. 213, A-03).

D-120.976 Pain Management

Our AMA will: (1) support more effective promotion and dissemination of educational materials for physicians on prescribing for pain management; (2) take a leadership role in resolving conflicting state and federal agencies' expectations in regard to physician responsibility in pain management; (3) coordinate its initiatives with those state medical associations and national medical specialty societies that already have already established pain management guidelines; and (4) will disseminate Council on Science and Public Health Report 5 (A-06), "Neuropathic Pain," to physicians, patients, payers, legislators, and regulators to increase their understanding of issues surrounding the diagnosis and management of maldynia (neuropathic pain). (Res. 809, I-04; Appended: CSAPH Rep. 5, A-06).

D-120.999 Use of Opioids in Chronic Noncancer Pain

(1) Further controlled trials be conducted on opioid therapy in patients with chronic noncancer pain in an effort to identify best practice with regard to selection of both medication and treatment regimens identify patient characteristics that predict opioid responsiveness provide support for guidelines on appropriate precautions, contraindications, and the degree of monitoring required in such patients. (2) Our AMA encourage states to create multidisciplinary task forces or pain commissions to study the barriers to pain management in their state, and to make and implement recommendations for policy that will create a practice environment conducive to effective pain management. Guidelines promulgated by medical boards are preferable to regulation or statutes. (3) Our AMA and relevant specialty societies promote educational offerings for physicians to facilitate learning about principles of pain diagnosis and treatment. (4) Our AMA encourage that appropriate education in pain evaluation and management be provided as an integral part of the core curriculum at all medical schools. (CSA Rep. 11, A-99).

D-120.971 Promoting Pain Relief and Preventing Abuse of Controlled Substances

Our AMA will: (1) urge the Drug Enforcement Administration (DEA) to publicly restate their commitment to balance in promoting pain relief and preventing abuse of pain medications; (2) support an ongoing constructive dialogue among the DEA and physician groups to assist in establishing a clinical practice environment that is conducive to pain management and the relief of suffering, while minimizing risks to public health and safety from drug abuse or diversion; (3) strongly urge that the DEA's upcoming recitation of the pertinent legal principles relating to the

dispensing of controlled substances for the treatment of pain maintain a patient-centered focus, including reaffirmation of its previous interpretation of law to permit practitioners to issue a series of prescriptions marked "do not fill" until a later date; and (4) strongly urge that the DEA should promulgate, in consultation with relevant medical specialty societies and patient advocacy groups, a rational and realistic set of FAQs to assist in providing education to health care practitioners and law enforcement and regulatory personnel about appropriate pain management, and measures to be taken to minimize drug abuse and diversion. (BOT Rep. 3, A-06).

D-170.999 Barriers to Appropriate Pain Management

Our AMA, in cooperation with relevant medical societies and organizations, will serve as an educational resource to the media by providing objective information regarding the management of pain disorders so that information presented to the public will be factually accurate reflecting appropriate medical perspectives. (Res. 506, A-01).

D-120.983 Concerning Pain Management

Our AMA will communicate to the President, the Secretary of the Department of Health and Human Services, and the Attorney General, its strong opposition to the inappropriate use of 21 Code of Federal Regulations Section 1306.04 or any other rationale that would involve placement of licensure restrictions on physicians who use opioid analgesics and other pain-reducing medications appropriately to treat patients with pain. To assist our AMA in opposing harassment of physicians, state medical and specialty societies will be requested to submit, to the AMA Office of General Counsel, examples of physicians who allegedly have been harassed by DEA agents for appropriate prescribing of controlled substances for pain management. (Sub. Res. 213, A-03)

Appendix 2.
Criteria for Evaluating State Pain Policies⁵²

Criteria that identify provisions that may *enhance* pain management

1. Controlled substances are recognized as necessary for public health
2. Pain management is recognized as part of general medical practice
3. Medical use of opioids is recognized as legitimate professional practice
4. Pain management is encouraged
5. Practitioners' concerns about regulatory scrutiny are addressed
6. Prescription amount alone is recognized as insufficient to determine legitimacy of prescribing
7. Physical dependence or analgesic tolerance are *not* confused with "addiction"
8. Other provisions that may enhance pain management
 - Category A: Issues related to healthcare professionals
 - Category B: Issues related to patients
 - Category C: Regulatory or policy issues

Criteria that identify provisions that may *impede* pain management

9. Opioids are considered a treatment of last resort
10. Medical use of opioids is implied to be outside legitimate professional practice
11. Physical dependence or analgesic tolerance are confused with "addiction"
12. Medical decisions are restricted
 - Category A: Restrictions based on patient characteristics
 - Category B: Mandated consultation
 - Category C: Restrictions regarding quantity prescribed or dispensed
 - Category D: Undue prescription limitations
13. Length of prescription validity is restricted
14. Practitioners are subject to undue prescription requirements
15. Other provisions that may impede pain management
16. Provisions that are ambiguous
 - Category A: Arbitrary standards for legitimate prescribing
 - Category B: Unclear intent leading to possible misinterpretation
 - Category C: Conflicting or inconsistent policies or provisions