

Sandra H. Johnson, Introduction, "Legal and Regulatory Issues in Pain Management"

Journal of Law, Medicine & Ethics, 26, no. 4 (1998): 265-66.

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The capacity to treat pain has never been greater; but, as you will read in the articles that follow, the problem of undertreated and neglected pain in the United States persists. Deep-seated perceptions and practices undergird this strong and well-documented pattern of neglect. Among the reasons frequently noted for the inadequacy of treatment for pain, however, is that the legal system actually penalizes effective interventions to relieve pain while it leaves neglect of pain unthreatened. It is the mission of the American Society of Law, Medicine & Ethics (ASLME) to explore areas, such as this one, where developments in medicine directly encounter the law and, in turn, create ethical issues for clinicians, regulators, patients, and lawyers.

This special issue of the *Journal of Law, Medicine & Ethics* is part of a multi-year project in which ASLME, with the wonderful support of the Mayday Fund, has worked to address legal and regulatory barriers to effective pain relief. The focus of the project, in line with ASLME's mission, has been on the impact of the legal system rather than on other factors such as professional training, institutional organization, or social constructs.

The first ASLME project on pain management, funded by the Mayday Fund in 1995, was both a research and an educational project. In 1996, the project produced an inter-disciplinary National Meeting on Legal, Ethical, and Institutional Issues in Pain Relief and a special issue of the *Journal of Law, Medicine & Ethics* that reported the research of the project itself, including a model Pain Relief Act and other influential articles. Completed in 1997, the first Mayday project at ASLME revealed other areas in which legal constraints or fears of legal sanctions may negatively affect practice in pain management. The project also brought to light the need for development of experts who could participate in public policy and educational efforts relating to the law and pain management.

In 1997, the Mayday Fund provided a substantial grant to ASLME for the Mayday Scholars Program. Building on what was accomplished in the original project, the Mayday Scholars Program had two goals: (1) to support efforts to disseminate the results of the first project through training programs for lawyers and others and through consultation with policy-makers, professional associations, and individual professionals; and (2) to fund researchers who would contribute importantly to new scholarship on legal and regulatory issues. The program expanded the scope of the original effort to include payment issues as well.

The Mayday Fund's commitment to dissemination of the results of the first project has had significant impact. Educational sessions were provided to many key groups, including state and federal judges and state medical board investigators and executive directors, among others. One of the most significant consultation efforts was the work done with the Federation of State Medical Boards (FSMB). FSMB recently issued Model Guidelines on the use of opioids in pain management. These guidelines clearly recognize the legitimacy of the use of opioids in the management of chronic pain, reject quantity and chronicity of medication as proof of inappropriateness, and identify outcomes in terms of relief and function as the major indicators of a successful treatment regimen.

The Mayday Scholars Program also stimulated significant research in unaddressed areas. This special issue of the *Journal of Law, Medicine & Ethics* publishes the work of some of the Mayday Scholars.

Payment systems may control access to any health care services, including access to effective pain management. The first two articles in this issue present the results of the first in-depth research efforts to examine current policies in payment for pain relief. In the first, Diane Hoffmann analyzes the practices and policies of Blue Cross Blue Shield Plans in relation to payment for pain management services. In the second, Timothy Jost examines the policies of the Medicare and Medicaid programs.

Pain relief has become a central issue in quality care for the dying and in the debate over assisted suicide. Although there have been substantial efforts to assure that dying patients receive adequate pain relief, there is a perception that providing pain medication at the end of life may present a risk of prosecution. In her paper, Ann Alpers examines criminal investigations and prosecutions of physicians and nurses in relation to pain treatment for patients at the end of life.

The Mayday Fund projects at ASLME began with an examination of the standards used in disciplinary actions against physicians for the use of controlled substances in pain management. Although the ASLME project emphasized reducing the threat of disciplinary action against physicians who appropriately treat pain, some have called for state medical boards to discipline physicians who under-treat. Ann Martino's paper examines the issues that arise should a state medical board take the step of viewing neglect or

undertreatment of pain as cause for disciplinary action. David Haddox and Gerald Aronoff's response to that proposal raises further issues.

ASLME is grateful to the board of directors of the Mayday Fund for its long-term support of the Mayday project and the Mayday Scholars Program. We appreciate its commitment to improving the treatment of patients in pain. We have also benefited greatly from the special support of Fenella Rouse, executive director of the Mayday Fund, for her guidance, wisdom, and encouragement throughout. For myself, it has been one of the most satisfying professional experiences to serve as co-principal investigator with Nancy Dubler and Robert Levine for the first Mayday project at ASLME and then as principal investigator of the Mayday Scholars Program. The Mayday Fund has my great gratitude for its support and for its call to make a difference; and the leadership and staff of the ASLME, in particular Benjamin Moulton and Michael Vasko, for their commitment to working in that uncomfortable borderland among the disciplines.

Diane E. Hoffmann, "Pain Management and Palliative Care in the Era of Managed Care: Issues for Health Insurers"

Journal of Law, Medicine & Ethics, 26, no. 4 (1998): 267-89.

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When I first went into practice in 1962 there was an old time GP who was very well liked and had a large practice. He did everything ... office calls, home calls, nursing home calls, deliveries, surgery ... you name it ... he did it. Often when one of his patients died ... usually in the hospital ... he would say to his colleagues ... "Mrs X died last night. BUT SHE HAD NO PAIN!" The point is ... in those days the physician was thinking of his/her patient's comfort and thought of the episode in those terms. Now we still think of the patient's comfort but we are forced into thinking in terms of ICD-9 CM [Clinical Modification] diagnostic codes and CPT [Current Procedure Terminology] ... codes. Neither one of these coding systems easily let us express ourselves in terms of the patient's comfort. This is particularly true in organized practices where billing and coding clerks make the decisions of how to document the physician's actions. Pain remains a symptom ... not a disease and I feel this hampers our collective efforts to deal with the issue(s). -- Blue Cross Blue Shield Medical Director

The problem of inadequate pain management for both terminally ill patients and patients with chronic pain has recently been documented by a number of authors and studies. A 1997 report by the Institute of Medicine (IOM), for example, states that "a significant proportion of dying patients and patients with advanced disease experience serious pain, despite the availability of effective pharmacological and other options for relieving most pain." There are particularly impressive data that pain associated with cancer is not adequately treated.

The problem has been attributed to (1) inadequate education of physicians on approaches to pain management and an often misguided belief that prolonged therapy with certain pain medication will lead to addiction; (2) legal obstacles, such as physicians' fear of criminal prosecution and other disciplinary actions by state licensing boards for overprescribing narcotics; and (3) inadequate insurance coverage as a result of narrow eligibility criteria for hospice care for Medicare beneficiaries, and inadequate reimbursement more generally for pain management and palliative care. While a body of literature is developing on the lack of physician education and knowledge about treatment of pain and on the legal obstacles to prescribing adequate pain medication, relatively little empirical data exist on the role of insurance coverage as an obstacle to adequate care for pain in either the fee-for service (FFS) or managed care context.

In response, I report on (1) the existing literature regarding insurance coverage and practices of managed care plans in dealing with pain management for patients with chronic pain and in dealing with pain management and palliative care for patients who are terminally ill; and (2) the results of an empirical study of medical directors at Blue Cross Blue Shield Plans (BCBS Plans) across the United States about their awareness of pain management and palliative care as issues for their insured populations and how they are dealing with various aspects of the problem, for example, coverage, policies, demonstration projects, and educational efforts.

Pain management and insurance coverage literature

Literature addressing topic

The literature on insurance coverage for pain management, both in FFS and managed care settings, is scant. What literature is available indicates that coverage for certain types of pain management may not be adequate. For example, a 1994 article based on a study, conducted by the Pain Research Group at the University of Wisconsin School of Medicine, found that "lack of coverage and uneven reimbursement policies for health care including prescription drugs, medical equipment, and professional services inhibit access to acute and cancer pain management for millions of citizens, in particular the poor, elderly and minorities."

As regards managed care plans, the literature contains anecdotal and speculative accounts about how managed care organizations (MCOs) perform with respect to pain management, but no hard data on actual outcomes. Susan Wolf, in an article on managed care and physician-assisted suicide, concludes that

[j]ust as research on pain is in its infancy, research on how well or poorly MCOs do in treating pain similarly seems to be at an early point. It is clear that "HMOs' outpatient prescription drug benefits frequently are subject to restrictions ... such as generic substitution, therapeutic substitution, and [limited] formularies." Moreover, these benefits may be available in some HMOs only by subscriber purchase of an extra "rider" to the coverage contract, and coverage affects access to pain-relieving drugs. Much remains to be determined about the effectiveness of MCOs in addressing pain, however, especially for patients at the end of life.

Cost as a focus

Some evidence exists that cost and effectiveness are significant issues in MCO coverage of pain management for specific problems. The issue of cost, however, has only recently become a focus of concern, in large part because of the development of newer, more expensive approaches to pain relief. A 1994 report, commissioned by the Panel for the Management of Cancer Pain of the Agency for Health Care Policy and Research (AHCPR) on cost issues related to pain management for cancer patients, states that until recently,

pain management was limited to oral medications or intramuscular ... injections, both of which are relatively inexpensive. The development of parenteral infusion devices, surgical techniques, and anesthetic approaches to pain has led to multiple treatment options the availability of which has resulted in far greater expense, both in direct cost and indirect expenses. Pain treatment is no longer a matter of selecting from orally or intramuscularly administered opioids, with a difference of a few dollars. Current treatment options for cancer pain vary by several thousand dollars and range from the orally administered opioid to the epidural opioid with an implanted infusion device.

The development of new technologies to treat pain has led to the creation of a new "health care business." Although orally administered opioids can be expensive, for example, they can exceed \$1,000 a month in high doses, they are not as expensive as the more high tech options. The use of a pump for patient-controlled analgesia (PCA) for a cancer patient, for example, can exceed \$50,000 annually. Moreover, as cancer patients live longer, these costs might be incurred over several years. Epidurally administered opioids are also expensive. The initial cost of placing an epidural catheter can be between \$10,000 and \$12,000. This includes the "initial placement costs, physician fees, hospital charges, and [the] initial cost of a port or infusion device." Costs of the medications delivered intraspinally must also be considered. Other costs associated with high tech pain management may include home nursing care when the technology is provided in the home. One study estimated that such home nursing costs can exceed \$724 a month.

Many of the high tech approaches to pain management can be categorized as surgical and anesthetic procedures, such as "neurostimulators, including implantation of dorsal column stimulators; nerve blocks (spinal injections); neuroablative surgery; initiating central IV [intravenous] lines; placement of implantable pumps or venous access devices; and the placement of epidural catheters." Although the data are thin on the cost effectiveness of these approaches, in terms of costs, they are at the high end of the spectrum of pain management (see Figure 1).

Orally administered analgesia is generally the "preferred route of administration," both because of ease of administration and cost. However, oral analgesics are often "ineffective." This has led to the exploration of alternative, but often more costly, forms of treatment.

Conflicts over coverage and effectiveness

Uncertainties about new technologies has, in a few cases, led to significant conflicts between insurers and providers (in particular anesthesiologists) and their patients. One such dispute rose to the level of a class action law suit. In *Semmler v. Metropolitan Life Insurance Co.*, the plaintiffs, members of the Empire Plan (a medical plan funded and administered by Metropolitan Life Insurance), had received one of two forms of postoperative pain management--either PCA or epidural narcotic administration (ENA). Metropolitan had paid 80 percent of the surgical anesthesia fee plaintiffs incurred on the day of their surgery, but it would not pay any additional bills received from the plaintiffs' anesthesiologists. The plaintiffs sought coverage for these postoperative procedures on the ground that they were "medically necessary." Metropolitan argued that the procedures were not medically necessary and were "not separately reimbursable services." It maintained that:

such pain management is covered by the package surgical fee paid to the physician performing the surgery and to the surgical anesthesiologist. Reimbursing plaintiffs separately for PCA would allegedly amount to double billing because the physician's package fee covers this treatment and because the physician, rather than the anesthesiologist, historically has been responsible for ensuring post operative pain treatment.

The defendant based its decision on "a traditional medical position that post operative pain is the responsibility of the operating surgeon, who prescribes pain medication and monitors the patient during his or her daily rounds in the hospital. The fees for such services are included in the surgical package fee."

The court treated the dispute as a breach of contract, to be governed by the terms of the policy, which state that coverage of all services must be "Medically Necessary" in terms of generally accepted standards as determined by the insurer, Metropolitan. The court denied the defendant's motion for summary judgment, finding that the decisions reached by the defendant were "unclear and ambiguous" and that an issue of fact remained as to whether these services were "medically necessary." In reaching its decision, the court made the following remarks:

In this case, there is a division among medical authorities as to the medical necessity of modern uses of medical technology. In reviewing defendant's arguments, one finds a certain inconsistency. At one point, defendant argues that it does not dispute the medical necessity of post operative pain management. In fact it holds the position such treatment is already represented as part of the surgical package, and is therefore, part of medically necessary services.... On the other hand, it claims that it has held PCA and ENA to be not medically necessary because of the nature of the procedure, e.g., non-doctors administer the procedure.

There has not yet been a decision on the fundamental question in the case, that is, whether the procedures were medically necessary, but the dispute highlights some of the difficult issues confronting the relationship between pain providers and insurers. These include new technology and new ways of delivering treatment, mistrust by insurers that providers are attempting to double bill, and perhaps some uncertainty on the part of insurers as to the need for some forms of pain management.

Chronic nonmalignant pain

While *Semmler* deals with postoperative pain management, and AHCPR's report and much of the pain management literature focus on treatment of cancer-related pain, a potentially more contentious area for providers and insurers is treatment of nonmalignant chronic pain. This area of pain management has "often been neglected, especially among those with nonterminal illness." In addition, it is a category of pain that has not been clearly defined. According to the recently developed clinical practice guidelines on the management of chronic pain in older persons,

[f]or some conditions, chronic pain is defined as pain that exists beyond an expected time frame for healing. For other conditions, it is well recognized that healing may never occur. In many cases, chronic pain is understood as persistent pain that is not amenable to routine pain control methods. Because there are many differences in what may be regarded as chronic pain, the definition remains flexible and related to specific diagnoses or cases.

The guidelines further classify chronic pain, based on pathophysiologic terms, into four categories:

[(1)] *Nociceptive pain* which] may be visceral or somatic ... is most often derived from stimulation of pain receptors. Nociceptive pain may arise from tissue inflammation, mechanical deformation, ongoing injury, or destruction. Examples include inflammatory or traumatic arthritis, myofascial pain syndromes, and ischemic disorders. Nociceptive mechanisms usually respond well to traditional approaches to pain management, including common analgesic medications and nonpharmacologic strategies. [(2)] *Neuropathic pain* results from a pathophysiologic process that involves the peripheral or central nervous system. Examples include trigeminal neuralgia, post-herpetic neuralgia, poststroke central or thalamic pain, and postamputation phantom limb pain. These pain syndromes do not respond as predictably as nociceptive pain problems to conventional analgesic therapy.... [(3)] *Mixed or unspecified pain* is often regarded as having mixed or unknown mechanisms. Examples include recurrent headaches and some vasculitic pain syndromes. Treatment of these syndromes is more unpredictable and may require various trials of different or combined approaches.... [(4)] *Psychogenic pain* results when psychological factors are judged to have a major role in the onset, severity, exacerbation, or persistence of pain.... Examples may include conversion reactions and somatoform disorders. Patients with these disorders may benefit from specific psychiatric treatments, but traditional medical interventions for analgesia are not indicated.

The literature supports the conclusion that the various causes of chronic pain make diagnosis and management difficult. Patients presenting with chronic pain may require extensive diagnostic tests and referral to specialists or multidisciplinary centers.

Anecdotal reports from pain care providers

The literature includes a number of complaints about managed care by physicians who treat pain. They assert that managed care plans may not refer patients when necessary to specialists or pain centers or that they may not make arrangements for patients to receive all of the diagnostic tests they need. According to one pain expert, difficulty in diagnosing the cause of chronic pain "can mean more X-rays, magnetic resonance imaging tests and other expensive diagnostic exams at which insurers, HMOs [health maintenance organizations] or employers with workers compensation costs might balk. The approach also requires access to appropriate specialists, often more than one."

Experts on the management of chronic pain also argue that treatment of patients with such pain "requires a comprehensive approach that pulls together several disciplines, including evaluation of a patient's quality of life, social environment, functioning and psychological state." Yet, some experts complain that insurers and managed care plans deny referral to pain centers and would rather pay for surgical interventions than intensive outpatient rehabilitation provided through a pain center. Pain providers have attributed this reluctance to refer to pain centers to both a lack of understanding of chronic pain as well as a wariness of "unscrupulous or unqualified providers in pain programs." As a result of concerns about qualified pain providers and incentives for primary care physicians (PCPs) not to refer to specialists when appropriate, pain experts assert that patients with chronic pain treated in managed care plans "often don't receive the comprehensive care they should--including a psychiatric evaluation." Moreover, lack of reimbursement or approval for psychiatric care or evaluation can often delay necessary treatment.

From the providers' perspective, dealing with insurers on reimbursement for chronic pain management is especially difficult. The following statement by an anesthesiologist, although in the Medicare context, may sum up providers' frustrations in dealing with insurers on this issue:

Chronic pain management is an even tougher billing headache [than billing for acute pain management] for most offices. Because there are so many options for treatment, everything from physical therapy or psychiatry, biofeedback and hypnosis or implanting spinal pumps and stimulators, and because treatments can go on for months or more, carriers are understandably wary when it comes to paying them.

Response from managed care plans

Managed care plans, for the most part, have been silent on pain management. The literature does not include comments from MCOs in response to these complaints by pain providers. However, one can infer from the literature more generally on managed care that such plans may be concerned about the cost effectiveness of some pain treatment modalities and about treatment by pain specialists or pain centers. In fact, some literature supports their concerns, that is, that managed care plans can offer at least the same results as FFS providers in treating certain kinds of pain, but at a lower cost. A 1995 *New England Journal of Medicine* article found, for example, that, among patients with acute low back pain, the outcomes are similar whether the patients receive care from PCPs, HMOs, chiropractors, or orthopedic surgeons. However, the mean total estimated outpatient charges were highest for the patients seen by orthopedic surgeons and chiropractors; they were lowest for the patients seen by HMOs and PCPs. Some evidence also suggests that clinical practice guidelines, which are more often used in managed care, can lead to more cost-effective care in pain treatment. A study by Health Risk Management, in Minneapolis, Minnesota, found that the use of clinical practice guidelines, advocating conservative therapy in managing 1,796 cases of low back pain or herniated lumbar disk, resulted in significant improvement in the patients' condition, with fewer surgeries than might have otherwise resulted and at considerable cost saving to employers.

Legislative debates

Despite the lack of evidence regarding managed care's performance in treating pain, concerns about managed care and pain management have led to some legislative activity. For example, bills proposed in 1997 in California included Senate Bill 687, which would have required every health care service plan contract issued after January 1998 to provide "current and prospective beneficiaries, enrollees, and subscribers of the plan ... with prescribed information regarding the medical pain management services covered by the plan," and Senate Bill 402, establishing the Pain Patient's Bill of Rights. Apparently responding to concerns that physicians inappropriately deny chronic pain patients access to adequate pain medication or to a physician who will prescribe such medication, Senate Bill 402 provides, "among other things, that a patient has a right to a referral to a physician who is willing to prescribe opioids." Furthermore, it "authorizes a physician who prescribes opioids to prescribe any dosage deemed necessary."

A recent public policy debate on the treatment of pain at the federal level demonstrated the concerns many MCOs have about the elusive nature of pain and the costs associated with its treatment (at least in the emergency department setting). The debate surfaced in June 1997, while Congress was considering the Medicare budget. At issue was a provision in the budget bill that would require managed care plans to cover the cost of emergency care services if a "prudent layperson" would regard the patient's symptoms as requiring emergency care. Senators Bob Graham (D. Fla.) and John Chafee (R. R.I.) proposed an amendment to the definition of emergency medical condition to make clear that "severe pain" alone might be a symptom constituting an emergency medical condition. In opposing the amendment, the American Association of Health Plans (AAHP), the national lobbying organization for managed care plans, argued in its "talking points" that "pain is a highly subjective term and has vast difference in meaning among consumers, depending on their threshold or tolerance for pain." Karen Ignani, president of AAHP, was quoted as asking in response to the debate, "If you have a root canal and experience severe pain, does that justify a visit to the emergency room?" Another managed care lobbyist said "Mr. Graham's amendment would require health plans to pay for patients who stubbed their toes and went to emergency rooms for treatment." This seemingly flippant treatment of pain by the industry sparked heated reaction from pain experts, one of whom made the following comment: "Severe pain can be a sign of serious life-threatening illness. Abdominal pain can be a sign of acute appendicitis. Severe head or neck ache can signal a hemorrhage in the brain. Severe back pain can be an early warning signal of an abdominal aneurysm or cancer of the pancreas."

Palliative care and insurance coverage

The literature on insurance coverage and palliative care, like that on pain management, is thin. And, palliative care, like chronic pain, has not been consistently defined. The 1997 IOM report defines palliative care as care that "seeks to prevent, relieve, reduce, or soothe the symptoms of disease or disorder without effecting a cure."

Most of the literature regarding managed care and its impact on palliative care focuses on hospice. According to a 1995 article on managed care and the provision of hospice care, approximately 80 percent of HMOs pay for hospice benefits. Some attribute the popularity of hospices among managed care plans to the belief that a hospice "provides an effective means by which managed care payers can reduce the costs of

treating terminally ill patients selected as eligible for hospice care." Yet, this belief is not consistently held. In her article, Wolf reports that the

literature suggests that although a hospice benefit is increasingly available within MCOs, it is not universally available. Moreover, mere approval of a patient's entrance into a hospice program does not guarantee the MCO will then approve specific treatments for the patient that may be relevant. In addition, MCO coverage of hospice has been attributed to the cost savings that can be realized by steering terminally ill patients away from acute hospital care to hospice care. Yet, there is a growing debate on whether hospice care indeed generates significant savings at the end of life. This raises the question of whether MCO enthusiasm for hospice care may dampen in the future, and hospice benefits decrease.

Hospice providers also appear to have varied experiences and different levels of enthusiasm for managed care. According to one hospice provider,

[t]here are ... the high-quality [plans] which--though committed to cost containment--look at hospice as a philosophical way of approaching care at the end of life. Once we establish working relationships with them, they tend to leave most of the judgment calls to us. On the other hand, some [plans] give us considerably less leeway. Perhaps it's because their pockets are not as deep.

Because many hospice patients are Medicare beneficiaries and this population is moving into managed care and because the non-Medicare population has already moved in this direction, hospices are having to seek formal affiliations with managed care plans and to adjust to managed care rules. According to one source,

[i]n order to get these contracts [hospices] generally have to settle for less than the Medicare per diem for "commercial" patients: those who for age or other reasons are not on Medicare.... Because there are a dozen or more hospice services in some markets, any hospice that doesn't make such price concessions risks losing its more lucrative Medicare referrals as well as its commercial ones.

Hospice providers also complain that the requirement to offer discounts has some unique detrimental effects on them. Although hospices are generally available to care for individuals with a life expectancy of six months or less, patients often are not referred to hospices until their life expectancy is much shorter--on average they survive only fifty-five days. Those individuals who are closer to the end of life typically require more intensive, more costly services than those who are several months away from death. As a result, hospices cannot average out the per diem rates across a longer period of time as they are able to do with patients who stay longer, making it more difficult for hospices "to make ends meet."

Apart from MCO coverage of hospice care, there is little information on managed care plans and the provision of palliative care. However, some data suggest that elderly individuals in managed care may suffer less at the end of life. According to a 1997 study published in the *Journal of the American Medical Association*, elderly patients in HMOs are less likely to get "prolonged, costly--and ultimately futile--care than those with traditional Medicare coverage." Such care is often associated with prolonging a painful death. The results of the study, however, were not without controversy.

Finally, aside from the hospice literature, there is a significant body of literature asserting that palliative care is not adequately financed. Medicare, for example, does not yet provide reimbursement for palliative care in the hospital setting, although the Health Care Financing Administration (HCFA) has initiated a demonstration project with an ICD-9 code for palliative care in the inpatient setting. Furthermore, Medicare does not cover prescription or over-the-counter drugs, a primary treatment for pain.

Literature summary

The literature on pain management, palliative care, and insurance coverage is sparse, and what exists provides insufficient data from which to derive a clear and objective picture of the role of managed care or insurance coverage, more generally, in the treatment of pain. What is available is largely anecdotal and comes primarily from providers.

Study of Blue Cross Blue Shield Plans

Background

To fill some of the information void on the role of commercial health insurers in the coverage of pain treatment and palliative care, researchers at the University of Maryland School of Law interviewed senior medical directors (SMDs) at BCBS Plans across the United States. The specific purpose of the interviews was to determine (1) the level of awareness among SMDs about their health plans and the problems of pain management and palliative care; (2) what, if anything, their plans have done to address these issues; and (3) what obstacles their plans face in addressing these issues.

BCBS was chosen as a vehicle to study this issue because BCBS operates in every state and offers the full range of health insurance products, including traditional indemnity plans, hybrid plans (that is, preferred provider organizations (PPOs) and point of service plans), and HMOs. BCBS Plans also serve the commercial insurance population and portions of the Medicare and Medicaid populations. Overall, BCBS Plans serve about 25 percent of the nation's insured population, or 68 to 70 million individuals. Of this number, approximately 12 million are in HMOs and 22.5 million are in PPOs. No single U.S. insurer or managed care plan covers this number of HMO members.

The BCBS Plans are loosely affiliated through the national Blue Cross Blue Shield Association (BCBSA). BCBSA is a confederation of fifty-five separate companies (or plans) that are licensed by the Association to use the BCBS name. Although BCBSA serves as the licensor for each of the fifty-five plans, each plan operates independently, has its own policies and procedures, and offers its own health insurance products. Nationally, BCBS offers over eighty HMO products. The volume of patients served by BCBS and the variety of products offered provides a unique opportunity to look at similarities and differences among the products in terms of how each deals with pain relief.

Methodology

A draft questionnaire was developed based on a literature review and consultation with the chief medical director of BCBS of Maryland. Staff at the University of Maryland Pain Clinic and its billing department were also consulted to determine some of the issues the Pain Clinic faces regarding insurance or managed care reimbursement for pain treatment. The questionnaire asked specifically whether the issues of (1) pain management for the terminally ill, (2) palliative care for the terminally ill, (3) pain management for chronic pain patients, and (4) opioid abuse by chronic pain patients have been identified at the SMD level as an issue requiring greater attention. If so, the questionnaire asked whether the plan had devoted additional attention and/or resources to the issue; and, if it had, in what way. The questionnaire also asked whether a decision had been made at the plan level (that is, across product lines) to cover or exclude from coverage specific pain treatment modalities, for example, transcutaneous electronic nerve stimulator (TENS) units, implanted pumps, nerve blocks, behavioral interventions, acupuncture, and so forth. Initially, the questionnaires were to be mailed to all plan SMDs.

Prior to finalizing the questionnaire, a draft was distributed to BCBS medical directors participating in a BCBS Northeast Medical Directors Conference in Annapolis, Maryland, on September 5, 1997. Approximately fifteen conference participants reviewed the survey questionnaire. These individuals were asked to provide feedback on the survey design and draft questionnaire. Based on this feedback, the survey questionnaire and data collection approach were revised. The medical directors strongly recommended that the initial survey be conducted in person or by telephone in order to receive a useful response rate. In addition, several indicated that a difficult issue for them in dealing with pain management was recognizing qualified pain experts. Following their suggestion, we included a question to address this problem.

The initial data collection was conducted by in-person interviews of BCBS SMDs attending a national conference in Chicago, Illinois, on October 13-14, 1997. Thirteen interviews were conducted. Efforts were made to contact the remaining plan SMDs by telephone. Interviews were conducted by the author and two research associates. The telephone interviews were conducted between November 1997 and July 1998.

Response rate

We conducted interviews with 39 SMDs or their designees (13 in person and 26 by telephone). These SMDs came from thirty-five plans. Thus, we received responses from 35 of 55 (64%) of all BCBS Plans. In four cases, two medical directors within the same plan were interviewed because each had knowledge about

different areas of the plan (either geographic or product line). Both sets of interviews are included in the results in terms of comments made, however, the two responses were counted as one for statistical purposes. Seventeen plans did not participate either because we were unable to reach the SMD or because the SMD refused to participate or referred the matter to another appropriate senior-level medical administrator. The most common reason given for refusal to participate was lack of time. In several instances, plans were undergoing significant reorganizations, and SMDs, as a rule, were not participating in any external surveys. Although the percentage of all BCBS Plans represented in the survey responses is high, a potential exists that those that did respond represent a disproportionately high percentage of the plans that are sensitive to this issue. We do not have any data to confirm this potential bias or reason to believe the respondents were more sensitive than nonrespondents to this issue.

Results

Given the nature of the questions, a wide range of responses were provided for each question. An effort has been made here to categorize some of the answers; however, in some cases, answers were unique and are reported as they were recorded by interviewers.

Pain management for terminally ill patients

In response to the question "Has pain management for terminally ill patients been identified by your Plan as an issue requiring special attention?," 13 (37%) of responding SMDs said yes; 20 (57%) said no. Reasons why it was brought to the SMDs' attention varied significantly, but can be categorized as (1) personal awareness of the issue by the SMD as a result of media coverage or other experience ("personal concern carried over from former position as head administrator for State of California nursing homes" and "media attention, literature, concern of 'under medication'"); (2) case management issues ("primarily surfaced through individual cases brought by case management nurses at weekly rounds--sense grew that coverage may not be meeting needs"); (3) employer motivated ("employer request; individual cases"); (4) hospice experience ("have had hospice for over ten years" and "by public and hospice; literature from Medicare"); and (5) provider requests ("requests from providers who want contracts with BC/BS"). Some indication also surfaced that the attention was cost- or utilization-driven ("creative claim filing by insured's physicians"; "medical necessity claims--physicians prescribing increased"; and "multiple requests for precertification").

Of those who said pain management for the terminally ill was an issue requiring special attention, 10 of 13 (77%) had developed a specific response or had devoted additional attention to the issue. The types of responses included: (1) contractual arrangements with or establishment of a hospice; (2) development of a pain management program; and, most frequently, (3) an attempt to develop guidelines or policies on pain management.

Other responses included the following:

- "established oncology care group and case management";
- planning to "develop packet of information directed to primary care physicians on care and techniques for pain control and palliative care";
- "working group discussed proper response to pain as part of total patient care approach"; and
- "statewide discussions about pain control and medical response [involving individuals outside of BCBS]."

In response to the question "Do you intend to commit additional resources to this issue in the future?," of the 13 who said this issue had been brought to their attention, 4 SMDs said yes; 5 said no, they were already adequately dealing with it; and 4 said they were uncertain. Of those who said yes or that they were unsure, some of their plans included: applying for a grant to look at uses of palliative care and working with a rehabilitation organization on a grant for pain control; "establishing a working group (physician management groups hold discussions of alternative methods of care)"; and "clarifying benefits and policies, developing consistent medical policies, then developing contracts." One respondent said he hoped "that this survey will give direction to establishing a quality improvement project that can be offered to physicians and [others]." Of those who said they had not or did not plan to develop a specific response, virtually all said that the issue was adequately dealt with through existing mechanisms, including arrangements with hospices.

The thirteen plans indicating that pain management was an issue requiring special attention were subsequently asked what level of priority the issue was given in the list of medical issues confronting the plan and to compare its priority with that of mental health issues. Specifically, SMDs were asked to indicate whether these issues were one of their top five, top ten, or top twenty priorities. Eleven plans responded. All but one ranked mental health as equal to or greater in priority than pain management for the terminally ill. Two plans gave the two issues equal priority. Only one said that this issue ranked in its top five priorities. Another plan said it ranked in its top ten. The remaining nine plans did not give pain management for the terminally ill significant priority. (See Table 1 for a comparison of the priority given to pain management for the terminally ill, to chronic pain management, and to mental health issues.)

Palliative care

In response to the question "Has palliative care been identified in your Plan as an issue requiring special attention?," 40 percent of plan SMDs said yes. Of those who said yes, some stated specifically that it was an issue with respect to policies for home nursing and hospice charges, that the issue focused on oncology patients, and that the issue was raised only as it related to pain medication and abuse. One respondent said that the issue was defining "palliative care." Of those who said palliative care was not an issue, several indicated that it was dealt with through arrangements with local hospices. Of those who said it had come to their attention, the reasons given for why it came to their attention included: (1) case management ("Case management nurses bring attention to individual cases"); and (2) problematic relationships with hospices ("fraud by hospice (national for-profit chain)" and the "hospice in particular wants to bundle charges into one fee, whether or not all services are needed or provided").

Two respondents also indicated that the issue came to their attention through employer requests. One indicated that the local ethics consortium had identified it as a concern. Two respondents indicated that they had become involved with an effort to apply for a grant to look at the issue. One said it was identified because the plan was "trying to determine what pain management, including palliative care, medications, and technology will be paid for." Another said the issue was identified by "staff, psychiatrists, medical director of Blue Cross whose family member was a patient."

Of the fourteen plans that identified palliative care as an issue requiring special attention, ten (71%) had developed a targeted response or devoted additional attention to the issue. Types of responses, by category, are listed below.

(1) Established a working group

- "established a working group which established guidelines and then contracted with another hospice group" (in response to a fraud experience with another hospice); and
- "established a working group which so far has had two meetings with across company representation; working with hospice."

(2) Applied for grant or participated in study

- "home health director has applied for grant to look at uses of palliative care; also working with a rehab organization on a grant for pain control";
- "cooperating in study with local university"; and
- "focused a study on public awareness and education. Study identified patients who opt for palliative care and then were randomized to group getting extra education."

(3) Contracted with a hospice or developed own hospice unit

- "contracted with various hospice organizations for care; is a fully covered benefit";
- "developed a special hospice unit"; and
- "developed a palliative care program; involved in a pilot program working with a local hospice."

Eight of the fourteen SMDs (57%) who said palliative care was an issue that had come to their attention stated that they planned to commit additional resources to this issue in the future. The types of activities envisioned included developing a palliative care program to enhance disease management; increasing staff working in contracts and audits to make sure they do not establish a relationship with a hospice engaging in fraud; sponsoring workshops or conferences on palliative care to educate providers and members; standardizing hospice benefits across products; identifying barriers to appropriate care; exploring ways to raise public awareness; and reviewing hospice policy to see if it meets newer needs. Of those who had not

and did not intend to develop a response to this issue, most claimed that it was adequately dealt with through existing mechanisms.

Management of chronic pain

In response to the question "Has pain management for patients with chronic pain been identified in your Plan as an issue requiring special attention?," 23 SMDs (67%) said yes and 12 (33%) said no. Explanations of how or why the issue came to their attention varied by plan, but some common elements included: (1) lack of uniformity by plans in response to claims for coverage; (2) concerns about fraud or inappropriate treatment (in some cases, treatment received at pain centers); and (3) high-cost users identified by various screening mechanisms. Specific responses falling within these categories are listed below.

(1) Lack of uniformity in plan response

- "providers desired to obtain coverage, there was no uniformity of response or benefits from BC plan or products";
- "claims department--no policy to guide refusals";
- "inpatient pain management requests are covered by a specific benefit, but out-patient treatment is a problem as they do not have alternative and so must be handled on an individual basis"; and
- "amount of utilization; indemnity issues; lack of coherent response to individual cases of complaints and abuses, mainly in spinal care."

(2) Concerns about fraud or inappropriate treatment

- "fraud division [of plan] alerted us to abuse in management of pain";
- "fraud in pain management";
- "brought up by pharmacy director and medical review; issue centers [on] individual patient's chronic over use and abuse";
- "inadequate and inappropriate care, fraud";
- "utilization review noted that the number of epidural blocks was rising when it was not considered particularly effective";
- "issue came up because of overuse and misuse through pain management centers ..., especially inpatient admissions for epidural infusions";
- "increasing number of referrals for injections by anesthesiologist";
- "trouble figuring out how to pay for these things [pain]; problem with existing pain centers which bill inappropriately and overutilize"; and
- "utilization review noted problem with increase in number of preapprovals requested for admission to inpatient pain clinic and increase in requests for services of freestanding chronic pain clinics, for example, [for treatment of] headaches."

(3) High-cost users

- "question arose as to whether multidisciplinary chronic pain programs are covered";
- "perceived need by MCO; patients fell outside of norm in terms of resources consumed, costs incurred"; and
- "anecdotal, case by case basis; disputes over mental health coverage; plan does screens of patients getting large amounts of pain medication and patients not seen by physician in a long time; claims analysis for medical necessity of inpatient stays; unusual or inappropriate requests."

Those twenty-three plans responding that management of chronic pain had been identified as an issue requiring "special attention" were subsequently asked what priority was given to chronic pain management at the plan level and to compare that with the priority given to mental health issues. Of the fourteen plans that responded, nine said that mental health was of higher priority, two gave them equal priority, and three gave greater priority to chronic pain management. One SMD said that this issue was one of the plan's top five priorities; five put it in their top ten priorities; the remainder did not give it significant priority. Overall, management of patients with chronic pain appears to be given higher priority than pain management for terminally ill patients.

Twenty of twenty-three (87%) respondents who stated this issue had come to their attention said they had either developed a special response to the issue or devoted additional resources to it. The types of responses included: (1) establishing a working group to develop guidelines for pain treatment; (2) hiring

consultants; (3) sponsoring workshops or conferences or other educational approaches; and (4) developing policies. Examples of responses within each of these categories are listed below.

(1) Established a working group

- "established a working group; worked with pain management specialists from the community; effort lasted for one year and did not succeed; were unable to come to agreement on appropriate guidelines for dealing with chronic pain"; and
- "established a working group; anesthesiologists working with BCBS committee to establish guidelines for both acute and chronic pain."

(2) Hired consultants

- "Hired a consultant; consultant panel helped identify and flag specific providers who are in pain management";
- "Working with local Institute exploring provision of guidelines, networks of pain management centers as well as direct patient care; are at the stage of reading and meeting; no contract signed with Institute but looks like promising relationship; is a very big issue";
- "Hired a consultant; contracted with organization known as ... that provides consultants to better organize care within oncology. Problems with chronic pain immediately surfaced"; and
- "Hired a consultant; attempted to bring academic pain management centers together with other centers to discuss conflicting opinions regarding treatment, but have been unsuccessful; will try again."

(3) Sponsored conferences or other educational approaches

- "sponsored workshop or conferences; people involved in pain management now come to medical panel meeting to advise and assist with policy";
- "sensitized staff but main efforts will be upcoming oncology group meeting"; and
- "convened symposium of all pain constituents in the state to define what is in a pain program, how to assess and treat pain."

(4) Developed policies

- "developed policies; Commonwealth [of Puerto Rico] now requires pain management specialists must be certified to practice; Blue Cross may only use certified practitioners";
- "Developed policies for proper pain block techniques"; and
- "developed policies; created managed care and claims payment policy."

Of those who said this was an issue that had come to their attention, eleven (48%) indicated that they planned to commit additional resources to the issue in the future. The types of activities planned focused on establishing policies or guidelines for pain management ("develop policies; continue to work with M.D. pain specialists to develop guidelines; one large area is the need to delineate ICD9 coding for various types of pain" and "hire a consultant; need to work with consultant to establish pain guidelines").

Of those who said they had not developed or did not plan to develop a response, most (six of nine) said they adequately dealt with the problem through existing mechanisms. Two of nine said it was not a high priority.

Addiction to opioids

In response to the question "Has addiction of opioid medication for the treatment of pain been identified by your Plan as an issue requiring special attention?," twelve respondents (34%) said yes. The primary vehicle through which opioid addiction came to the attention of those who said yes was pharmacy data: "pharmacists had data, so it was an issue we could respond to"; "analysis of pharmacy data/claims"; "pharmacy claims review process; claims screens--look at emergency room data and pharmacy experience"; and "pharmacy recognition of over-utilization, in particular in conjunction with headache center admissions." Other reasons are listed below:

- "inpatient detox case--abuse or rehabilitation";
- "increasing number of physicians who reported cases of their patients who had become non-functioning while taking opioid med[ication]s";
- "chronic pain patient was addicted and needed services because patient had exhausted all BC/BS providers";

- "patient wanted an override on pharmacy benefits so medical director investigated; led to a formal grievance against the physician who was prescribing"; and
- came to our attention through "risk management, utilization management."

Of the twelve plans that identified this as an issue requiring special attention, eight SMDs said they had developed a special response or devoted additional attention to it. These responses, for the most part, involved developing ways to identify high-volume users, communicating with physicians about the problem, restricting patients to a single physician, and limiting coverage of narcotics.

Two plans intended to do more about this issue in the future. One SMD indicated the plan intended to coordinate different departments to tackle the problem and to establish case management dedicated to this issue. Another said the plan would continue to develop a full spectrum pain program taking this issue into account. Those who said they did not intend to do anything more felt that the issue was being adequately addressed through existing mechanisms. Table 2 summarizes the level of awareness and activity of BCBS Plans regarding the four issues explored.

Coverage of specific pain treatment modalities

SMDs were asked whether their plans explicitly did *not* cover some of the more high tech as well as nondrug alternatives to pain management. These alternatives included: behavioral interventions, such as biofeedback and stress management; acupuncture; implanted pumps; TENS units; and nerve blocks.

Most plans did not cover behavioral interventions. Sixteen of 35 SMDs (46%) said categorically that their plans did not cover behavioral interventions. An additional six said specifically that their plans did not cover biofeedback. Thus, 22 of 35 plans (63%) explicitly do not cover biofeedback. One SMD said that his plan did not cover stress management. One respondent said the plan did not cover biofeedback but did cover stress management. Another indicated that behavioral interventions were covered through mental health benefits (with prior authorization). He also said that, at this time, "criteria are outdated." Three respondents said that coverage decisions were made on a case-by-case basis.

One plan, which provided its policy language, stated specifically that biofeedback "is not covered unless specially added to the subscriber certificate" and that, even when "biofeedback is covered by the certificate, it is NOT covered for muscle tension or psychosomatic conditions." With regard to their Medicare members, however, the policy states:

Even though biofeedback is not proven, for our Blue Care 65 members only, we must provide coverage according to local Medicare guidelines, when biofeedback is "reasonable and necessary" for:

- re-educating specific muscle groups or
- treating pathological muscle abnormalities such as spasticity, incapacitating muscle spasm, or weakness (muscle tension does not qualify)
- when conventional treatments (heat, cold, massage, exercise, support) have not been successful.

Twenty-eight plans (80%) explicitly did not cover acupuncture; however, one SMD said that, even though it had not been covered historically, the plan had announced that it would cover the procedure for chronic pain beginning in July 1998, in accordance with the recommendation of a National Institutes of Health (NIH) consensus committee. Of those who said it was not covered under their plan, two were reconsidering this policy. Another SMD thought his plan would cover it in the future. One stated that, although the plan did not generally cover it, it considers individual requests. Two said that although most contracts did not cover the procedure, some did. Policy language from one plan states that:

We do not cover acupuncture, except for members of the accounts who had added a special addition to their subscriber certificate to cover this service. For those members, acupuncture is covered for any diagnosis. However, the National Institutes of Health (NIH) has concluded that acupuncture is promising for the following conditions:

- adult post-operative nausea/vomiting
- chemotherapy nausea/vomiting
- post-operative dental pain

The NIH also concluded that there were other situations for which acupuncture may be useful as an acceptable alternative, or as part of a comprehensive management program: nausea of pregnancy, addiction (but not for smoking cessation), stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma.

Six of 35 plans (17%) did not cover implanted pumps. One of the six did not cover pumps for terminal pain; another did not cover pumps for chronic pain. Four other respondents said that coverage was determined on a case-by-case basis. Of the thirty-five plans, ten (29%) said they did not cover TENS units. One SMD said that the plan covered the treatment, but that patients needed prior authorization. Policy language provided from one plan states:

We do not cover TENS units (... [except] for Blue Care 65 patients ...) because they have not been proven to be more effective than placebo-TENS in treating any clinical condition, including the following:

- chronic back pain
- pain associated with child birth
- chronic pain
- post-surgical pain

As regards Medicare patients, the policy states:

We cover TENS units for Blue Care 65 members only, in accordance with HCFA regulations, under the following circumstances, even though it is not proven:

- chronic pain not responsive to other methods of treatment; pain must be longer than 3 months duration. Headache, deep abdominal pain, pelvic pain, and TMJ (jaw joint) are NOT eligible for coverage.
- Acute post-operative pain, only in the first 30 days after surgery.

All respondents said their plans covered nerve blocks. See Table 3 for a summary of coverage decisions.

Respondents were also asked if other specific pain care modalities were not covered. Responses varied considerably and were often specific. Many fall under the category of alternative medicine.

Finally, respondents were asked to explain why their plans had decided not to cover a certain item. Behavioral interventions (in particular, biofeedback) were not covered largely because they were considered ineffective, although some plans were reviewing their policies (the "benefit exclusion is being reevaluated by medical affairs").

As regards acupuncture, again, most SMDs indicated that they had determined or literature review has found that it was not effective ("Outcomes unclear, lack of scientific validation" and "it's our medical policy developed after review of the literature established a lack of scientific validation of effectiveness"). Two respondents acknowledged that acupuncture had been deemed ineffective in the past, but that this might change in response to a recent NIH report. One respondent stated that it was not covered by the plan because it "needs to be performed by an MD and none have ever billed for it."

Concerning why implanted pumps were not covered, one respondent claimed that they had not been requested; another said they were not effective for chronic pain. For TENS units, responses included: "national [BCBS] policy"; "technical assessment review done by medical policy group [found the procedure to be ineffective]"; and "unproved technology."

Experts on pain management and palliative care

In response to the question "Do you have available to you either in-house or out of house an expert or consultant on pain management?," 28 of 35 Plans (80%) said yes. In response to the same question about palliative care, 13 of 35 (37%) said yes. Respondents were also asked to describe the expert's or consultant's background and experience in each area. Most experts in pain management had backgrounds in anesthesiology. In some cases, the anesthesiologist had "pain management certification" or was board certified. For example, one respondent said he used a part-time consultant who is board certified in pain management and is a practicing anesthesiologist. In another case, the "expert" had done a fellowship in pain management. In other cases, the anesthesiologist simply had an interest in pain management. The backgrounds of other pain specialists were neurology, pharmacy, behavioral psychology, neurosurgery, family medicine, and psychiatry. In three cases, the expert was on the faculty of a state medical school. In two cases, plans relied on consulting firms, some with expertise in chronic care rehabilitation.

As regards experts in palliative care, the most common background was oncology, and often the individual also worked with hospice patients. One respondent admitted that he was unsure what constituted an expert in palliative care.

Of those five who did not have a pain management expert available to them, one expressed a desire to have such an expert, three said they did not want one, and one said "maybe ... [it] depends on who, oncologist--yes, pain clinic--no." Of those nineteen who said they did not have an expert in palliative care on staff or available on a consulting basis, seven said they would like to have one. One of these respondents added that his plan was interviewing for an additional medical director and was looking for someone with palliative care expertise. Nine respondents said no, they were not interested, either because palliative care had not been identified as a problem or because they did not see the need for such expertise.

Significant findings

Lack of uniformity

Our most significant finding was that BCBS Plans seem to deal with treatment of pain and coverage issues on a case-by-case basis (often through case managers) and, for the most part, have not established uniform pain treatment or coverage guidelines. The data reveal inconsistencies in plan approaches due to different levels of awareness of and attention paid to the problem; uncertainty and lack of consensus in how to approach pain management, in particular, the management of chronic pain; and different experiences with hospices, pain treatment specialists, and pain centers. This finding of inconsistency appears to affirm the comments, of one group of providers (anesthesiologists), that

[p]ain management is considered a mystery by many payers. [They must be educated] both in conversation and in documentation, on pain control services, how they work and why they're needed by patients with particular diagnoses. Because there are so many options of treatment, particularly with chronic pain, and because its success is tough to quantify, pain management is known as a "murky" field.

The results are also consistent with the comments of one provider who heads a pain rehabilitation center. He asserts that "[c]linical criteria for obtaining authorization for care ... are as variable as the plans, with no discernible patterns."

Treatment of chronic pain

As is consistent with the literature, our data suggest that treatment of patients with chronic pain is of concern to more plans than treatment of pain or palliative care for terminally ill patients. Over two-thirds of the plans (67%) responded that chronic pain management was an issue requiring special attention as compared with approximately 40 percent of the plans that responded that pain management and palliative care for terminally ill patients was an issue requiring special attention. The most obvious reason for this heightened concern is the increased utilization of health care services and associated costs with treatment of chronic pain. A number of SMDs, in fact, indicated a concern regarding high-cost users. Moreover, considerable uncertainty and lack of consensus seem to exist about how to manage or treat chronic pain patients. This was evident in the responses from two plans. One respondent said that his plan had brought together experts in pain management from the community to develop guidelines or a consensus approach to treatment of chronic pain patients, and, although they had met during the course of a year, the effort had

failed because participants were unable to reach agreement. The other stated that his plan had hired a consultant and had attempted to bring academic pain management centers together with other centers to discuss conflicting opinions regarding treatment, but that they were also unsuccessful.

Another finding relevant to the treatment of chronic pain patients was the significant mistrust some SMDs had of pain management centers. There was strong sentiment that these centers often treat inappropriately and that some engage in fraudulent practices. One SMD specifically stated, "I wish I could share with you the abuse we find in record review of pain centers." A number of plans appear to be searching for a way to determine whether a pain center is, in fact, a quality provider.

Treatment of terminally ill patients

As stated above, care of terminally ill patients both for pain and, more broadly, in the context of palliative care was not recognized by the majority of plans as an issue in need of special attention. Plans had established few guidelines in this area, other than referral to a hospice provider. Experts in palliative care have not been identified by most plans and, although the American Board of Hospice and Palliative Medicine certifies physicians specializing in palliative medicine, most states have very few physicians in this category. Some medical directors were uncertain what palliative care is and who a specialist in it is.

Despite this lack of awareness on the part of a few SMDs, most felt they were adequately dealing with this aspect of plan members' care. This type of care was most often provided through a contractual relationship with a hospice. In some cases, the plans seemed to have a good working relationship with a local hospice provider. In others, that relationship had problems. One plan referred to fraud on the part of the hospice, another referred to "bundled" billing charges.

Coverage of specific pain treatment modalities

Our study asked explicitly whether plans excluded from coverage any of the following: behavioral interventions, acupuncture, implanted pumps, TENS units, and nerve blocks. Virtually all plans covered nerve blocks and most covered TENS units and implanted pumps. By contrast, the large majority did not cover alternative therapies such as acupuncture or biofeedback, primarily because they are considered ineffective.

Discussion and explanation of findings

Pain control as an area of practice

Perhaps the primary reason for the lack of a consistent approach to coverage and treatment of various pain care modalities was best expressed by an SMD who said, "This is not an established area of medical practice with a wide network of practitioners and accepted methodology by the provider community." While guidelines for pain treatment are emerging, they are all relatively new. For example, it was not until 1990 that the World Health Organization published guidelines on cancer pain treatment, and 1992 when the American Pain Society (APS) published guidelines on analgesic medication for acute pain and cancer pain. More recently, AHCPR has developed guidelines on the management of acute and postoperative pain, on the treatment of chronic cancer pain, and on the management of acute back pain. Guidelines on the treatment of nonmalignant chronic pain, however, have been largely neglected. Only after the data collection effort for this study of BCBS Plans was completed did the American Geriatrics Society publish its clinical practice guidelines on the management of chronic pain in older persons. Moreover, it was only in 1991 that the American College (now Board) of Pain Medicine was established. This organization conducts examinations and provides certification for physicians in pain medicine. And, it was not until 1993 that the American Board of Medical Specialties (ABMS) approved a specialty in pain management for board-certified anesthesiologists.

Randomized controlled trials and evidence of cost effectiveness

Although some treatment guidelines are now available, they do not appear to have been widely adopted and not all have been based on or subject to randomized, controlled studies for purposes of verification. Even where trials have been conducted, the results do not appear wholly to guide the recommendation of the

guideline drafters. For example, the recently developed clinical practice guidelines on management of chronic nonmalignant pain for older persons state that "[n]onpharmacologic approaches, used alone or in combination with appropriate pharmacologic strategies, should be an integral part of care plans for most chronic pain patients." The authors admit that "[a]lthough many of these interventions provide short-term relief, few have been shown to have greater benefit than placebo controls in randomized trials for the long-term management of chronic pain in older people." Yet, they recommend the use of these alternatives in combination with appropriate drug regimens as they "often improve overall pain management, enhancing therapeutic effects while allowing reduction of medication doses to prevent or diminish adverse drug effects."

Although these are treatment, not coverage, guidelines, BCBS Plans would be unlikely to provide coverage of these nonpharmacologic approaches under these circumstances. For example, the decision of most plans not to cover behavior therapies, biofeedback in particular, is consistent with the recommendation of BCBSA's Medical Advisory Panel (MAP). The panel's decision was based on a review of the available literature by BCBS's Technology Evaluation Center to determine whether biofeedback improves health outcomes. The assessment, dated January 1996, states that

There were 9 conditions for which controlled studies of biofeedback have been reported in the literature. These conditions are anxiety disorders, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud's disease, and insomnia. The available literature on other indications consisted of reports of uncontrolled studies. Most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction. The evidence does not suggest that biofeedback adds to relaxation exercises or behavioral instruction in improving health outcomes. Although a substantial number of studies reported improvement in the biofeedback group relative to the no-treatment group, there were generally no differences when biofeedback was compared with relaxation or behavioral therapy alone.

Plans also followed the lead of BCBSA's MAP in its decision not to cover acupuncture. In its assessment, issued January 1997, MAP stated that "Twenty-nine randomized placebo controlled trials of acupuncture for pain were identified. No clear answer regarding the efficacy of acupuncture in the treatment of pain emerges from these studies."

The recent evidence that acupuncture may be effective for some types of pain, as put forth in the November 1997 NIH consensus statement, seems to be influencing some SMDs about the merits of this therapy. As a result, some plans may soon begin to cover acupuncture for some types of pain.

Although the majority of SMDs said that their plans cover TENS units for pain treatment, this was not consistent with the recommendation of BCBSA's MAP. In its January 1997 assessment, it stated that "[w]hile early studies, comparing TENS to no treatment, appeared promising, recently there has been growing concern regarding the efficacy of this treatment relative to placebo." The assessment concluded that "TENS for the management of chronic or postoperative pain does not meet the Blue Cross and Blue Shield Association Technology Evaluation Center criteria." It is not clear what accounts for the divergence between BCBS Plan policies and the MAP recommendation other than, perhaps, a greater difficulty in denying coverage once it has been provided.

Most plans do cover implantable pumps, even though BCBSA's MAP has not conducted an assessment of this pain care modality. These pumps are designed to deliver morphine or other drugs directly into a patient's spinal fluid. Some evidence in the literature suggests that such pumps are cost effective, but only for a certain category of patient. These include patients "who've tried all of the more conservative treatment options but are still in excruciating pain. In those cases, analgesic pumps are more cost-effective, despite higher initial costs." These considerations are evident in Medicare coverage policy, which states that "Medicare covers implantable infusion pumps for the administration of opioid drugs for chronic, intractable pain in patients who have a life expectancy of at least three months and who have proven unresponsive to less invasive medical therapy."

The findings for some of the modalities, for example, biofeedback and TENS units, indicate that some plans do not cover these approaches for their commercially insured subscribers but do cover them for their Medicare beneficiaries. This fact also illustrates the lack of consensus and consistency on the part of payers about the effectiveness of these interventions.

Views regarding cost effectiveness may also influence plan decisions, especially in the managed care context. Most plans may not explicitly consider cost effectiveness in making coverage determinations because their contract language states that they will cover a procedure or proposed treatment if it is medically necessary. However, cost may be a factor in a managed care setting if lower cost treatments are considered as effective as a proposed alternative. Few studies assessing cost effectiveness of alternative pain care modalities have been conducted. This may contribute to the inconsistency across managed care plans regarding coverage or reimbursement for different pain management techniques.

Measuring effectiveness

Agreement on what is effective and cost effective in pain management has been hindered because pain is subjective and hence difficult to measure. As one group of providers stated when describing their difficulties in obtaining reimbursement for pain treatment from Medicare, "pain relief is highly subjective and therefore difficult to quantify and document. Consequently, billing and reimbursement policies vary widely from carrier to carrier." This point was also made by AHCPR's Cancer Pain Panel, which stated:

pain relief has been viewed only in subjective terms as the relief of suffering. As such, it is difficult to put a price tag on comfort. Questions of cost are further diminished as the outcome of care becomes centered on the quality of life rather than traditional measures of morbidity, length of stay, or direct treatment costs.

The provision of palliative care in the hospice setting provides a good example of the difficulty in assessing effectiveness based on outcomes. There are only a few authoritative studies on the "effectiveness" of hospice, and the industry itself has done little research on its services. One possible reason for the lack of agreement on hospice effectiveness is that the outcomes associated with hospice are not improved health status, but less tangible or measurable outcomes, such as improved comfort, reduced depression and grief, and improved psychological status on the part of patients' family members.

Attitudes toward and experience with pain providers

Some SMDs admitted that they mistrust pain centers and suspect fraud by hospices. These accusations have some merit, at least in Medicare reimbursement. In 1996, the Office of the Inspector General targeted fraud among hospices based on abuses uncovered in Puerto Rico and Florida. A 1994 audit of Puerto Rican hospices found such abuses as patients admitted to hospices with a primary diagnosis of arthritis, a disease that is rarely fatal, and large numbers of patients who were being cared for for more than seven months. Auditors found that two-thirds of these individuals were not terminally ill and should not have been admitted to a hospice. A Medicare Advisory Bulletin listed the following questionable practices by hospices:

incorrect determinations of an individual's life expectancy for purposes of meeting hospice eligibility criteria, marketing/sales strategies that offer incomplete or inadequate information about Medicare entitlement and restrictions under the hospice and thereby [encourage beneficiaries to] waive other treatment benefits; encouraging beneficiaries to temporarily revoke their election of hospice during a period when costly services covered by a plan of care are needed so that the hospice can avoid the obligation to pay for these services.

Such experiences may taint plan-hospice relationships or make plans more cautious in establishing relationships with hospice providers.

Attitudes toward treatment of chronic pain

Differing attitudes toward the use of opioids for the treatment of chronic pain may also contribute to the lack of uniformity in BCBS Plans' approaches to treatment of pain and coverage of pain care. Although our survey did not directly explore SMDs' attitudes in this regard, their identification of addiction to pain medication as an issue requiring further attention raises a question as to which school of thought plans subscribe regarding the role of long-term opioid use to control chronic nonmalignant pain. Experts now generally agree that "a selected population of patients with chronic pain can attain sustained analgesia [with opioids] without significant adverse consequences." According to Dr. Russell Portenoy, an expert on pain management, "[t]his perspective ... is not uniformly accepted by pain specialists and has not been widely disseminated to

other disciplines or the public. Rather, the more traditional perspective, which ascribes both transitory benefit and substantial cumulative risk to long-term opioid therapy, continues to predominate."

The traditional view results in withholding opioid therapy "for all but the most extreme cases of chronic nonmalignant pain." A clue to how some plans approach the issue is provided by policy language from one plan document. Although in the context of a policy for Methadone Treatment for Opiate Addiction, the definition of "opiates" provided is suggestive of the predominant view:

Opiates are narcotic drugs such as morphine, heroin, and others. Morphine is used to treat severe pain short term, or in dying patients. Opiates are not often used long-term, because they are addictive. However, in some cases, these drugs are used long-term in people with severe, chronic pain. Once a person is addicted, if they were to suddenly stop taking the opiate, they might go into "withdrawal," including uncomfortable and sometimes serious side effects.

Pain specialists

Another reason for the inconsistency in insurers' approaches to pain management may be the uncertainty surrounding the need for referrals to specialists in the treatment of pain. This question seems to arise most often in managed care where pain specialists criticize plans for failure to approve referrals of patients to pain specialists. Yet, again, there are no authoritative guidelines as to when referral to such specialists is appropriate. One palliative care physician with whom I corresponded argued forcefully that such referrals are rarely appropriate. "Pain," she said,

is a problem that everyone tries to avoid recognizing and thus it becomes like the monster in the closet--big, frightening, and blown out of proportion. As long as this mystique is maintained, everyone will believe that managing it is very difficult and requires expertise beyond that of the general practitioner. In fact, every general practitioner should be able to manage 80% of the pain experienced in our country. All one needs to do is follow a set of guidelines developed by the World Health Organization in the 1980s. This is not rocket science but it is very time-consuming. It is unconscionable that pain is not relieved. We are caught up in the Judeo-Christian work ethic that says we must be tough; grin and bear our adversities. What nonsense--someone should do a cost analysis of the time lost at work because of unmanaged pain.

However, she also acknowledged that there are "problems when the GP [general practitioner] is not knowledgeable or has personal reasons for not wanting to manage pain."

Identifying experts and quality providers

Finally, when pain specialists are necessary, insurers and managed care plans appear to have difficulty identifying both pain experts and good quality pain centers. This may be because the credentialing of such specialists and centers is confusing and, in some cases, inadequate. Although "there are a number of routes to becoming certified in pain management," the only route currently approved by ABMS is American Board of Anesthesiology certification in pain management for board-certified anesthesiologists. The American Board of Pain Medicine (ABPM), affiliated with the widely respected American Academy of Pain Medicine, also conducts examinations and provides certification for physicians in pain medicine. ABPM certification in pain medicine is recognized by the American Medical Association (as a self-designated specialty), but not by ABMS. The ABPM certificate is available to physicians in specialties other than anesthesiology. Even though ABPM is a well recognized source of certification, according to one source, the lack of recognition by ABMS of certification of specialists other than anesthesiologists has led "to some conflict with other ... 'self-designated boards' that also issue certificates."

As regards pain centers, in fact, "no uniform method has been developed to certify pain facilities." The Commission on Accreditation of Rehabilitation Facilities (CARF), with assistance from APS, has developed standards for multidisciplinary clinics, but accreditation does not guarantee that providers are competent or that outcomes are better. It simply indicates that the clinic has a multidisciplinary approach to pain treatment. Moreover, there are relatively few CARF-accredited clinics in the United States. There are, however, many nonaccredited facilities that advertise themselves as pain clinics, but they often consist of a single practitioner, "such as a chiropractor or biofeedback specialist" or "a physician with an interest in pain who is attempting to treat chronic problems in the way that he knows best." Patient advocates for pain

management have warned consumers that going to a so-called pain clinic, even in a university setting, does not guarantee that you will get comprehensive treatment. Such advocates have described pain clinics in the following way:

Pain clinics are often influenced by the special interests of their directors. At the extreme, they might fall into one of three categories, the first of which are nerve block outfits: pain clinics set up by anesthesiologists. While some are good, others might overly emphasize quick fix treatments.... "They may not want to take on patients who need careful adjustment of their medications over a long term." The second type of clinic is dominated by psychiatrists. "Patients seen at such pain clinics could get the demeaning message that their pain represents a type of character flaw, or that it's all in their minds...." The third pain clinic type is dominated by rehabilitation specialists and psychologists.... "These are the folks who will essentially look at almost all aspects of pain as problems of motivation and activity."

Implications of findings

Inadequate care and treatment bias

Given the lack of guidelines on pain treatment and significant discretion given to case managers to make individual coverage and payment decisions, the potential for undertreatment, as a result of misunderstandings about adequate pain medication or the potential for inequality in the allocation of pain treatment modalities, is very real. A recent nursing home survey, for example, found that nursing home patients with cancer are often undertreated for pain and that African Americans and the oldest patients are more likely than others to be overlooked. Without consensus as to what constitutes appropriate pain management, we can expect to see variation in treatment and coverage from patient to patient. In some cases, the difference in approach may be based on inappropriate, nonmedical factors.

Delayed referral, treatment, and care

Mistrust and lack of awareness about the benefits hospices and pain centers can provide may also contribute to inadequate care of patients with chronic pain or with pain from a terminal illness. These attitudes and ignorance may result, for example, in delayed referrals to pain centers or hospices. This may mean that patients do not receive the full benefit that these approaches can provide. Hospice providers have, in fact, commented that if "managed care organizations are to be convinced that hospice services are a good value, they will also need to be persuaded to refer patients earlier so that hospices can have a sustainable base of resources not only for the medical interventions they offer, but [also] for the social interventions that are part and parcel of their philosophy."

This comment reflects both provider and insurer concerns about bundling services. This issue is identified in the literature and in our survey responses about both pain centers and hospices. For each, SMDs expressed skepticism about the package of services offered by the provider and often want to unbundle the package and to pay for only the more medically related services for which outcomes are more clear. Plans are more likely to balk at paying for grief counseling in the hospice setting or for the "therapeutic milieu" required in a pain center. This skepticism, again, derives from the lack of good data on the effectiveness and cost effectiveness of the package of services provided and is likely to continue until such data are available.

vCredentialed specialists and more costly treatment

Mistrust of pain centers and uncertainty about what constitutes a pain management expert undoubtedly lead insurers and managed care providers to look for some means to evaluate quality. For the most part, they rely on certification or accreditation. The confusion over what constitutes adequate expertise in pain management and the limited recognition of pain specialists by ABMS may contribute to plan reluctance to refer patients to pain specialists. Moreover, because ABMS has only recognized anesthesiologists as a specialty to be certified in pain management means that plans are more likely to form relationships with anesthesiologists when they are looking for a pain expert. Consequently, plans will be steered toward the types of pain modalities that are more often administered by anesthesiologists. These modalities are often the more costly, high tech interventions. In some cases, this may lead plans to cover more expensive modalities than they might otherwise; in others, it may result in more disputes over pain management as plans question the medical necessity of these high tech interventions.

Recommendations and conclusions

Based on these findings, it is clear that additional resources and attention need to be devoted to developing guidelines for treatment of various types of pain and that more research needs to be conducted on the effectiveness and cost effectiveness of various pain treatment modalities and palliative care. Pain research has more recently become a focus of several well recognized foundations, as well as NIH, and these funders should focus attention and resources on this aspect of pain care. Additionally, there needs to be broader recognition of what constitutes a pain specialist and when a referral to a pain specialist is appropriate. ABMS, for example, should consider the merits of establishing a specialty in pain medicine. Furthermore, CARF, or provider organizations that focus on pain management, should develop more quality-based standards for certification of pain centers that include evidence of competence on the part of affiliated providers.

Until more widespread consensus develops on what constitutes effective treatment of pain, especially chronic pain, or agreement on credentials for certification of pain providers, we can expect insurers and MCOs to be reluctant to approve coverage of some forms of pain treatment and continuing variation across plans in the way they deal with this issue. These two efforts alone, that is, consensus on effective and cost-effective approaches to pain treatment and standards for provider certification, will likely go a long way to improving the approaches of health insurance plans in dealing with pain management.

Timothy S. Jost, "Public Financing of Pain Management: Leaky Umbrellas and Ragged Safety Nets"

Journal of Law, Medicine & Ethics, 26, no. 4 (1998): 290-307.

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The United States, unlike all other industrialized nations, does not have a comprehensive public system for financing health care. Nevertheless, the magnitude of America's public health care financing effort is remarkable. Of the one trillion dollars the United States spent on health care in 1996, almost half, \$483.1 billion, was spent by public programs. In 1995, Medicare--our social insurance program for persons over sixty-five and the long-term disabled--covered 37.5 million Americans; Medicaid--our program for indigent elderly and disabled persons and indigent children and their families--covered 36.3 million. In 1996, Medicare and Medicaid spent \$203.1 and \$147.7 billion, respectively. The payment policies of these massive public health care programs have a profound effect on the provision of health care.

Many of the recipients of Medicare and Medicaid suffer pain. In 1994, 376,200 Americans over age sixty-five died of cancer. Virtually all of these would have been Medicare recipients, and as many as 70 percent of them died in unrelieved pain. Nearly four million Americans over sixty-five endured the pain of inpatient surgery in 1995, again nearly all of whom were Medicare recipients. The Medicare hospice benefit provided palliative care to 266,000 suffering persons in 1994. In some states, Medicaid covers almost half of all persons with acquired immune deficiency syndrome (AIDS)--another very painful disease--and Medicaid's share of AIDS-related expenditures is increasing. Medicare and Medicaid, therefore, play a critical role in paying for pain management in the United States.

Although Medicare and Medicaid pay for a great deal of pain management, they often stand in the way of, or at least fail to facilitate, the provision of adequate pain management services. First, many persons who suffer debilitating pain and are not covered by private insurance, are not eligible for Medicare and Medicaid or any other public health insurance program. Each of our public health care financing programs covers only those who fit into certain eligibility categories--the aged, the disabled, children--and some have financial eligibility requirements as well. This is not accidental--as a nation, we try to limit our programs to those truly and justifiably in need.

Second, even persons who are covered by Medicare and Medicaid face significant gaps in benefits. Medicare, for example, does not cover oral prescription pain medications for most noninstitutionalized beneficiaries. Though most states voluntarily cover prescription pain medications through their Medicaid programs, many

do not cover over-the-counter (OTC) pain medications, and some programs impose significant restrictions on drug coverage.

Third, institutional participation and payment structures limit the usefulness of some available benefits. A Medicare beneficiary, for example, cannot simultaneously receive Medicare hospice and skilled nursing facility (SNF) benefits, thus SNFs have a disincentive to refer their residents to hospices. Medicare and Medicaid SNF certification standards, however, emphasize a rehabilitative rather than a palliative model of care, and are thus not oriented toward addressing terminal pain.

Fourth, in recent years, aggressive utilization review and fraud and abuse surveillance and enforcement have, some believe, deterred the adequate provision of pain management services. In many states, for example, Medicaid prescribing is subject to both prospective and retrospective utilization review. Under federal law, state Medicaid drug utilization review (DUR) programs are responsible for assuring that drugs are not overused, abused, or misused. Though some state DUR programs have taken the lead in trying to educate physicians and pharmacists in pain management, inquiries sent by DUR programs to physicians questioning pain medication prescribing practices may deter physicians from prescribing adequately high dosages of medication in some situations. Highly publicized fraud and abuse prosecutions of health care professionals who prescribe controlled substances may also be a deterrent. As a society, we are uncomfortable with controlled substances. Our programs to control their use can, however, limit legitimate (as well as illegitimate) uses.

These gaps and deficiencies in public program coverage of pain management services should concern us for several reasons. First, the alleviation of pain is one of the most fundamental obligations of health care professionals. The ethical codes of both the medical and nursing professions recognize an obligation to "relieve suffering." Indeed, the Agency for Health Care Policy and Research (AHCPR) has opined that "The ethical obligation to manage pain and relieve the patient's suffering is at the core of a health care professional's commitment." The obligations of beneficence and respect demand that health care professionals provide adequate treatment for pain. Health care financing programs that pay for care for a wide variety of medical conditions but discourage adequate pain management threaten the ethical practice of health professionals.

Second, adequate pain management is necessary as an alternative to assisted suicide. Congress took a strong position opposing assisted suicide in the Assisted Suicide Funding Restriction Act of 1997. Research has consistently shown, however, that uncontrolled pain is an important contributing factor in suicide by cancer and AIDS patients, and one of the most common reasons for requests for euthanasia or physician-assisted suicide (PAS). An effective program for limiting euthanasia and PAS must provide for adequate pain management.

Third, funding of a full range of pain management modalities is cost effective. As is explored below, Medicare tends to cover expensive modalities for pain management, such as internal infusion pumps, but not less expensive modalities, such as oral medication. A patient may be covered for the \$4,000 cost of morphine delivered through an infusion pump, but not for the \$100 cost of an oral morphine solution. Medicaid programs cover prescription pain medications, but usually do not cover less expensive OTC preparations.

In this article, I survey the Medicare and Medicaid programs, examining the pain management benefits they provide and exploring the barriers each poses to effective pain management. I also explore the problems caused by Medicare and Medicaid fraud and abuse enforcement for the treatment of pain. At the end of each section, I make recommendations for changes that may encourage better provision of pain management services.

Medicare

Medicare is our nation's largest health care financing program, both in terms of expenditures and number of recipients. Medicare covers virtually all persons in the United States who are over sixty-five, as well as persons who have been disabled for more than two years and persons with end-stage renal disease. Medicare is in fact not one program, but two, or perhaps three, programs. First, Medicare Part A, the Hospital Insurance Program, pays for care received in hospitals or other health care institutions. Second, Part B, the Supplemental Medical Benefits Program, covers services provided by physicians and other health

care professionals, as well as some medical devices and supplies. Third, the Balanced Budget Bill of 1997 created Part C, the Medicare+Choice managed care program, which essentially covers the benefits provided by Parts A and B in managed care settings.

Medicare beneficiaries suffer from a variety of pain problems. Beneficiaries in hospitals suffer from postoperative pain. Beneficiaries in SNFs are often recovering from painful fractures or suffer from painful disabilities. Beneficiaries in hospice, in particular, but in other settings as well, often experience the pain associated with terminal illness. Medicare beneficiaries often suffer from the chronic pains that accompany advanced age and disability.

Medicare only covers pain management services to the extent that they fall within the categories covered by Parts A, B, and C. Thus pain medication provided in a hospital, SNF, or hospice is covered by Medicare, as is medication covered by a risk-based managed care organization (MCO) as a supplemental benefit. Pain medication injections and some pain management technologies are also covered.

The greatest limitation of Medicare financing of pain management is that it does not cover oral medications received in outpatient settings, including pain medication. This means that Medicare beneficiaries must either pay for their own pain medication or receive it through a more expensive modality or in a more expensive setting.

Another overarching problem with Medicare is the limitations of its payment for physicians' services for pain management. Medicare pays for physicians' services based on its resource-based relative value scale (RBRVS). A physician cannot bill for a service unless that service corresponds to a Current Procedure Terminology (CPT) code recognized in RBRVS. If a physician's service does not involve a procedure otherwise assigned a CPT code, the physician must use the CPT evaluation and management (E and M) or consultation codes to bill Medicare. The level at which physicians can bill for E and M and consultation CPT codes, however, is closely related to the amount of time they spend face-to-face with patients in outpatient settings or at the bedside or on the floor in inpatient settings. CPT Codes 99358 and 99359, which cover prolonged service without patient contact, are not covered by Medicare. The only opportunity physicians have for billing for service time not involving face-to-face patient contact is the care management codes for hospice and home health patients, CPT Codes 99374 through 99378. These codes can only be billed once a month, however, and only then for management of hospice or home health care.

These coding rules create particular problems for physicians who practice pain management. Pain management tends to be heavily cognitive. For every hour that a physician spends face-to-face with a patient, he/she may spend several hours reviewing records of previous treatment and several more hours devising and writing a care plan report. Medicare does not adequately compensate doctors for this preservice and postservice time, and thus deters adequate treatment.

As noted, Medicare only covers pain management services in certain specific settings. Each of the settings in which Medicare will cover pain medication has its attendant opportunities and limitations. These include the following: injections; infusion pumps and electrical stimulation; hospital services; SNF services; hospice benefit services; and Medicare managed care.

Injections

Medicare Part B covers drugs administered by a physician incident to the physician's professional services. The drugs must be of a type that cannot be self-administered and that is commonly furnished in a physician's office or clinic without charge or included in a physician's bill. Ordinarily, this means that the drug must be injected. Injected medication is not covered, however, if standard medical practice indicates oral administration.

The Medicare statute seems intended to discourage doctors from providing medication injections. Injections cannot be billed separately to Medicare unless no other physician fee schedule service is billed at the same time. Moreover, payment for postoperative pain control medication may be included in the global fee paid for the surgery and thus may not be separately billable. A doctor also can only be reimbursed for 95 percent of the wholesale price of a drug he/she provides. For some pain patients, however, injections that their doctors are willing to provide are the only available relief that will be covered by Medicare.

Infusion pumps and electrical stimulation

Medicare covers some of the technologies used for pain management. Medicare covers external and internal infusion pumps used to deliver pain medication, and the pain medication provided through them. Infusion pumps are covered under Medicare's Part B durable medical equipment (DME) benefit. External infusion pumps are only covered by the DME benefit under limited circumstances, but these include morphine infusion via an external infusion pump when necessitated by intractable pain caused by cancer, both in inpatient and in outpatient settings, including hospice. The morphine necessary for the use of the infusion pump is also covered if reasonable and necessary.

Medicare also covers implantable infusion pumps to administer opioids intrathecally or epidurally for treating "severe chronic intractable pain of malignant or nonmalignant origin." To be eligible, patients (1) must be expected to live for at least three months; (2) must have proven unresponsive to less invasive medical therapy, such as systemic opioids, and (3) must have completed a preliminary trial of intraspinal opioid drug administration with acceptable pain relief, acceptable side-effects, and patient acceptance. Again, necessary drugs for infusion are also covered. Infusion therapy is normally managed by a home health provider. In cases where infusion pumps are covered, therefore, but less expensive and invasive therapies may also be effective, Medicare incurs additional expense because it must pay both for the pump and for the professional (usually home health care) staff to maintain it.

Medicare will cover electrical nerve stimulation under some circumstances. Transcutaneous electrical nerve stimulators (TENS) units are covered under Medicare for acute postoperative pain as hospital supplies or supplies incident to a physician's services. They are also covered for chronic intractable pain under the DME benefit. Implanted electrical nerve stimulators are covered, but only as a last resort, after other modalities have failed and the patient has been evaluated by a multidisciplinary team. Medicare presumes that patients can be trained to use stimulators, hence it does not cover electrical nerve stimulation provided by physicians or physical therapists in an office or clinic on an ongoing basis.

Hospital services

The hospital benefit is arguably the most basic Medicare benefit. Part A covers inpatient hospital care for up to ninety days for any "spell of illness," plus up to sixty "lifetime reserve" days available on a one-time basis. Because about one-quarter of all persons between ages sixty-five and seventy-four and almost one-half of all persons over seventy-five are hospitalized each year, and about one-half of all deaths occur in hospital, a great deal of pain is treated under the Medicare hospital benefit.

Medicare hospital coverage includes the provision of drugs and biologicals. Under the Medicare regulations, drugs are only covered if (1) they represent a cost to the hospital, (2) they are ordinarily furnished for the care of inpatients, and (3) they are furnished to an inpatient for care within the hospital.

A hospital stay solely for the purpose of administering a drug is not covered by Medicare. Medicare will, however, cover inpatient hospitalization for pain rehabilitation where hospitalization is reasonable and necessary, the patient's condition is attributable to a physical cause, usual methods of treatment have not been successful in alleviating pain, and the pain has resulted in a significant loss of ability to function independently. Medicare also covers outpatient treatment necessary for pain. The new hospital outpatient prospective payment scheme will have a special payment category for nerve blocks.

Medicare-participating hospitals must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), unless they are independently certified for Medicare participation. JCAHO requires that hospitals address care at the end of life, including "managing pain aggressively and effectively." Most Medicare participating hospitals should be addressing pain management under this requirement.

Though the Medicare hospital benefit facilitates the provision of pain relief services to Medicare beneficiaries, it has serious drawbacks. In part because of diagnostic-related group (DRG) reimbursement, hospital lengths of stay are very short. For instance, the average length of stay in 1995 for persons with malignant neoplasms, age sixty-five to seventy-four, was 7.3 days. Issues of pain can only be addressed in the most transitory way during these short stays. Hospitals that keep patients for longer periods of time, however, begin to lose money dramatically. Medicare has introduced a new ICD-9 Code for palliative care, but, at this point, is only using it to test the feasibility of a special DRG reimbursement category for palliative care. Until

hospitals are compensated adequately for the costs of palliative care, they are unlikely to focus on pain management.

SNF services

Medicare Part A covers pain medication through the SNF benefit. Medicare covers up to 100 days per spell of illness of posthospital extended care for beneficiaries in a SNF. Medicare covers the cost of drugs and biologicals provided to Medicare beneficiaries resident within the facility.

The Medicare SNF benefit, again, plays a limited role in providing pain relief. The SNF benefit is intended as an extended care benefit, supplementing hospital care for acute episodes. It is ordinarily available only if the resident has been hospitalized for at least three days within the thirty days preceding admission. The average length of SNF Medicare coverage per admission is quite short, 27.4 days.

The articulated goal of SNF services under Medicare is to "attain or maintain the highest practicable physical, mental, and psychosocial well-being for each resident," and each resident must have a plan of care to this end. Although Medicare criteria governing the need for skilled services recognize that not every SNF resident has "restoration potential"--for example, that "terminal cancer patients may need some ... skilled services"--the orientation of the SNF benefit, the SNF participation requirements, and the SNF survey process are geared toward restorative rather than palliative care. This regulatory neglect of pain within SNFs is, not surprisingly, reflected in poor performance of nursing facilities in pain management.

Regulations governing the SNF survey process in particular pay little attention to pain management. The Health Care Financing Administration's (HCFA) survey procedure guidelines, for example, lists sixteen issues on which surveyors are supposed to focus in assessing the extent to which the physical, emotional, psychosocial, or spiritual needs of residents are being met, but pain management is not on that list. Pain management is not even listed among the 141 issues of concern that a surveyor can check on the observation/interview worksheet provided on HCFA's SNF inspection form. Nor is pain mentioned in HCFA's care guidelines for SNF inspections, which come to 136 pages in the *Code of Federal Regulations*--not even under the section dealing with observation of terminally ill residents.

Pain is beginning to appear in subregulatory guidelines and manual provisions related to the SNF survey process and certification. One of the items that facilities must report on a HCFA resident census form is the number of patients in pain management programs. Surveyors are supposed to identify hospice patients and interview them in the survey process. Pain is also addressed incidentally in the process of reviewing other care issues. Though HCFA is interested in addressing pain more expressly in its guidelines and protocols, pain is still largely ignored in the survey process.

Pain is noted in the SNF patient assessment process and in the most recent iteration of the minimum data set (MDS). MDS is a computer-reported resident assessment tool, which since 1995 has tracked, among other factors, pain symptoms, frequency, and site. Final rules for resident assessment in long-term care facilities, published on December 23, 1997, in the *Federal Register*, require resident assessment based on MDS. Though the regulation does not list pain as one of the eighteen items that states must consider in resident assessment instruments or as one of the eighteen items that states must address through resident assessment protocols (RAPs), pain is discussed in the preamble of the regulation. Specifically, the preamble, in the context of discussing comments on the proposed regulations, notes the pain items in MDS and suggests that these items might be considered in evaluating special populations.

Most important, the preamble seems to acknowledge the inappropriateness of the rehabilitation-oriented "aggressive work-up to determine causal factors" that contribute to lack of functioning (which is normally required for SNF residents) for SNF hospice patients receiving palliative care. The preamble encourages states to focus on RAPs appropriate for the special needs of hospice patients, that is, to focus on increasing residents' comfort level and on helping patients to die with dignity. It also recognizes that more work needs to be done to devise appropriate regulatory tools for addressing the needs of hospice patients in SNFs. In the end, however, HCFA's regulatory scheme for nursing facilities under Medicare and Medicaid still largely ignores pain management. Nursing facilities, which are largely financed by Medicaid and to an increasing degree by Medicare, have, therefore, faced few regulatory incentives to improve pain management, or even to attend to pain. This may be changing, but further change needs to be encouraged.

Because the Medicare SNF and hospice benefits are mutually exclusive, Medicare hospice services cannot be provided to Medicare beneficiaries in SNFs while they are under the SNF benefit. Thus, some Medicare SNFs have a financial incentive, in some instances, to hold onto patients who might appropriately be referred to hospices. That is, not only does Medicare not provide incentives for adequate pain management in SNFs, but it also provides disincentives for SNF referral of residents to hospices, where their needs could be more adequately met.

Hospice benefit services

The Medicare hospice benefit is the primary Medicare pain management benefit, at least for the terminally ill. The benefit was created in 1983, in part to save money for the Medicare program by moving beneficiaries requiring end-of-life care out of more expensive treatment settings. It has been estimated that about 77 percent of hospice patients are covered by Medicare nationally. Though the Medicare hospice benefit has made hospice services available to many who might not otherwise have obtained them, it has also made hospices heavily dependent on Medicare and subservient to Medicare requirements.

Because the hospice benefit was designed to reduce costs, eligibility has always been strictly limited, specifically to Medicare beneficiaries who are "terminally ill." Medicare considers a beneficiary to be terminally ill if the beneficiary's attending physician certifies that the beneficiary has a life expectancy of six months or less. A beneficiary who elects hospice care must waive his/her right to Medicare coverage of any other treatment of the terminal condition (other than physician's services), though the beneficiary may subsequently revoke the waiver and leave hospice care. Hospices are paid on a per diem rate, based on four different payment levels, subject to a cap in all cases. Though the Medicare hospice and SNF benefits are mutually exclusive, hospices do provide services to dually eligible (Medicare and Medicaid) beneficiaries receiving Medicaid-funded nursing facility care.

For a number of years after its introduction, the Medicare hospice benefit was fiscally insignificant. In 1986, the program paid out \$77 million. In recent years, however, the program has grown rapidly. During 1995, program expenditures reached \$1.85 billion, a 36 percent increase from the preceding year. The program has begun to attract more attention from government, including attention from the Department of Health and Human Services Office of Inspector General (OIG), which polices fraud and abuse.

The hospice program was significantly revised by the Balanced Budget Act of 1997 (BBA), which addressed many problems that affected the hospice program, but difficulties remain. Perhaps the most important is the short and rapidly declining length of hospice stays. Although the hospice benefit is available to persons in their last six months of life, most patients remain in hospices for a much shorter time. A study using 1990 Medicare claims data found that the median hospice patient survived thirty-six days after enrollment in a hospice. The study found that 28.5 percent of patients died within two weeks after entering hospice. A more recent, as yet unpublished, study has found a decline in median length of stay, using 1995 data, to twenty-nine days. One hospice director asserted that, in the last quarter of 1996, the median length of stay had declined to twenty-one days.

A number of factors may contribute to the declining length of stay. One, as discussed below, is the increased pressure being placed on doctors both through regulation and enforcement to refrain from referring patients to hospices until death is almost certain. A second is Medicare DRG hospital reimbursement, which both discourages hospitals from admitting patients until their condition is grave and encourages hospitals to discharge patients as rapidly as possible, making it tempting for discharge planners to make a quick home health referral rather than a more time-consuming hospice referral. A third might be changing trajectories of dying, brought on by new treatments that often permit patients to remain in the community with symptoms controlled for a much longer time than previously, followed by a precipitous death when the treatments finally fail. A final reason, also discussed below, may be the reluctance of other Medicare providers, such as SNFs or home health agencies, to refer patients to hospices until the patient is in the last stages of dying because of the exclusivity of the hospice benefit.

Whatever the cause of the decline, its implications for hospices are very serious. Hospices are paid on a per diem basis, but most of their expenses are incurred during the first week of care--when the plan of care is being established and resources are marshalled for the patient--and the final week--when death is being managed. Hospices can survive because their income may be greater than their costs in the intervening weeks. If there are no intervening weeks, however, hospices face serious financial problems.

As noted above, one reason why patients come to hospices late in the dying process is the Medicare requirement that a physician must certify that a patient has only six months to live before the patient can receive the hospice benefit. The "death sentence" requirement imposes an immediate barrier to hospice entry because it requires that before the patient can receive hospice benefits--and the pain management hospice affords--(1) the patient must come to terms with his/her own mortality and (2) the treating doctor must essentially admit defeat in curing the patient. The Medicare requirement that patients waive curative treatment for their terminal condition reinforces the relinquishment of hope that the certification requirement documents.

As hospices increasingly move beyond simply caring for cancer patients, and take on patients with other diagnoses, and as new treatments for cancer emerge, prediction of death trajectories becomes more difficult. A particular problem arises when physician certifications for patients who did not die as early as predicted are reviewed retroactively by investigative agencies. Prognoses are always easier to make retrospectively. Reviews are especially problematic for noncancer hospice patients, where certification standards have only recently been clarified. When earlier physician certifications are reviewed under recently promulgated standards, documentation deficiencies may be found which could be interpreted by a reviewer as demonstrating an inappropriate referral. With the encouragement of OIG, fiscal intermediaries have become more aggressive in retrospectively reviewing hospice certifications. This review may be deterring doctors from making appropriate referrals to hospices, because no doctor wants trouble with OIG.

Hospices are also facing increasing problems in functioning within Medicare payment rates. Hospices are responsible for all costs related to terminal illnesses and must cover them within their Medicare per diem rate. It is not always clear, however, whether costs are related to a terminal illness. Hospices are clearly responsible for the costs of opioids required by a dually eligible Medicaid patient for pain management; but Medicaid should have to pay independently for that patient's insulin if the patient is a diabetic, because the diabetes is unrelated to the patient's terminal condition and insulin is not palliative care. Some Medicaid DUR programs, however, have reportedly taken the position that hospices must pay for all medications hospice patients receive. Hospices are also arguably responsible for the costs of chemotherapy for cancer or immunosuppressive medication for AIDS therapy, which relieve the pain and other symptoms caused by incurable conditions. Antiretroviral therapy medication for AIDS therapy can cost more than \$10,000 a year, however. The ever-increasing costs of these therapies severely taxes the ability of hospices to deliver care within the per diem rates granted by Medicare.

Another area of concern is coordination between hospice and other Medicare or Medicaid providers. Though a patient receiving the Medicare hospice benefit is not eligible for the Medicare SNF benefit, dually eligible Medicare and Medicaid recipients may receive the Medicare hospice benefit and Medicaid payment for their nursing facility care. The state Medicaid agency must pay the hospice at least 95 percent of the rate the agency would pay for nursing facility services, and the hospice in turn must contract to pay the nursing facility for board and care services. Many hospices, however, pay nursing facilities at least 100 percent of the Medicaid rate the facility would otherwise get from the state, with the difference coming from the hospice. Over 17 percent of Medicare hospice patients lived in a SNF in 1995, and many of them were dually eligible.

The hospice/nursing facility benefit has met with increasing suspicion in recent years. In 1997 and 1998, OIG issued two reports examining the hospice/nursing facility benefit and a fraud alert, suggesting that the benefit is resulting in excess payments, duplicative coverage of services, underservice by each provider, and inappropriate referrals. Further clarification of responsibilities, at the very least, seems necessary.

Coordination between Medicare managed care and hospices is problematic as well. When a Medicare beneficiary enrolled in managed care elects hospice, the beneficiary's managed care enrollment ceases. The attending physician with the MCO can still treat the patient and the MCO can provide services unrelated to the terminal condition; but the MCO must now bill Medicare on a fee-for-service (FFS) basis. Although many MCOs are quite willing to refer to hospices dying patients, whose care is usually very expensive, MCOs in some parts of the United States where Medicare rates are very favorable, as well as MCOs that do not understand the hospice benefit, are reluctant to refer patients.

Hospices must meet Medicare certification requirements, and must be audited by the states to assure compliance with these requirements. States also audit hospices to assure compliance with licensure requirements. Few states have sufficient hospices, however, to maintain a substantial hospice certification or licensure program. Many rely on nursing facility surveyors. These surveyors may not, however, understand

sufficiently well the philosophy and practices of hospices, or even the nature of prescribing medications in hospices. Not only can this result in misunderstandings in the survey process, but it also deprives hospices of the guidance that knowledgeable surveyors might bring to them.

Medicare managed care

Over 18 percent of Medicare beneficiaries are currently enrolled in Medicare managed care. The BBA created Medicare Part C, which is intended to increase dramatically enrollment in Medicare managed care. Under both the traditional Medicare risk-sharing health maintenance organizations (HMOs) and competitive medical plan benefit, and the new Part C benefit, contracting MCOs are responsible for providing their members with services beyond those that Medicare covers on the FFS side, to the extent that the payment the organization receives from Medicare exceeds the cost of Medicare-covered services. This provision requires that economies achieved by Medicare MCOs be passed on to beneficiaries. Among the additional services that Medicare MCOs may offer are coverage of prescription drugs and biologicals.

Coverage of prescription drugs (including oral pain medication) is one of the most popular benefits offered by Medicare managed care. In December 1998, 226 of the 338 risk-based Medicare plans reported that their benefits covered outpatient drugs. If Medicare managed care expands, therefore, it is likely that more Medicare beneficiaries will have their pain medication covered. Although this is generally a positive factor, grounds for concern arise here.

First, MCOs generally have been more aggressive in managing pharmaceutical benefits than public programs have been. Insofar as MCOs have experience with pain management, it might well be with a younger population and with musculoskeletal pain, where pain management approaches are quite different. Some education and adjustment, and perhaps ultimately regulation, may be necessary to assure adequate protection for the elderly, as the current HCFA regulations leave MCOs considerable discretion to "determine the level and scope" of this benefit. There is also concern that, as MCO payment rates are tightened under the payment methodology of the BBA, MCOs may begin dropping the drug benefit. Moreover, insofar as Medicare policy-makers are primarily focused on the task of moving Medicare beneficiaries into managed care, they may slight the problems of the vast majority of beneficiaries left behind in FFS Medicare, who currently do not have adequate access to pain medication.

Recommendations

First, Medicare Part B should be expanded to cover oral outpatient pain medication. Part B has been expanded to cover other medications, including oral anticancer chemotherapeutic agents and antiemetics used as part of a chemotherapy regime, prescription drugs for immunosuppressive therapy for organ transplant recipients, and erythropoietin for dialysis patients. Oral pain medications are relatively inexpensive compared with many of these medications, and are just as necessary for those for whom they are indicated.

Second, E and M and care planning CPT codes used under RBRVS physician reimbursement should be reviewed and revised as necessary to assure that they adequately reflect the resource use necessary for pain management.

Third, adequacy of pain management should be added as a factor explicitly considered in SNF survey and certification requirements. Medicare SNF participation requirements should be amended to recognize that pain management is as important as restoration of function for patients with intractable pain. As nursing facility prospective payment systems are implemented, attention should be paid to providing adequate payment for pain management.

Fourth, hospice eligibility should be based on the need for palliative care, regardless of expected survival time. Patients in intractable pain suffering from incurable conditions should be able to elect hospice services (including pain management), even though it cannot be predicted with certainty that they will die within six months. This may increase costs, but may be necessary to keep the hospice benefit viable.

Fifth, oral anticancer chemotherapeutic agents should be covered by Medicare Part B for hospice patients when needed for palliative care. As noted, oral anticancer chemotherapeutic agents are normally covered by Medicare Part B. Hospice patients, however, must generally waive Medicare coverage for treatment of their

terminal illness. When hospice patients require anticancer treatment for symptom control not for curative reasons, the oral anticancer agents must currently be paid for by the hospice from its per diem rate. These medications are very expensive, and strain hospice resources.

Medicaid

Medicaid is a joint federal-state program that pays for health care for the poor. Although most Medicaid recipients (about 70%) are children and their parents, most Medicaid expenditures are for the elderly (30.4%) and disabled (41.1%). Many elderly persons who are dually eligible for Medicare and Medicaid receive prescription drug benefits through Medicaid. Many disabled persons who have not yet been disabled for two years or who otherwise do not meet Medicare eligibility requirements also receive Medicaid benefits. Many poor persons in pain, therefore, depend heavily on Medicaid for payment for pain relief.

Medicaid programs must cover inpatient and outpatient hospital care, nursing facility care, and physicians' services. Although the state and territorial Medicaid programs are not required by federal law to cover prescription drug services, all in fact do. Twenty-eight programs also cover hospice services. Medicaid programs, therefore, pay for a significant range and volume of pain relief services. Because Medicare does not cover most outpatient medication, the most significant Medicaid benefit with respect to pain management is probably prescription drug coverage. I will focus, therefore, on the prescription drug benefit.

Medicaid prescription drug coverage limitations

In 1995, prescription drugs accounted for about \$9.7 billion in Medicaid vendor payments, 8.1 percent of all Medicaid payments. The role of Medicaid in financing pain management medication cannot be overemphasized. One of the few studies of access to pain medication by patient payer status reported that Medicaid cancer patients received more pain medication--and more effective pain medication--than did patients covered by any other type of payer.

There are, however, important limits to Medicaid coverage of pain medication. Prescription pain medication is, in most instances, included in Medicaid drug coverage. In fact, ten states cover aspirin, acetaminophen, or other specified OTC drugs when prescribed by a physician. Many states, however, place limits on prescription drug coverage that affect pain management. For example, federal law permits state Medicaid programs to impose nominal cost-sharing requirements on Medicaid recipients, as long as children, pregnant women, patients in hospitals or residents in nursing facilities, emergency services, HMO services, hospice services and family planning services are excepted. Twenty-seven states currently impose copayments on prescriptions, ranging from \$.50 to \$3.00 per prescription. Most states charge variable copays, with lower copays for less expensive drugs or generics and higher copays for more expensive or brand-name drugs.

The Medicaid statute also permits states to limit the minimum or maximum quantities per prescription or the maximum number of refills to discourage waste. About half of the states impose limits on the amount of drugs that can be dispensed under one prescription (usually a thirty- or thirty-four-day supply or 100 units) and/or on the number of refills per prescription (usually five in six months). More significant, eight states limit the number of prescriptions or refills a recipient may obtain in one month (between three and seven), while a few others limit the number of dispensing fees that a pharmacist may receive in a month for filling a particular recipient's prescriptions. Given that pain management patients often require frequent dosages of medication (sometimes thirty to fifty pills a day), these limitations may become a real barrier to adequate treatment. In most states, quantity limits can be exceeded with prior authorization, but this still poses a deterrent to adequate pain management.

A number of studies have examined the impact of state Medicaid drug reimbursement policies on Medicaid recipients. One looked at the effect of New Hampshire's imposing a limit of three paid prescriptions per month on Medicaid recipients, which was replaced a year later by a \$1.00 per prescription copayment. The study found that prescriptions filled for multiple drug users (with three or more prescriptions per month) dropped from 5.2 per month before the cap to 2.8 during the eleven-month cap period, climbing back to 4.7 when the copayment was introduced. The use of prescription analgesics declined 31 percent from 28.3 to 17.5 prescriptions per hundred patients per month after the introduction of the cap.

Attempts to limit Medicaid coverage of prescriptions, including pain medication, through the use of caps in particular is likely to have an adverse effect on pain management. Studies have also shown that copayments

of as little as \$1.00 per prescription have led to 5 to 10 percent declines in drug use, including essential as well as nonessential drugs.

Medicaid prescription drug use control programs

Medicaid prescription drug coverage is also subject to administrative controls. These grow, by and large, out of the Omnibus Budget Reconciliation Act of 1990 (OBRA), which contained extensive provisions intended to control the cost of the Medicaid prescription drug benefit, while also assuring more appropriate prescribing for Medicaid recipients. Most important for our purposes, OBRA required states to establish prospective and retrospective DUR programs. These programs, which were to have been established by January 1, 1993, are supposed to review prescriptions for outpatient drugs to assure that the drugs are appropriate, medically necessary, and not likely to cause adverse results. More specifically, the program must be:

designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and under-utilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

DUR programs must cover all outpatient prescribing and may cover drugs dispensed in nursing facilities as well. Where DUR programs identify problems in prescribing, they are authorized to issue written, oral, or electronic reminder notices; to initiate face-to-face discussions with providers; or to initiate intensified review or monitoring. When necessary, DUR programs also refer providers or recipients to state surveillance and utilization review (SUR) programs for further investigation, including possible fraud and abuse investigations.

The Medicaid DUR program has the potential to play a key role in encouraging and discouraging proper pain management prescribing. On the one hand, state programs that take seriously their mission in drug use education can have a significant impact on increasing physician knowledge about appropriate prescribing for pain management. A central mission of DUR programs is, in fact, education regarding therapeutic appropriateness and underutilization. On the other hand, if DUR programs routinely generate warning notices to doctors who prescribe higher than average volumes of controlled substances without adequately considering the circumstances under which the drugs are prescribed, DUR may intimidate legitimate prescribers and discourage appropriate pain management.

Because of the potential impact of Medicaid DUR programs on pain management prescribing, Leonard Tomlin, Sheryl Ingram, and I surveyed state Medicaid DUR programs with respect to their policies and practices. Twenty-seven states completed and returned the forms, including states from all regions of the United States. Of the states surveyed, twenty-one conducted both prospective and retrospective DUR; six conducted only retrospective. Twenty-three of the DUR programs reviewed drugs dispensed to nursing facility residents.

Ten of the twenty-one programs that conducted prospective DUR stated that they had developed standards and criteria specifically for prospective review of pain management prescribing. Twelve of the twenty-seven states stated that they had standards and criteria that specifically addressed retrospective review of pain management prescribing. Several of the states that responded negatively to the question of whether they had standards or criteria addressing pain relief, however, noted that their DUR contractors applied their own criteria or guidelines.

Very few states described or provided copies of their criteria. Those that we received dealt, predictably, with multiple prescriptions or doctors, drug-drug interactions, multiple dosages, and side-effects. These criteria appeared reasonable on the surface. However, not all DUR programs have reasonable criteria. A doctor whose prescribing had been challenged by a DUR program that did not respond to our survey sent us a copy of that DUR program's narcotics overutilization criteria, which deemed prescribing of more than one dose of opioids per day for a patient as overutilization. This level of surveillance seems inappropriate.

A major focus of our study was to determine which interventions state DUR programs pursued when they identified either inappropriate or potentially abusive prescribing of pain management medication. The DUR programs were first queried about what interventions they use to address these issues. The intervention used by the most prospective utilization review programs both for inappropriate and abusive prescribing was an electronic notification to the dispensing pharmacist. The second most common was notification of denial of Medicaid payment for the prescription, subject to an override by the pharmacist. Other interventions pursued included denial of Medicaid coverage, written or oral notification to the prescribing physician or dispensing pharmacist, or referral to the SUR program.

With respect to retrospective utilization review, the intervention used by most programs for both inappropriate and abusive prescribing was a written notification to the prescribing physician; the second most common a written notification to the dispensing pharmacist. In situations of suspected abuse, about half of the states identified as a possible intervention locking the patient into a particular physician or a particular pharmacist. Several of these programs noted that the lock-in would have to be effected through the SUR program.

The states were also queried as to the number of interventions they had undertaken with respect to pain medication prescribing. The vast majority of interventions consisted of written or electronic reminder to pharmacists or physicians. Ten DUR programs generated more than 100 notices to physicians regarding pain management prescribing in 1996, and two sent out more than 1,000. Twelve DUR programs sent more than 100 notices to pharmacists regarding pain management in 1996, and six more than 1,000.

Several programs provided sample letters sent to prescribers. These, on the whole, were similar. They seem intended to be nonthreatening, asserting that the purpose of the communication is to provide information and to assist the prescriber rather than to challenge prescribing practices. Some letters were less tactful, though none seemed particularly offensive. Where there is a concern that patients are using multiple pharmacies or physicians, prescribers are often sent recipient drug utilization profiles. Letters also often contain side-effect or interaction information with respect to particular drugs. The most elaborate sample letter provided was sent by one DUR program to doctors who used opioids in combination and for a considerable period of time for treating noncancer pain. It contained a summary of AHCPR guidelines on treatment of chronic pain; a summary of a consensus statement from the American Academy of Pain Medicine and the American Pain Society on opioid prescribing, and sample Patient Selection and Evaluation and Pain Assessment forms, including a contract to be signed by the patient. It was an impressive attempt at education.

Notice letters always invited responses from the providers to whom they were addressed. The articulated purpose of the request for response was normally to improve DUR criteria or otherwise to adjust the program. The response forms provided by some programs seemed genuinely oriented toward ascertaining whether information was useful to the provider. On the other hand, some notice letters seemed to demand rather than request a response, and some requested providers to specify the actions that they have taken in response to the notice. A doctor otherwise skittish about pain management prescribing may well find a DUR written notice to be threatening, but the samples we received did not seem on their face to be easily interpreted as threats.

Interventions other than written or electronic notices were far less common. Only eight programs had had face-to-face discussions regarding prescribing of pain medication with physicians in 1996, and all had had fewer than twenty such discussions. Nine programs had had face-to-face discussions regarding pain management prescribing with pharmacists in 1996, and all but two had had fewer than twenty. Ten programs had had some physicians under intensified review regarding pain management prescribing at some point during 1996, seven of these in fewer than twenty instances.

A number of the programs had also referred physicians, pharmacists, or patients to SUR programs, Medicaid Fraud Control Units (MFCUs), or licensure boards for pain medication prescribing, dispensing, or use. In 1996, twelve of the twenty-seven programs had referred physicians to SUR units, ten to MFCUs, and eight to licensure boards. In all instances, fewer than twenty referrals of physicians were made, except that two programs referred more than twenty physicians to SUR units. In the same year, nine had referred pharmacists for pain medication dispensing to SUR units, seven to MFCUs, and five to licensure boards. In every instance, fewer than twenty had been referred. The group receiving the greatest number of referrals for potential abuse of pain medication was patients, that is, Medicaid recipients. Nineteen states had referred patients to SUR units and eight to MFCUs for pain medication abuse. Six programs had referred

more than twenty to SUR units and one more than fifty. Two programs had referred between twenty and fifty patients to MFCUs.

Several reporting DUR units seemed aware of and/or sensitive to concerns regarding pain management. Seven reported either excluding from review or otherwise treating specially cases involving the prescribing of pain medication for conditions with intractable pain, such as cancer or AIDS. This usually involved suppressing DUR messages regarding the chronicity, dosage, or duration of prescribing of controlled substances for cancer patients. A couple of other states mentioned that they were unable to do this because they lacked sufficient diagnostic information to identify such patients, suggesting that they had considered this measure.

DUR programs are required by federal law to provide educational programs to "educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices." Three of the surveyed programs had conducted special studies of prescribing pain medication. Twelve reported sponsoring educational outreach programs or providing informational material regarding appropriate pain management prescribing. Several supplied us with educational materials they had generated or information on studies they had conducted. Three states sent program newsletters addressing pain management prescribing. Two of these articles included pain management guidelines. One noted the possibility of underprescribing pain medication. DUR programs should play a more active role in educating providers with respect to undertreatment of pain. To the extent that providers fear, rightly or wrongly, that aggressive pain management prescribing will get them in trouble with the DUR program, DUR's emphasis on the risks of underprescribing in educational programs, newsletters, or informational mailings could serve as a healthy antidote.

In sum, it is possible that DUR program interventions may be discouraging aggressive pain management in some cases. Although reducing DUR scrutiny of pain management could permit abusive prescribing, current levels of scrutiny risk encouraging underprescribing for pain. DUR programs should become more sophisticated in detecting and protecting appropriate pain management, and in educating prescribers about the need for adequate pain management.

Medicaid managed care

Enrollment in Medicaid managed care programs jumped 37 percent, from 9.8 million recipients in 1995 to 13.3 million in 1996. Currently, 40 percent of all Medicaid recipients are in managed care. Although the greatest and fastest movement to managed care involves programs for families and children, state Medicaid programs are also beginning to move their disabled and elderly populations into managed care systems. The BBA generally encourages this move.

Little information is currently available concerning how pain management is being addressed by Medicaid managed care. A recent study of Medicaid managed care contracts found that thirty of the thirty-seven general Medicaid managed care contracts or requests for purchase studied required "pharmacy" or "prescription drug" coverage. Most state contracts do not set out specific limitations or exclusions in their contracts for prescription drug coverage, though some limit coverage to "medically necessary" drugs, and others address the use of mail order pharmacy. There is no evidence that access to prescription drug coverage is either expanding or contracting under managed care.

One particular concern here may be the approach that Medicaid managed care plans take to DUR. Medicaid managed care plans generally use their own pharmaceutical benefits management policies and procedures in lieu of the state DUR program. Some speculate that these programs may be more rigorous than the DUR programs have been in controlling access to prescription drugs for Medicaid recipients. If this turns out to be true, the result could be more undertreated pain.

Medicaid nursing facility coverage

One of the most important functions of Medicaid is to finance nursing facility care. The Medicaid statutes require states to cover skilled nursing benefits. In 1996, Medicaid spent \$37.5 billion on nursing facility care, 47.7 percent of total national expenditures on nursing facility care, and 26.8 percent of all Medicaid expenditures. Many of the 1.4 million Medicaid recipients who live in nursing facilities are in pain, thus the Medicaid nursing facility benefit is critical when studying pain management financing.

Medicaid nursing facility standards are essentially equivalent to those applied under the Medicare programs. Indeed, the survey and certification programs are nearly identical. Therefore, the criticisms of the Medicare nursing facility benefit related above apply here, essentially unaltered. In short, the Medicaid nursing facility survey process and certification standards do not attend to pain management and offer facilities little encouragement for providing adequate pain management. Many Medicaid nursing facility patients also receive the Medicare hospice benefit. The issues that attend this benefit were also discussed above. Though the Medicaid nursing facility benefit is useful and necessary for many persons in pain, much work needs to go into rethinking the standards under which this benefit is administered to make it of optimal value to this population.

A final pervasive problem with Medicaid is the barrier that low payment rates, payment delays, and bureaucracy pose to Medicaid provider participation. In many states, Medicaid pays physicians a fraction of what they make from treating their private, or even Medicare, patients. Delays in payments to pharmacies, exceeding 100 days in some states, threaten program participation. An undetermined, but certainly significant, number of Medicaid recipients probably lack adequate pain management because they cannot get access to professionals who will provide them with adequate pain management under the Medicaid program.

Recommendations

First, states should exclude pain management medication from limitations imposed on the number of prescriptions they will cover per month. Recipients in intractable pain should also be excused from copayment obligations, as are several other categories of recipients (children, nursing facility residents, and so forth).

Second, DUR programs should review their criteria to assure that they are not discouraging appropriate prescribing for patients in pain. They should, if possible, avoid sending intervention letters suggesting excessive prescribing to physicians or to pharmacists dispensing high dosages of narcotics for patients diagnosed with cancer, AIDS, or other conditions that cause intractable pain. DUR programs should become actively involved in pain management education.

Third, Medicaid managed care contracts should be drafted to clarify the obligations of MCOs to provide adequate care for Medicaid recipients in pain, including adequate pharmaceutical benefits and hospice benefits.

Fourth, Medicaid nursing facilities certification and survey requirements should be reviewed to emphasize the obligation of nursing facilities to provide adequate pain management for their residents.

Fraud and abuse law

It is odd that the fraud and abuse laws should appear as a component of a study of the influence of public health care financing programs on pain management practices. The fraud and abuse laws, and there are many of them, are intended to deter and punish fraud against and abuse of public health care financing programs. An important subsidiary function of the fraud and abuse laws, however, is to police compliance with federal and state program requirements, especially with billing requirements. Filing a claim for payment for a service that was not provided in compliance with program requirements, or that was not medically necessary, or even that did not meet acceptable quality standards might be characterized as fraud and abuse. The fraud and abuse laws, therefore, pervasively affect every federal and state health program benefit, including pain management. Some have perceived them as having a particularly negative effect on pain management.

The federal and state governments have available a host of tools for addressing fraud and abuse involving Medicare and Medicaid, including criminal, civil, and administrative sanctions. Physicians who prescribe large quantities of controlled substances for pain relief have long risked the attention of state and federal authorities who enforce the narcotics control laws. Increasingly, however, providers also worry that they could also be charged with violating fraud and abuse laws, with all of the calamitous consequences such charges entail.

A variety of fraud and abuse claims can in theory be brought for inappropriate prescribing or dispensing of controlled substances. In fact, in the past few years, health care fraud and abuse claims have increasingly been joined with controlled substance violation claims in federal criminal prosecutions. Violations of the Racketeer Influenced and Corrupt Organizations Act and mail fraud are occasionally joined as well.

Pharmacists who dispense drugs and bill a federal or state health care program for payment knowing that the drugs are not dispensed for legitimate medical purposes can be found liable under various federal and state statutes prohibiting false claims and mail fraud. This is particularly true if pharmacists dispense without a prescription or forge prescriptions. Physicians who dispense medication for illegitimate purposes and then bill a federal or state health care program may also face false claims charges.

It is less clear on what grounds physicians can be held liable if they issue illegitimate prescriptions filled by another. In this situation, physicians are not filing a false claim with a federal or state health care program, because the physicians are not paid for the prescription. Arguably, they could be liable under criminal laws prohibiting

- participating in "scheme or artifice to defraud" a health care benefits program;
- making a materially false statement or making or using a "materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry" in a health benefits program;
- making a false or fraudulent statement to the federal government; or
- "causing" a false claim or statement of material fact to be made in a federal or state health benefits program.

Physicians may also face civil liability for making a false statement, or an administrative penalty for causing a false claim to be presented. In sum, any physician who issues an illegitimate prescription could be prosecuted under a variety of federal criminal, civil, and administrative laws either for making a false statement or for causing a subsequent false claim filed by a pharmacist.

A review of reported cases and of newspaper reports of cases reveals that most physicians charged with Medicare or Medicaid fraud in connection with prescribing of controlled substances are not charged for prescribing, but for conduct related to the prescribing. The charges most common are that:

- a physician fraudulently billed for physician visits related to the prescriptions;
- a physician fraudulently billed for diagnostic testing related to the prescriptions;
- a physician received a kickback related to the prescriptions; or
- a physician permitted unlicensed persons to examine patients and billed for their services.

In a typical case, a physician sees large number of patients, all or most of whom receive prescriptions for narcotics. Often, the patients travel long distance to get to a particular doctor, bypassing other doctors who provide legitimate pain management. The physician bills Medicaid for office visits and for diagnostic tests, but there is no evidence that the physician actually examined the patient or that the tests given were necessary or used in any way. Prescriptions may be written by receptionists or other untrained personnel. In some cases, the physician also receives a kickback from the pharmacy or clinical laboratory. Some cases include additional indicia of the absence of legitimate treatment, such as the exchange of drug prescriptions for sex or, in one case, the provision of psychotherapy for patients who were dead.

Although it is possible that some of the reported cases involved legitimate prescribing for pain management, it is hard to perceive this in the facts as reported. In one case, the physician admitted to illegitimate prescribing. In others, the facts seem to point overwhelmingly against legitimate prescribing, as in cases that involve drug for sex exchanges. The few reported cases that actually involve pain management were marginal, such as one involving a dentist.

To determine the extent to which doctors who prescribe large quantities of opioids for pain management are at risk for fraud prosecutions, I interviewed prosecutors and attempted to interview potential defendants and their attorneys. I interviewed a variety of experts, including the heads of the MFCUs of three states who have been active in prosecuting narcotics fraud cases, a regional administrator of the MFCU of another active state, an assistant U.S. attorney who works with narcotics fraud cases, the director of the national

MFCU organization, an attorney from the American Medical Association, an attorney with OIG, two attorneys who represent physicians charged with Medicaid fraud, and a physician who had been involved in a Medicaid fraud investigation. I also attempted to identify other doctors who had allegedly been charged with fraud claims.

Prosecutors uniformly asserted that they were not interested in using their limited resources to pursue doctors who were engaged in legitimate prescribing. They have investigated cases involving the prescribing of large quantities of narcotics, which were reported to them by SURs, pharmacy boards, or the Drug Enforcement Agency on the basis of pharmacy audits or police information. Several said, however, that they terminated the investigations when they found that the source of the prescriptions was a legitimate pain clinic. One prosecutor said borderline cases were referred to a medical board or peer review organization. The prosecutors said that they would not pursue physicians who keep good records and use a broad spectrum of pain management techniques. The prosecutors uniformly said that they were most likely to pursue physicians if their medical records did not document that patient visits billed to Medicaid had actually occurred or that tests billed to Medicaid were appropriately ordered.

One attorney had represented several physicians in recent years in health care fraud cases based on prescribing of controlled substances. He stated that cases which several years ago would have been brought as narcotics cases are increasingly being brought as both narcotics and health care fraud cases. None of the cases he defended had been brought exclusively as fraud cases. All had been brought as criminal rather than civil or administrative fraud cases--one had been a false statements case based on the prescriptions themselves, and the remainder had been false claims cases based on charges that services billed by the doctor had not been provided or were unnecessary.

The attorney stated that he believed these cases were usually initiated on the basis of information provided by private insurers or police informants, rather than by Medicaid DUR. In virtually all instances, however, the doctor was not given an opportunity to explain or discuss his prescribing until law enforcement teams showed up at the office.

Based on these interviews, one is left with the impression that the doctors who are most likely to get into trouble are not those who specialize in pain management or who care for terminal cancer patients, but rather those who use opioids to treat persons with chronic nonterminal pain, often in workers' compensation cases, and who do not document adequately their attempts at using alternative treatment modalities or their consultations with pain specialists. Even though these doctors may be well meaning, their actions are open to alternative interpretations, which can get them into trouble with drug enforcement agencies and, secondarily, with fraud enforcement agencies. Because many doctors who occasionally prescribe for pain management meet this description, however, a considerable number of doctors are exposed to fraud and abuse prosecution.

The most substantial and immediate threat of health care fraud enforcement to pain management might not be found in the handful of criminal fraud prosecutions brought against doctors engaged in prescribing pain medications, but in the high level of scrutiny that OIG is applying to the Medicare hospice program.

As noted in the discussion of the Medicare hospice benefit, OIG has released a series of reports in recent years based on investigations of hospices, focusing particularly on the hospice-nursing facility relationship and on hospice eligibility certifications. More significant, OIG has recently released a fraud alert addressing hospice relationships with nursing facilities. Fraud alerts are high profile signals of the intention of the federal fraud oversight agencies to pursue enforcement aggressively in particular areas. They are intended to have an effect on provider conduct, and usually do. Some of those I interviewed believe that doctors are already being deterred from certifying patients for hospice because of a fear that they will face fraud investigations if their patients fail to die in six months. To the extent that this results in patients being denied palliative care, this effect is very unfortunate.

Similarly, one doctor interviewed commented that it is, from time to time, necessary in treating patients with complex pain problems to provide medical procedures at a rate in excess of those recognized as appropriate under Medicare-carrier local medical review policies. When these aberrations show up in audits (often conducted years later), the carrier may threaten fraud and abuse prosecutions if the provider does not agree to drop or pay back the claims.

As is often true with enforcement of the criminal laws, the reality perceived by law enforcers is very different from the reality perceived by defendants and those who fear that they may become defendants. Law enforcers, who are acutely aware of the scope and seriousness of health care fraud, reject the suggestion that they would consume their limited resources persecuting conscientious doctors engaged in legitimate pain management. Doctors, on the other hand--who have heard of a case in which federal agents have invaded a doctor's office with guns drawn--become nervous when they receive a routine DUR inquiry regarding their prescribing.

Perhaps the primary need in this area is education. Enforcement agents need to be made more aware of the legitimate role of narcotics in pain management. They also need, perhaps, to take a more realistic view of the difficulty of predicting the course a patient's illness after a referral to a hospice. Conversely, doctors need to understand that inquiries from DUR or even SUR units are not the equivalent of the filing of criminal charges, and need to be willing to justify candidly their prescribing. Both DUR and fraud and abuse programs deal with real problems in the controlled substances area, and a complete hands off approach would risk real abuse. Doctors also have to be scrupulous in documenting their care of patients when they prescribe controlled substances in case surveillance agencies inquire. For the foreseeable future, pain management providers and fraud and abuse enforcers are likely to have an uncomfortable relationship as these competing needs are reconciled.

Conclusion

We do not have a coordinated approach in the United States to pay for health care for those who do not have private or employment-related insurance. Rather, we have an odd and tattered assortment of leaky umbrellas and ragged safety nets. Not surprisingly, we do not have a coordinated approach to paying for pain relief either. Some programs cover some pain modalities for some recipients or beneficiaries under some circumstances. I have identified some of the gaps and deficiencies in the federal and state health care programs that play the largest role in paying for pain management.

Beyond the specific limitations of these specific programs, however, larger issues exist. First, the philosophy of our health care financing programs, like that of our medical care system generally, is curative and rehabilitative. Palliative care fits poorly into this model, and is thus only poorly accommodated by our programs. This may be changing, but very slowly.

Second, we are profoundly ambivalent about public provision of health care services--anxious that someone who is not truly qualified might receive public health care benefits. Pain is by its nature subjective, hence it is often hard to verify objectively. Those who receive public benefits solely because of pain, therefore, are sometimes met with suspicion. Controlled substances, moreover, also make us very uneasy; we are leery of those who use them. While persons who claim to be in pain receive our sympathies, they also provoke our distrust, particularly when the cause or the extent of pain is not easily quantified. We seem as a nation to be deeply ambivalent about the public financing of pain treatment.

Third, health care professionals and legislators need to think creatively about health care financing and provision programs that will provide comprehensive approaches to pain management provision, that will transcend our present limited and compartmentalized approaches. Several such approaches are described in the 1998 Report to Congress of the Medicare Payment Advisory Commission. Included among the approaches mentioned in the Commission report are the Hospital Palliative Care Initiative of the United Hospital Fund of New York, which will create a palliative care position at Brooklyn Hospital Center to coordinate palliative care, including care for discharged patients receiving home care, and a palliative care consultation team at Saint Vincent's Hospital; the OPTIONS program of HealthCare Partners Medical Group of Los Angeles, which provides multidisciplinary care emphasizing symptom management, pain control, and quality of life for the terminally ill; and the Medicaring Project proposed by George Washington University's Center to Improve Care for the Dying, to provide extended hospice-style services for those in the last phase of life.

A final recommendation, therefore, is that research and education continue to be promoted to help the public generally--and policy-makers in particular--understand the condition and needs of persons who suffer pain, to perceive how our health care financing system fails these persons, and to see the opportunities that need to be pursued for improving access to pain management for Americans who need it.

Ann Alpers, "Criminal Act or Palliative Care? Prosecutions Involving the Care of the Dying"

Journal of Law, Medicine & Ethics, 26, no. 4 (1998): 308-31.

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Two significant, apparently unrelated, trends have emerged in American society and medicine. First, American medicine is reexamining its approach to dying. The Institute of Medicine, the American Medical Association, and private funding organizations have recognized that too many dying people suffer from pain and other distress that clinicians can prevent or relieve. Second, this past decade has marked a sharp increase in the number of physicians prosecuted for criminal negligence based on arguably negligent patient care. The case often cited as a watershed is *People v. Einaugler*, which involved a New York nursing home patient whose physician was convicted in 1993 of two criminal misdemeanors after he ordered an elderly dialysis patient to be tube fed through a peritoneal dialysis catheter.

How is the growing awareness of dying patients' pain and the increasing willingness of prosecutors to charge physicians with crimes connected? Pain at the end of life is frequently treated with narcotics, prescription drugs that are closely regulated by state and federal law. That complex web of laws--and a growing fear of legal sanctions--has deterred physicians from prescribing controlled substances. As those legal sanctions move from disciplinary actions to criminal charges, physicians' fears may expand.

In this article, I discuss and analyze what actions have put physicians or nurses at risk for criminal investigation or prosecution in connection with their care of dying patients, particularly their management of pain. I do not survey all criminal actions against physicians and nurses. Some physicians have been investigated, prosecuted, and convicted for providing gross or culpable departures from the ordinary standard of care. For example, a California physician was convicted of involuntary manslaughter when he wrote illegal prescriptions for controlled substances and his patient used the opiates to commit suicide. Rather, I focus on pain management for dying patients and so limit discussion to the criminal investigations and actions brought against physicians for care, particularly pain control, at the end of life.

Background cases: Is too much morphine murder?

In 1982, *Commonwealth v. Capute*, a highly publicized murder trial in Fall River, Massachusetts, raised the question of whether a caregiver's use of opioids could betray an intent to kill. After five weeks of testimony, Anne Capute was acquitted of both a murder charge and a second charge, illegally dispensing morphine. In 1990, the county attorney and the medical examiner in Hennepin County, Minnesota, accused five physicians of committing homicide in two separate cases. Both cases involved terminally ill patients who received large doses of morphine before they died. The county attorney chose not to carry the cases forward to a grand jury and, instead, he issued guidelines for treating end-of-life pain. Although the county attorney determined that the deaths were homicides, he believed that he had little chance of conviction because the elements of the crime could not be proved beyond a reasonable doubt.

Physicians may prescribe large doses of morphine because dying patients do suffer excruciating pain. Patients' distress is magnified because they not only face physical pain, but they also remain anxious that physicians will allow needless discomfort to pervade the dying process. Myriad testimonials illustrate this dilemma. Beyond anecdotes, data suggest that despite the existence of effective pain control, such fears are justified. Patients in the SUPPORT study suffered considerably: the families of half of the patients who died reported that the patients experienced moderate or severe pain during most of their final three days of life.

Several factors contribute to physicians' failure to use high dose opioids to manage the pain of dying patients. Survey data suggest that some physicians and nurses lack the knowledge and skill to use pain medications effectively. The same data also indicate that physicians and nurses fear criminal prosecutions resulting from the administration of large amounts of morphine at the end of a patient's life. This fear may extend to health care professionals who specialize in palliative care. Dr. Timothy Keay, a palliative care expert at the University of Maryland, described his approach to morphine use by noting, "I want to practice good medicine. But it has to be squeaky clean, or you can wind up in big trouble." Media attention to physicians' fears may fuel professional anxiety as well. For example, NBC's *Today Show* reported that the U.S. Supreme Court's decisions in *Washington v. Glucksberg* and *Vacco v. Quill* "could make murder charges against doctors more common." These cases did not involve criminal actions, and nothing in the Supreme Court's holding, that there is no general constitutional right to physician-assisted suicide (PAS), suggests

that states will prosecute more physicians. However, physicians are correct in noting that they, as a profession, have become more vulnerable to criminal actions. Even though criminal prosecutions of physicians are still rare, they have become more common in the United States within the past ten years, and the prosecutions involving the use of morphine or other analgesics or sedatives to treat severe pain must be considered in light of this trend toward criminal prosecutions for lapses in clinical judgment.

Although data are scarce, anecdotal evidence indicates that criminal prosecutions for pain medications given to dying patients frighten doctors, nurses, and hospital administrators. Reports in Massachusetts and Minnesota following *Capute* and the Hennepin County cases suggest that health care professionals hesitated to provide appropriate doses of morphine for dying patients. *Minnesota Medicine* quoted the family of a seventy-five-year-old cancer patient who had died in pain. "The nurses and the physician said, 'There are these morphine cases out there,'" reported one family member. "'One [nurse] even said, 'You know they can send people to jail for this.'" Eight years ago when the Minnesota cases were investigated, lawyers and ethicists assured physicians that "Nobody has gone to jail for administering too much morphine to a dying patient." That statement no longer holds true. In 1997, a Kansas jury found Dr. L. Stan Naramore guilty of attempted first-degree murder after he gave injections of fentanyl and Versed to a seventy-eight-year-old woman who was dying of cancer. Naramore was also convicted of second-degree murder in connection with his decision to withdraw respiratory support from an eighty-one-year-old diabetic male patient who had suffered a stroke. Sentenced to concurrent terms of five to twenty years, he served thirty months in jail before being paroled. In February 1998, his appeal was argued and submitted to the Kansas Court of Appeals. In July 1998, that court summarily reversed the convictions.

Research methodology

In 1990, the legal landscape pertaining to end-of-life care shifted. At the end of 1989, the Supreme Court implicitly held, in *Cruzan v. Director, Missouri Department of Health*, that a patient has a liberty interest in refusing unwanted medical care, including life-sustaining therapy like nutrition and hydration. This decision became the cornerstone of a trend that began with a California appellate court decision, in *Barber v. Superior Court*. In this case, the California Court of Appeals held that a physician charged with murder and conspiracy to commit murder had not committed an unlawful act when, with permission from the patient's family, he removed hydration and nutrition tubes from a comatose patient. A physician, the court found, has "no duty to continue treatment, once it has proved to be ineffective." Because it was unclear whether withholding or withdrawing care was a criminal act prior to 1990 in states other than California, cases from the period before the Supreme Court's *Cruzan* opinion could muddy the analysis and provide little useful contemporary information. Therefore, the search for cases here focused on instances of alleged criminal activity after 1990, after the Supreme Court had decided *Cruzan*.

For this article, searches of national data bases within the LEXIS-NEXIS system were conducted to identify physicians who had allegedly given a patient a lethal dose of medication and were under criminal suspicion. Cases that were not discussed through public media (including print journalism, radio, or television reporting), criminal indictment proceedings, or a trial might not have been included. Civil cases, which include malpractice suits, are not part of this analysis. Neither are homicide cases that concerned physicians but did not involve patient care. The data base searches focused on reports of medical professionals who were associated with alleged homicides in relation to dying patients by using keywords to identify those issues. Numerous telephone interviews with prosecutors, defense lawyers, state medical board staff members, reporters, and others with knowledge of alleged crimes were also conducted to obtain detailed information about individual cases and to discern local and national trends. Although unreported cases of physicians allegedly ending a dying patient's life with pain medications might not be included here, it is likely that every case since 1990 that resulted in indictment or prosecution is.

Killers and pain-killers: a primer on homicide and opioids

Physicians, like all citizens, must abide by the social norms of behavior that criminal laws reinforce. A crime usually contains two basic elements. First, there must be a criminal act. Second, with the exception of manslaughter statutes, most criminal laws covering unlawful deaths require the act to be intentional. Malice, whether express or implied, is always necessary to convict a person of any degree of murder. Crimes like rape, fraud and abuse, or suicide assistance, whether or not the alleged perpetrator is a physician, have one common element: they involve intentional criminal acts. A physician's use of opioids to treat a patient's pain, on the other hand, need not, and usually is not, an intentional criminal act. Prosecutors must find evidence of a physician's intent to kill or a reckless disregard for a patient's well-being.

Homicide and criminal codes

The cases considered here cover investigations for a number of alleged crimes. Because crime is an area of law traditionally left to the states, each state has its own penal code and may define homicidal crimes slightly differently. Some states choose to divide murder into degrees. For example, in California, first-degree murder is generally a willful, deliberate, and premeditated killing, while second-degree murder covers "all other kinds of murder." New York divides homicides into five categories: criminally negligent homicide; first- and second-degree manslaughter; and first- and second-degree murder. The American Law Institute has created a model on which state legislatures can pattern their codes, and its general definitions are useful background here. According to the *Model Penal Code*, murder occurs when a homicide is committed purposely, knowingly, or recklessly "under circumstances manifesting extreme indifference to the value of human life." In all states and in the *Model Penal Code*, criminal attempts, like attempted murder, are also crimes. Gross physician negligence, which does not require intentional and expressly or implicitly malicious killings, could result in a charge of involuntary manslaughter in a state that uses that derivation of the crime. California defines involuntary manslaughter, in part, as "the commission of a lawful act which might produce death, in an unlawful manner, or without due caution and circumspection." "Aggravated, culpable [and] gross negligence" are necessary for an involuntary manslaughter conviction. Finally, physician negligence could also result in a criminal charge of reckless endangerment. Although jurisdictions may differ in the details, all states criminalize homicidal behavior and, depending on a prosecutor's decision and the facts of the case, a physician may be criminally liable for any act that grossly deviates from the standard of care and results in a patient's death.

Medication for the palliation of pain

Dying patients receive several types of drugs for palliative care, a category of care that refers to the management of patients with active, progressive, far-advanced disease that cannot be cured. Palliative care aims to control pain and other symptoms and to achieve the best quality of life for patients and their families. Almost all of the patients in the cases analyzed here would be eligible for palliative care. It is not surprising, however, that many of them did not receive adequate palliation because the quality of end-of-life care in America remains low. For example, numerous studies have mapped the prevalence of pain for dying patients, particularly those with advanced cancer.

The major group of drugs used in cancer pain management are opioid analgesics. *Opioid* is a general term that describes naturally occurring and semisynthetic drugs derived from the juice of the opium poppy (like morphine and fentanyl) and completely synthetic drugs (like methadone) that produce their effects by binding to opioid receptors. Respiratory depression is the most serious adverse effect of strong opioids. The morphine-like agonists act on brainstem respiratory centers to produce, as a function of dose, increasing respiratory depression to the point of apnea. Significant respiratory depression rarely occurs in a patient whose opioid dose has been gradually adjusted against pain. However, tolerance to opioids is relative and almost never complete. Even a cancer patient who has developed tolerance to high doses of strong opioids can have the drug tolerance overcome with doses that are significantly greater than the patient's current opioid blood level. For example, in a five-year study of physicians in the Netherlands, where euthanasia and assisted suicide are practiced with increasing openness, 84 percent of all respondents reported that they had administered opioids in such doses that they may have shortened a patient's life. Many of the cancer patients could tolerate opioids because they were taking opioids for pain management.

Benzodiazepines are sometimes used as adjuvant medication for some malignant pain. They are also the primary pharmacologic treatment for anxiety during the dying process. In general, benzodiazepines act as depressants of the central nervous system (CNS), producing all levels of CNS depression, from mild sedation to hypnosis to coma. Opioids, when combined with benzodiazepines, act to cause more severe respiratory depression and a simultaneous drop in blood pressure. Some of the cases analyzed here involve acute administrations of Versed or Valium (benzodiazepines) with fentanyl or morphine (opioids).

Several of the cases involved potassium chloride, a drug that is regularly used in an intravenous drip to treat potassium deficiencies that often result from treatment for common diseases like heart failure and high blood pressure. Potassium chloride can be fatal because, in excessively high blood levels, it can stop the heart. Blood levels become dangerously high either when too much potassium chloride is given or a correct amount is given too quickly. The drug is used in some states for lethal injections and has also been used by Dr. Jack Kevorkian in his suicide machines. In 1987, the *Journal of the American Medical Association* published a brief report of a "proud and private man" with circulatory insufficiency, small vessel disease in both legs. The patient declined amputation and dialysis and then asked his physician to "shoot [potassium] right into my vein." He argued, "What's the difference?" Without dialysis, "the potassium in my blood will

build up and then my heart will stop." The potassium injection would be "similar to what will happen by itself, but ... it will save me the agony of waiting and pain."

Cases from 1990 to present: Criminal acts or end-of-life care?

Discussion of criminal cases should begin with the observation that physicians and nurses who provide good palliative care to patients have little to fear from the criminal law. This research shows no systematic efforts by any state or local government to target health care providers or dying patients for routine investigation or review. Treatment of terminal pain is never investigated unless someone knowledgeable about the treatment informs either a hospital supervisor, an ethics committee, or a local prosecutor. State boards in all of the criminal cases studied here reacted to the investigations of hospitals or local prosecutors; none of them initiated any of these actions. In other words, these cases represent intercollegial discord and miscommunication or disagreements between providers and families, rather than suspicious or overzealous prosecutors. Furthermore, the number of cases identified is small and probably underestimates the actual number of times physicians have used lethal doses for the primary purpose of ending a patient's life. For example, a recent national survey of physicians likely to care for dying patients reported that 4.7 percent of respondents said they had administered at least one lethal injection. Another survey of 355 oncologists found thirty-eight cases where physicians had injected a patient with a lethal dose of a drug or had written an order to that effect. It is therefore possible, and perhaps likely, that many more health care providers use controlled substances to hasten death than are ever investigated or prosecuted.

Overview

Tables 1, 2, and 3 show the results of searches of national data bases of print and broadcast journalism and of legal data bases of court opinions. Table 1 shows the reports of physicians who have been criminally investigated but not indicted or formally prosecuted. Since 1990, at least thirteen physicians have been criminally investigated but not formally indicted or prosecuted. Table 2 lists the cases of physicians who have been formally charged or indicted for homicide. Three have been tried for murder in connection with their treatment of dying patients and two more have been charged with or indicted for murder. Table 3 shows the experience of nurses with the criminal justice system. Two nurses have been criminally investigated and two more have been indicted. One of the nurses indicted, Orville Lynn Majors, still awaits trial.

Most of these cases involve a single health care provider. The Hennepin County cases involved five physicians; the New Haven case involved two physicians (the attending surgeon and a resident), and the Volusia County hospice case involved an undisclosed number of physicians and hospice workers. This Florida hospice case is the only criminal investigation that examined the activities of health care team members of different disciplines. These cases represent a total of at least twenty-three investigations of professional caregivers, eight indictments, four murder trials, and two physician convictions. One set of convictions (for attempted first-degree murder and second-degree murder) was reversed on appeal.

The seven indictments in the last eight years represent a substantial increase in criminal prosecutions of end-of-life care. In the fifty-five preceding years, from 1935 to 1990, ten physicians were charged with killing terminally ill patients. Those ten charges resulted in seven trials leading to one guilty plea, one conviction, three acquittals, and three dismissals. None of the physicians involved in those cases served jail time, and one is notable as a case of withdrawal of support at the request of the patient. Such withdrawal of treatment is no longer considered a criminal action.

Where were providers prosecuted?

Indiana is the only state where more than one health care professional has been indicted. Dr. Marilyn Dargis was indicted by a Michigan City grand jury in 1992 for reckless homicide following her alleged inappropriate use of morphine and suffocation of a patient. Dargis injected a sixty-six-year-old man who had suffered a heart attack with morphine following an attempt to resuscitate him. Though the patient was believed to be dead, two nurses told the Indiana Medical Licensing Board that they noticed him breathing again. At that point, they saw Dargis inject the man with morphine in order to stop his breathing. Dargis entered a plea agreement to perform community service in return for a suspension of the charges against her. The case of Majors concerns a licensed practice nurse who allegedly used potassium chloride to kill at least four, and perhaps more, patients in an intensive care unit (ICU) in rural Indiana. Majors was indicted, arrested, and pleaded not guilty to murder charges in December 1997, and he continues to await trial.

Two cases in California were investigated but none of the health care workers in either was formally charged. The other cases arose in Massachusetts, New York, Georgia, Florida, Minnesota, Kansas, Texas, and Oregon. The most notable element of these cases is geography: they tend to be rural. With the exception of the Hennepin County and the San Francisco and Beverly Hills investigations, none of which proceeded to indictments or formal charges, all of the cases occurred in small towns or rural counties. Many of the health care providers were outsiders--either newly arrived, members of racial or ethnic minorities, or living alternative lifestyles. Given that criminal processes can reflect majoritarian power, this last observation may reflect troubling patterns of prejudice or injustice.

Where did patients die? What was their relationship to the physicians?

All the cases involved deaths in hospitals, with the exception of the investigation of Sharon LaDuke and her actions at a skilled nursing facility in New York State. Only one of the physicians was related to or a friend of the patient (Dr. Frederick Curren of Massachusetts allegedly prescribed analgesics and sedatives for his ex-wife who used them to commit suicide.) This trend differs from the cases reported prior to 1990. Five of those ten doctors were prosecuted for deaths that occurred in the patient's homes. Three of those five physicians were related to the patients, and a fourth had been a long-time friend of his patient. The earlier cases may reflect the potential exposure of family members and close associates to criminal liability.

In the 1990s, criminal investigations of health care workers for treatment of patients at the end of life have involved professional relationships between physicians and patients. The patients in Tables 1 and 2 sought care because they were seriously ill. In the cases that proceeded to murder trials, the patients did not have ongoing relationships with the physicians, nor did they choose these doctors individually. For example, Dr. Naramore was the only active physician in the rural Kansas county where he practiced; and Dr. Ernesto Pinzon-Reyes, while on call over a weekend, was the attending physician when a patient of his colleague died.

None of the patients seen by the four physicians accused of murder or attempted murder requested suicide assistance. During the four murder trials, evidence was put forth that neither the families nor the physicians accepted euthanasia or PAS as appropriate, ethical treatments. These cases differ from those involving Dr. Kevorkian because his patients have specifically sought him out for help in hastening death. The fact that none of the cases reviewed here involves PAS or right-to-die issues also distinguishes them from most of the earlier criminal prosecutions involving care of the dying. Few of the pre-1990 cases involved morphine, and none of the physicians in those cases argued that he/she used the various fatal agents to manage pain or provide palliative care.

How did prosecutors become involved?

All of the cases reported here involve an informant, someone who participated in caring for the patient or was knowledgeable about the patient's care and reported concerns about the way in which the patient died. Apparently, the criminal justice system plays a passive role in policing physician and nurse behavior. Even in the cases where potassium chloride was administered, the medical examiner, local prosecutor, and state medical board depended on informants to flag the cases. Routine institutional review processes failed to catch these cases. In one instance, the case of Dr. C. Douglas Wood, where the surgeon gave his patient a potassium chloride injection, Wood himself filed an incident report; however, nurses who witnessed the injection also served as informants.

The Majors case from Indiana demonstrates how informants play such key roles. In this case, the hospital administration launched a herculean effort to investigate Majors after nurses and family members reported their suspicions. Before dismissing the nurse, Vermillion County Hospital conducted an exhaustive internal review that revealed that patients were almost forty-three times more likely to die when Majors was on duty.

Who were the informants?

As Table 4 indicates, nurses were the most frequent sources of information about potentially inappropriate terminal care. In the case of Naramore, the family raised the initial concerns. Physicians are conspicuously absent as informants. Research has not uncovered a single case either in the most recent wave of prosecutions or in the earlier cases where a physician provided information about another physician.

What kind of end-of-life care raises suspicions?

Several of the cases involve treatment flowing from the decision to withdraw ventilatory or other life-sustaining treatment from the patients. Two of these withdrawal cases occurred in emergency departments

and so include a special kind of withdrawal: the decision to stop resuscitative efforts because they have not succeeded in restoring circulation or breathing or because they have failed to meet the patient's or family's goals of care.

These withdrawal cases are significant and raise particularly difficult issues regarding the role of physician intent in evaluating treatment at the end of life. Physicians who withdraw support, either at the patient's or family's request or on their own initiative but with consent or assent, foresee and may in some way intend the patient's death. Some physicians act not only to rid the patient of unwelcome technology, but also to help the patient end his/her suffering by dying sooner. The fact that the physicians, in some sense, intend the patient's earlier death has not created ethical or legal trouble so long as other conditions, such as informed consent, lack of benefit from the treatment, or futility, are in place. Physicians' intent raises difficult questions in the withdrawal cases, as discussed below, when the other conditions, including professionally competent methods of withdrawal, are not present.

Several of the cases involved potassium chloride. Dr. Wood, an Oklahoma surgeon, was convicted of involuntary manslaughter after he injected 20 mL of potassium chloride into a patient who was suffering from congestive heart failure. Wood argued that he used potassium chloride in an attempt to restart the patient's heart. In a separate incident, an unidentified nurse in Texas was charged with murder after he/she injected potassium chloride into the feeding tube of a terminally ill patient. In San Francisco, an unidentified physician was investigated after he/she gave a nine-year-old child in a pediatric ICU a bolus of potassium chloride. Dr. Pinzon-Reyes of Florida, was tried for first-degree murder because he injected potassium chloride into the intravenous port of a seventy-year-old man with metastatic lung cancer. The use of potassium chloride raises questions about the physicians' and nurses' purposes in administering the drug because it has no palliative function and does not treat pain.

Criminal prosecutions arising from care of the dying and attempts to manage pain in the terminally ill fall into three broad categories: withdrawal of life-sustaining treatment and any accompanying use of pain medication; the administration of morphine or other analgesics and sedatives; and terminal care that includes the use of a potentially fatal agent, such as potassium chloride, insulin, or chloroform. Because these cases are few and quite bound to their facts, it is useful to look closely at the details. Examination of the facts is particularly important because these cases have as much to do with the personalities of the health care workers, the patients, and the communities as they do with the actual care given or withheld. For example, one of these murder trials involves withdrawal of support and another involves the administration of potassium chloride. However, the San Francisco case where a child received potassium chloride following withdrawal of support was never taken to a grand jury. Here follow significant examples of each of these three types of cases.

Criminal prosecutions and withdrawal of support

Withdrawal of support raises several issues that recur in the criminal cases. Most important among these is the doctrine of double effect and its role in assessing physician intent. Ethicists distinguish morally permissible care that results in death from inappropriate killing by applying the rule of double effect. The doctrine has always been controversial in moral philosophy, in medical ethics, and in criminal law. It plays a critical role in evaluating the actions of physicians and nurses in treating patients at the end of life, both from the prosecutor's perspective and the hospital's or institution's. Therefore, it is essential to understand the rule and its clinical and legal application to end-of-life decisions. The withdrawal cases present a unique lens through which to view intent because, in at least some cases, physicians and nurses have multiple motivations.

A significant number of the criminal cases involving end-of-life care reviewed in this research involve withdrawal of support. Notable among these is the case of Dr. Eva Carrizales, whose murder trial for withdrawing ventilatory support and then smothering a thirty-nine-day-old male neonate with multi-organ failure ended with a hung jury. The baby's parents also argued that they had not consented to withdrawal of treatment. The district attorney dismissed the charges after polling jurors and considering evidentiary difficulties. One nurse changed her pretrial testimony--that the physician had applied pressure to the baby's carotid artery to choke off the blood supply to his brain--and instead testified that her supervisor urged her to give evidence against the physician.

Withdrawal cases have also involved alleged excessive use of opioid analgesics or bolus administration of potassium chloride. For example, the LaDuke case involved a criminal investigation of a nurse for giving too

much fentanyl to a patient with advanced lung disease who was experiencing severe pain after her ventilatory support had been withdrawn. The Hennepin County cases also involved high doses of opioid analgesics combined with benzodiazepines, following the withdrawal of ventilatory support. The following case is a relatively straightforward instance of withdrawal of support because it involved neither pain medication nor potassium chloride and withdrawal was done with the consent of the patient's family.

The Naramore-Willt case

Dr. Naramore was an outsider in a small town. He moved to St. Francis, Kansas, a farming town of fewer than 1,500 in the northwest part of the state, in 1992. St. Francis is the seat of Cheyenne County, which has a population of 3,200. Naramore had a strained relationship with the community. The medical writer for the *Kansas City Star* noted that he "didn't quite follow the code of friendliness and modest behavior." He "played the ponies. Drank and smoked. Drove his flashy red Lincoln too fast." Naramore was recruited by the Cheyenne County Hospital board of directors when St. Francis's long-time doctor retired and his predecessor resigned. The hospital guaranteed Naramore a monthly income of \$10,000.

Naramore's guaranteed income, urbane attitude, and penchant for expensive electronics drew attention. He and his family were the object of town gossip. Stories circulated that he was an alcoholic and a drug addict. Even though many of the physician assistants with whom he worked admired his skill, prominent citizens resented Naramore's sharp criticism of St. Francis's politics. For example, Naramore wrote a blistering letter to the chairwoman of the St. Francis Chamber of Commerce castigating community members for their management of the hospital. He publicly criticized the town council's plan to create a network of federally funded clinics.

Naramore had a busy practice. Among his patients was Chris Willt, an eighty-one-year-old man with severe diabetes, high blood pressure, and kidney and liver disease. In August 1992, Willt was brought to the emergency department with a possible diagnosis of cerebral vascular accident or stroke. Willt had to be restrained in the emergency department. He was then given a shot of Norcuron, a paralytic agent used to assist in intubating individuals, and intubated. Because St. Francis Hospital did not have a ventilator, medical technicians had to attach a bag to Willt's breathing tube and squeeze it manually to provide oxygen. Naramore and the hospital staff manually ventilated Willt, shocked his heart, and gave him intravenous fluids for over three hours.

At some point during Willt's time in the emergency department, his brother, Rudy Willt, was summoned. Naramore told Rudy that his brother had suffered a severe stroke and that further treatment might be futile. He added his opinion that Willt was likely to be a "vegetable." Dale White, a nurse who was also the hospital administrator, was working in the emergency department. Naramore told White that he thought Willt was brain dead. White told Naramore that it would be permissible to stop life support if a second physician agreed with the diagnosis of brain death. Rudy spoke with his niece and with the Lutheran minister. He concluded that Chris would not want to live in a vegetative state or be artificially maintained.

Meanwhile, White noticed that Willt was moving his arms and legs. Naramore attributed these movements to seizure activity. White suctioned Willt's mouth to remove saliva and Willt gagged. Naramore believed the gagging could affect Willt's ability to receive oxygen through the breathing tube so he administered a second shot of Norcuron. White believed the gagging showed that Willt could not be brain dead. Ernest Cram, St. Francis's long-time physician and county coroner, was called in to confirm that Willt was brain dead. Cram did a brief exam. He noted that the pupil of Willt's eye was fixed, and found no pulse in the carotid arteries of Willt's neck. Cram declared Willt dead and Naramore stopped resuscitation.

When resuscitation stopped, White informed Cram that Willt had been given the neuromuscular blocking agent, Norcuron. White described himself as "stunned" that Naramore withdrew ventilation while Willt was still under a neuromuscular block. He added, "I think there's a difference in trying to ease discomfort and in taking away the ability to breathe and then stopping the breathing." He initiated a review of Naramore's care of Willt and of another patient, Ruth Leach. That review led to the hospital's reporting both incidents to the Kansas State Board of Healing Arts. In September 1992, the hospital took away Naramore's staff privileges. In October 1992, the Kansas Bureau of Investigation began looking into the Naramore cases. In October 1993, he was hired by North Big Horn Hospital in Lovell, Wyoming, but the hospital terminated his contract because of patients' complaints. In July 1994, Naramore was arrested in Lovell, and charged with second-degree murder of Willt. He was also charged with attempted first-degree murder of Leach, a case I discuss.

Naramore's bond was set at \$500,000. He spent the eighteen months from arrest to trial in jail because he could not post bail. At trial, the prosecution argued "[T]he evidence ... show[ed] that [Naramore] killed [Chris Willt]" by administering a paralyzing drug and then cutting off his oxygen supply. Naramore argued that he could not have killed Willt, who was dead already. Some testimony suggested that Willt was not, in fact, brain dead and that Naramore and Cram had used the term brain death loosely to mean permanently unconscious rather than to meet the Harvard Brain Death criteria or the Uniform Declaration of Death Act criteria. The jury was not instructed (nor were such instructions requested) on appropriate resuscitation attempts. After a two-and-one-half week trial, Naramore was convicted of the second-degree murder.

This case is primarily a withdrawal of life support case. Willt was resuscitated and bagged for approximately three hours, during which time Naramore failed to see improvement in his condition. He recommended that life-sustaining treatment (the use of intubation and a bag to provide oxygen) be withdrawn. With the consent of Willt's brother, support was withdrawn; however, the withdrawal was handled inappropriately. Standard protocols for withdrawal of ventilation or other life support include stopping neuromuscular blocking agents, such as the Norcuron given to Willt before extubation.

The doctrine of double effect

The foundation for the right of patients and their families to refuse life-sustaining treatment rests on early actions against physicians for withdrawing care. Perhaps the best-known case involved the death of Clarence Herbert. Herbert had a coronary arrest in the recovery room following routine surgery, was resuscitated and placed on a ventilator, but suffered injury to his brain. After three days in the ICU, physicians estimated that he would not regain consciousness and Herbert's family asked that ventilatory support be withdrawn. Herbert was extubated but continued to breathe and showed minimal brain activity. Two days later, at the family's request, physicians ordered removal of nutrition and hydration and the patient died. A nurse who disagreed with the decision to withdraw support alerted the district attorney, and the surgeon and internist were charged. The California Court of Appeals, in a decision widely followed in other jurisdictions, dismissed the criminal information because failure to continue unwanted or nonbeneficial treatment is not unlawful failure to perform a legal duty, even when the physicians know that the patient will die as a result.

Many medical ethicists cite the rule of double effect to explain why a clinician is permitted to administer high doses of opioids to relieve a terminally ill patient's severe pain, even in amounts that would cause a patient to die sooner than otherwise. The more severe and intractable a patient's pain, the greater the justification for risking premature death. Thus, the amount of opioids that are given and the rapidity with which the dose is increased must be proportional to a patient's pain and suffering. Despite the rule of double effect, some physicians and nurses have been reluctant to use sufficient doses of opioid pain-relievers, even when dying patients are suffering. This reluctance stems from ethical and legal fears about hastening death and from moral or psychological rejection of the alleged difference between intent to cause death and foreseen possibility of causing death. Caregivers' rejection of differences between actions intended to hasten death, as opposed to actions foreseen to do so, draws support from research that shows clinicians act from multiple motives in providing end-of-life care. Research on the use of sedatives and analgesics in ICUs has shown that hastening death is a motivation, albeit not the most important one, for some physicians and nurses.

The criminal law has incorporated the doctrine of double effect primarily in the context of decisions to withdraw or withhold life-sustaining treatment, as described in *Barber*. The law permits, and sometimes requires, clinicians to forgo treatment at the request of a competent patient. The Supreme Court in *Quill* recently accepted the rule of double effect in the context of intensive palliative care related to a refusal of life-sustaining treatment. The Court noted that "Just as a State may prohibit assisting suicide while permitting patients to refuse unwanted lifesaving treatment, it may permit palliative care related to that refusal which may have the foreseen but unintended 'double effect' of hastening the patient's death." Physicians who apply the legal iteration of double effect, that the primary intent of the physician is implementing the wishes of the patient, to pain management at the end of life, use informed consent.

Informed consent complicates the analysis of potentially criminal acts, however. First, its relevance, strictly speaking, is unclear because patients or families cannot consent to killing. Nonetheless, consent clearly matters to prosecutors who know juries will not convict when a physician's actions reflect a patient's wishes. Second, the informed consent process with patients or families can sometimes begin the miscommunication that leads to criminal investigations. Patient requests to discontinue treatment or to receive pain medication can alarm a health care worker who rejects hastened death as an appropriate outcome. Finally, the anguished setting of a patient dying in pain can foster misunderstanding. Physicians who fear the legal

ramifications of treatment that can hasten death, use informed consent to shield themselves from liability. Such a defensive posture can confuse and alienate families.

The final role of double effect is its potential impact on prosecutors, grand juries, and petit juries. The doctrine in the context of palliative care emphasizes the caregiver's desire to relieve pain and soothe the dying patient. Although the law does not distinguish between a killing with a benevolent motive, like euthanasia, and any other intentional killing, the public may view a compassionate health care worker with sympathy. The pattern of the criminal cases analyzed here suggests that prosecutors and juries are influenced by a physician's motive despite the criminal law's focus on purpose or intent. For example, the physician who treated Doris Duke admitted that he gave her enough morphine to hasten death. He was quoted as explaining, "I increased the morphine so that she would not linger, that she would not suffer, and ultimately that she would die perhaps shortly or sooner than she would have otherwise died from her medical conditions, which I judged [to be] within a 48-hour period [given the] terminal nature [of her conditions]." Despite his admission, prosecutors decided there was no credible evidence of murder. In the case of Dr. John Coe, a California physician who assisted a patient with acquired immune deficiency syndrome to commit suicide by prescribing an overdose of morphine, the prosecutor refused to bring charges because Coe was "motivated by compassion." The California prosecutor's concerns echoed those of the Hennepin County prosecutor four years earlier, that a jury would be extremely unlikely to convict a physician whose stated motive was to ease suffering. These cases support earlier indications about the difficulty in successfully prosecuting physicians who appear to be acting compassionately. In the early 1980s, before the law on withdrawal of treatment was settled, a prosecutor opined that, even in a case of active euthanasia, "the likelihood is that a successful conviction will not be obtained" when the physician is motivated by mercy.

Why the Kansas jury considered Naramore's decision to withdraw support as evidence that he intended to cause Willt's unlawful death is unclear. Evidentiary difficulties with Naramore's intent contributed to the reversal of the conviction, as discussed below. However, the fact that Naramore's conviction was reversed does not negate the importance of his conviction. Few physicians would be willing to undergo criminal prosecution and incarceration on the likelihood of reversal on appeal. Naramore's actions did not show direct evidence of criminal intent. A reasonable case could have been made that both a loose definition of brain death and the use of a neuromuscular block during extubation were within at least minority practice among physicians. Indeed, five medical experts testified at the trial that Naramore's actions in stopping resuscitation were medically appropriate. Willt's prognosis was grim, even if he did not meet the technical definition of brain death, and his family agreed that he would not have wanted intensive interventions to prolong biologic existence. The Naramore case shows a potential flaw in the principle of double effect, at least where one jury was concerned. When the physician knows that the patient will be dead immediately after treatment is withdrawn, it can be hard to assume that he intended anything other than to secure death.

Criminal prosecutions and high doses of opioid analgesics

Prosecutions for homicide based on medical treatment measure the conduct of physicians, unlike other potential criminal defendants, against the professional standard of care to assess whether their actions depart severely enough from accepted practice to violate the criminal law. Physicians must make egregious mistakes before they will be held criminally responsible. For example, various courts have noted the necessity of acts that are "wanton," "reckless," "irresponsible and totally inappropriate," or are a "gross deviation from the standard of conduct a reasonable person would observe." However, the use of opioid analgesics to treat severe pain demonstrates that this protection may fail because the standard of practice both varies considerably from community to community and is frequently well below what experts agree is necessary to relieve terminal pain. At its best, the standard of care may offer scant protection; at its worst, it may perpetuate undertreatment. The following case illustrates a criminal prosecution and conviction resulting from the use of high doses of opioid analgesics to treat terminally ill cancer patients.

The Naramore-Leach case

Dr. Naramore also cared for Ruth Leach, a seventy-eight-year-old woman with advanced metastatic breast cancer who was from a prominent St. Francis family. Leach was admitted to St. Francis Hospital in May 1992. Her breast cancer had metastasized to her bones, lungs, and brain. On August 2, 1992, her son and daughter-in-law, who had been frequent visitors, noticed that she had dramatically deteriorated. She was suffering severe pain. The nurse, Carolyn Bizer, called Naramore. He came to the hospital and agreed to prescribe more pain medication for Leach. He advised her son, Jim Leach, that higher doses of pain

medication could suppress respiration. Naramore and Jim and Cindy Leach returned to the patient's bedside. Naramore gave Leach 4 mg of Versed and 100 ug of fentanyl. According to Bizer's notes, Leach's respiration immediately slowed and grew irregular; her eyes rolled to the back of her head. Jim Leach became upset and asked if his mother was going to die. Naramore said yes, but told the family that the effects of fentanyl could be reversed using Narcan. Bizer testified that she thought this was unusual because Narcan, in her experience, is not given unless there has been an overdose. Naramore began to set up an intravenous line to continue supplying Leach with pain medication. Jim instructed Naramore, "Don't give her any more. I would rather my mother lay there and suffer for 10 more days than for you to do anything to speed it up." Naramore answered, "It just gets terrible from here on out. The next few days for her are just going to be absolutely awful." Naramore asked Leach if he would hold him responsible if his mother's condition worsened. Leach said he would. Naramore removed Leach's intravenous line and left the hospital.

Jim Leach testified that Naramore was trying to set a trap for the family to see if it would allow him to kill his mother. He described Naramore's conversation with the family as an invitation to a mercy killing. Leach reported his suspicions to Dale White, the hospital administrator. Bizer also gave White the syringes that Naramore had used that night. Leach transferred his mother to Goodland Hospital the next morning. She died there three days later. After Leach died, her son complained to the county prosecutor about Naramore, and the prosecutor informed the state attorney general's office.

Naramore was tried for attempted first-degree murder of Leach in the same trial in which he was convicted of the second-degree murder of Willt. The prosecution argued that Naramore intended to kill Leach because "it was not the good Lord who made the decision to put Ruth Leach on death's doorstep" but Naramore. Naramore countered that he intended only to treat Leach's pain. Naramore did not request and the jury did not receive instructions on the nature or practice of palliative care. He was convicted of attempted first-degree murder.

Naramore served one year of his three-year sentence and was paroled in January 1997. His appeal of both convictions was argued before the Kansas Court of Appeals on February 3, 1998. On appeal, he contended that neither conviction was supported by sufficient evidence and that he was denied his right to a fair trial, particularly with regard to his change of venue motion, which was denied. At oral argument, the court expressed particular concern about the trial court's failure to consider an affidavit that suggested jurors reached guilty verdicts because they were afraid that, if acquitted, Naramore would sue the county for a large sum that could raise property taxes. Both of Naramore's convictions were reversed on appeal. That reversal is discussed below.

The Naramore-Leach case illustrates an attempted first-degree murder conviction for the use of opioid analgesics to manage terminal cancer pain. The prosecution argued, based on reports from the family and Bizer, that Naramore intended to kill Leach with fentanyl and Versed (midazolam). The Leach family's anger shows the powerful effects of miscommunication during the informed consent process. This case also demonstrates the difficulty in measuring opioid pain management against standard medical practice, because the range of appropriate doses for opioid analgesics is so broad and patient-dependent. Given the wide variation between standards of practice, the generally poor quality of pain management in the United States, and the broad range of acceptable doses, comparisons with the standard of care may offer scant protection.

Researchers have consistently noted the considerable variability in the practice of cancer pain management. Variability should be even more pronounced for terminally ill patients with other diseases for which pain control is less understood. Part of the variation in practice comes from the absence of a set of consistent pain management practice principles and part comes from general undertreatment of pain. This variability creates a dilemma for the criminal law, which measures these treatment cases against a professional standard of care.

Although the *New England Journal of Medicine* published clinical practice guidelines for the management of pain in cancer patients in 1994, cancer pain is still widely undertreated, and there are no such guidelines for pain suffered by other terminally ill patients. Furthermore, the wide range of potentially appropriate doses and the different periods of time over which doses are administered make it hard for professionals to assess dosage appropriateness. The clinical cancer guidelines state that "[t]here is no ceiling or maximal recommended dose for full opioid agonists: very large doses of morphine (e.g., several hundred milligrams every four hours) may be needed by some patients with severe pain." Health care providers who practice together can disagree sharply over appropriate doses of opioids. For example, the nurse caring for Leach

thought the dose Naramore administered was too high. A similar problem arose in the Pinzon-Reyes case (discussed below), in which a nurse refused to give the initial bolus of morphine because she thought it was too much. Yet neither of these doses (10 mg of morphine prescribed by Pinzon-Reyes or 100 ug of fentanyl from Naramore) is beyond the range of appropriate doses for terminal cancer patients whose pain has been treated with opioids for at least one year. In fact, a leading palliative care textbook recommends that patients with severe pain that is not controlled should begin one of the opioid agonists at a dose equivalent to 10 to 20 mg of oral morphine. In the Naramore trial, two experts testified that the doses given to Leach were excessive; two others testified that they were appropriate. One defense witness said that if a physician intended to kill a patient, "you would use ten times those doses." On the other hand, a state expert said that combining fentanyl with Versed was a clear overdose, done for the purpose of hastening Leach's death.

Comparison with the Hennepin County cases shows similar problems of analyzing doses. One patient received 120 mg of morphine in forty-five minutes and another was given 395 mg of morphine and 40 mg of midazolam in five hours. On the basis of these doses, the deaths of the two patients were ruled homicides. Even though these doses are large, it is difficult to evaluate them without other information about the patients' individual case histories of pain and of opioid use and tolerance. In jurisdictions where medical examiners consider liberal use of opioids to be the standard of care for dying patients, large doses of morphine or other opioid analgesics, by themselves, will not excite prosecutorial attention. However, as the Pinzon-Reyes, Naramore, and Hennepin County cases show, morphine doses ranging from 20 to 120 mg can raise suspicions.

Given the difficulty in establishing physician intent with regard to high doses of opioids, the view of the family is significant. Because experts disagreed about whether the analgesics given to Leach were inappropriate, the primary evidence relied on by the state during Naramore's trial and appeal was Jim Leach's testimony that Naramore meant to kill his mother. Leach's testimony shows the potential problems with informed consent to high doses of opioid analgesics. Opioid drugs are commonly used to treat a variety of symptoms in patients with advanced disease who are actively dying. Communication with the family and the exchange of information necessary to secure consent to various treatments, including palliative care, occur in the context of the distress and suffering experienced by the family as the patient approaches death.

Patients and families, as well as physicians and nurses, are confused about the role of opioid drugs in the care of dying patients. Most palliative care experts agree that informed consent has been overlooked in palliative care and that it is essential to good care of dying patients. Open discussion among patients and families dispels concerns and fears about pain management as well as addresses more global concerns about distress and suffering. Such discussions can be complicated because they frequently occur when the goals of care for a patient change. Ambivalence about opioid use on the part of the family or the patient may reflect not only misunderstanding about these drugs but also denial about the closeness of death. A continued desire to prolong life inevitably will conflict with the needs of an actively dying patient, particularly the need to alleviate suffering. Ambivalence about Leach's approaching death probably colored her son's reaction to the information Naramore provided about the effects of opioid drugs. Naramore also fueled the myth that pain control with opioids is a form of euthanasia. Respiratory depression should not be a significant limiting factor in the management of patients with pain because, with repeated doses, patients develop tolerance to this effect. If physicians in the outpatient setting use escalating doses titrated to relieve a patient's symptoms, respiration should not become compromised. In the inpatient setting, where the escalation can occur over several hours, as opposed to several weeks or months, the increases may be smaller; however, palliation of symptoms generally will be the primary goal of care despite some risk of respiratory depression.

Criminal cases involving potassium chloride

The Pinzon-Reyes case represents one of the most contentious types of end-of-life treatment: those involving the use of potassium chloride. The use of agents like potassium chloride (or neuromuscular blocks) as part of terminal care, either during the withholding or withdrawal phase, or as part of palliative care for an actively dying patient, has been considered inappropriate because these drugs have no inherent therapeutic benefit other than hastening death. Many ethicists argue that clear distinctions exist between sedatives and analgesics, on one hand, and potassium chloride and neuromuscular blockers, on the other. The first are given to manage pain and other symptoms at a patient's or family's request. The latter, because they provide neither pain nor symptomatic relief, are given only to cause death, whether or not a patient or family so desire. The Pinzon-Reyes case provides a lens through which to view the utility of this distinction for the criminal law.

The Pinzon-Reyes case

Dr. Pinzon-Reyes was born in Colombia and attended medical school in Puerto Rico. He moved to Sebring, Florida, a citrus town of 8,900 people, in 1996. He practiced there for only ten months before a grand jury indicted him for first-degree murder in connection with his care of a terminally ill cancer patient.

Pinzon-Reyes is a nephrologist in private practice who specializes in kidney disease. One weekend in October 1996, he covered his senior partner's patients at Highlands Regional Medical Center. One of those patients was Rosario Gurrieri, a seventy year old with metastatic lung cancer. Gurrieri was in severe pain. His attending physician estimated that he had only a few days left to live, and a social worker had arranged for him to be discharged to a hospice program that would provide support while he died at home. This plan was consistent with Gurrieri's wishes. He had executed a living will in which he rejected aggressive measures and stated his desire to receive pain medication, even if it would hasten death. In the meantime, Gurrieri would spend the weekend at Highlands Regional where he could receive intense palliative care.

On October 5, Pinzon-Reyes prescribed a morphine patch. The next day, he set up a morphine pump to allow Gurrieri to give himself 2 mg doses of morphine every six minutes. Gurrieri continued to experience significant pain, however. His wife and son, who were among the dozen family members and friends with him, were also concerned about his suffering. A nurse, Bethany Crane, testified that Gurrieri's son Paul told her he wanted someone to give his father a shot to put him to sleep. Crane wondered whether this was a request for PAS or euthanasia. She called Pinzon-Reyes, who had left the hospital, and he prescribed a 10 mg dose of intravenous morphine. Another nurse, Carol Drew, refused to administer that dose, because she considered it too high. Pinzon-Reyes canceled the order and returned to the hospital.

Pinzon-Reyes then gave Gurrieri 20 mg of morphine, followed within one hour by six injections totaling 117 mg of morphine and 10 mg of Valium. There was contradictory testimony as to whether Gurrieri was still conscious or suffering pain at this point. Gurrieri's widow said her husband fell unconscious after two injections, but that Pinzon-Reyes put his hand to the patient's chest and said that he still had "an active heart." Pinzon-Reyes testified at an administrative law hearing that Gurrieri remained alert. Drew, who was also present, testified that Gurrieri's neck and chest veins pulsed visibly, even after he fell unconscious. Drew also testified that Pinzon-Reyes then injected 10 to 20 mEq of potassium chloride into Gurrieri's intravenous port. Pinzon-Reyes's notes in the patient's chart, however, say that he gave 30 mEq of the drug diluted in saline through an intravenous infusion. This slower delivery system would minimize the risk of stopping Gurrieri's heart. Testimony at trial indicated that Gurrieri continued breathing for at least fifteen minutes after the potassium chloride was administered. He died within the hour. His widow testified that the family was surprised that he died so fast. "I would say it would take a while for him to die, for God to take my husband," she said.

Drew noticed the misrepresentation in the notes and reported it to the nurse-administrator Ginger Carroll. Carroll interviewed Pinzon-Reyes. According to Carroll, Pinzon-Reyes stated that he had given Gurrieri potassium chloride to stop his heart because the family wanted to end the patient's life. Defense attorneys won a motion to suppress Carroll's statement because it grew out of the hospital's peer review process. Although Florida law protects quality assurance and peer review meetings from discovery in the civil context, it was not clear whether such information was protected from criminal subpoenas. The defense argued that the civil privilege should apply to serve the public good of encouraging peer review and that the legislature must have intended to protect confidentiality in mandating a peer review system. Pinzon-Reyes later told state investigators that he gave potassium chloride to slow Gurrieri's heart rather than to stop it. Two oncologists, one of whom reviewed the case for state regulators and another who heads Florida's pain commission, concluded that the use of potassium chloride was unindicated and that its administration, particularly through an intravenous push, showed that its "intended effect" was "to hasten the death of" Gurrieri. A grand jury indicted Pinzon-Reyes for "willful, premeditated and unjustified murder."

As the case proceeded to trial, Pinzon-Reyes's former patients and other residents of Sebring supported him. In addition, former patients cited his "soothing manner," "attentive care," and willingness to spend time with his patients as reasons why they believed him to be wrongly accused. Pinzon-Reyes originally retained Geoffrey Fieger, the Michigan attorney who represented Kevorkian, but quickly hired two local well respected lawyers. One of the attorneys, Jack Edmund, is a local legend.

During the one-month trial, Pinzon-Reyes's defense team succeeded in suppressing his statements to the Highlands Regional Medical Center's administrators about why he wrote false statements in Gurrieri's chart and why he administered potassium chloride. They introduced testimony from expert witnesses that the 137

mg of morphine given to Gurrieri was well within the standard of care for patients in intense terminal pain, although the jury received no special palliative care instructions. They also introduced expert testimony that the potassium chloride could not have caused Gurrieri's death because almost one hour elapsed between its administration and the patient's death. Had the dose been large enough to kill Gurrieri, experts testified, it would have done so quickly. Jurors who were interviewed after they acquitted the defendant said the time lapse between the administration of potassium chloride and the patient's death convinced them that Pinzon-Reyes did not cause Gurrieri's death. Pinzon-Reyes "was really trying to help his heart rate," said juror Robin Nichols.

Four months after the acquittal, an administrative law judge concluded that Pinzon-Reyes did not kill or intend to kill Gurrieri with drugs. Judge Robert Meale found him guilty of one violation: lying in the patient's chart to conceal his unorthodox use of potassium chloride. On December 6, 1997, the Florida State Board of Medicine (FSBM), which had suspended Pinzon-Reyes's license in summary proceedings two weeks after Gurrieri's death, voted 7 to 6 to suspend Pinzon-Reyes for two years, with credit for time served and a stay for the remainder of the sentence. He resumed seeing patients when FSBM's decision was officially filed.

Special problems with potassium chloride

Because potassium chloride has no palliative function, its use in dying patients can raise serious questions. However, of the eight potassium chloride cases found in my research, only one (Wood) has resulted in a criminal conviction. Potassium chloride cases raise three problems for prosecutors, all of which were present in the Pinzon-Reyes case. First, although there is no question that a bolus of potassium chloride can cause cardiac arrest and death, there are often causation issues because patients who receive potassium chloride are severely compromised and near death when the drug is injected. Second, the use of potassium chloride shows an intent to hasten death, but does not detract from a physician's possible motive of mercy. Third, the potassium chloride cases raise the issue of jury nullification because jurors themselves fear a painful and prolonged dying process.

Causation can be hard to establish in potassium chloride cases. Jurors polled after the Pinzon-Reyes acquittal thought that the forty-five-minute lapse in time between administration of potassium chloride and Gurrieri's death raised significant doubts about whether the drug had caused the death. Such a time lapse can be misleading, however, because the physician who administers potassium chloride is usually the physician who declares the patient dead. Even when death follows closely in time after the administration of potassium chloride, reasonable physicians can debate the "cause of death" for purposes of the death certificate. First, potassium chloride can be difficult to administer in a lethal dose. A fairly large dose, somewhere near 100 mEq, is required to be fatal, and that amount can be difficult to introduce into a patient's veins in a single bolus. A physician may signal an intention to hasten death by administering potassium chloride, but if the dose is insufficient to stop the patient's heart, the prosecution may encounter causation problems.

Second, many terminally ill patients have severely compromised hearts and so are very near death when they receive potassium chloride. If the patients have recently been removed from ventilators and are thus breathing a lower percentage of oxygen, they may experience severe hypoxemia, which can also destroy the brain and heart. Their hearts will stop and so they may die more quickly, but they do not die differently than they would without potassium chloride. In other words, the cause of death will still be cardiopulmonary failure. Third, potassium chloride has therapeutic uses. It was given by Dr. Carrizales, the neonatologist who was tried for murder in a separate case in Georgia, to another neonate, resulting in a civil suit where causation again was a problem. In that case, Carrizales argued that she had been using potassium chloride for weeks to treat the infant's hypokalemia.

The potassium chloride cases also raise issues of intent or purpose. Physicians from FSBM who reviewed the Pinzon-Reyes case prior to prosecution decided that the use of potassium chloride evinced a deliberate intent to kill. The grand jurors who indicted Pinzon-Reyes said that because there was "no medical reason" for administering potassium chloride, because potassium chloride is "used in some states to carry out the death penalty by lethal injection," and because he had "falsified ... [the] medical chart ... to indicate that potassium chloride was administered through an intravenous infusion instead of directly into the intravenous port at the wrist," there was probable cause to believe that he had committed "willful, premeditated, and unjustified murder."

Although Pinzon-Reyes and Naramore faced serious charges, it is distinctly unusual to charge physicians for first-degree murder in connection with their treatment of terminally ill patients. In a case without

premeditation that lacks extraordinary circumstances like a financial motive to kill, it is difficult to prove the requisite criminal intent. Most cases of potassium chloride administration arise when a physician acts quickly to end the grimacing, clutching, and labored breathing, which characterize the dying process. Even given the fact that a physician's purpose in giving potassium chloride is to hasten death, the motive may be to end suffering. Thus, although families and patients cannot consent to giving potassium chloride given the clarity of the criminal law, most prosecutors and medical examiners consider a family's position because it reflects on a physician's motive of compassion or mercy.

Finally, the clear distinction between therapeutic agents like analgesics and nonpalliative ones like potassium chloride may break down with regard to physician intent. Even though opioid analgesics and sedatives have therapeutic value, they are sometimes used with two purposes: to treat pain and to hasten death. For example, many patients in ICUs are given such high doses of sedatives and analgesics before extubation that they cannot live after their ventilators are removed. Several prominent physicians and ethicists have argued that the intent of physicians who use this practice differs little from active euthanasia. In the actual practice of caring for dying patients, the differences between palliative care and potassium chloride administration may blur.

The fact that a physician may be motivated by compassion explains the last phenomenon, jury nullification, in most of the criminal cases involving terminal care, and particularly those involving potassium chloride. These cases would include the Kevorkian cases, some of which involved potassium chloride. Despite his outspoken support for PAS, Kevorkian has never been convicted. As the Pinzon-Reyes case illustrates, juries are reluctant to convict compassionate physicians, even when they act outside the standard of care or deliberately hasten a patient's death. Neither the Pinzon-Reyes nor the Naramore jury was instructed on jury nullification. However, a normative view of the jury's function would favor jury nullification as a corrective device that allows the criminal law to adjust to conventional public morality absent an applicable legal defense. Juries could also nullify prosecutions on charges like manslaughter, which do not require specific intent and so might apply to medical mistakes like failure to reverse a neuromuscular block before extubation. Research using mock jurors in hypothetical euthanasia cases shows sizable nullifications (25.3 percent not guilty and only 35.9 percent convictions for first-degree murder). A defense verdict will not repair the loss of income, reputation, and emotional strain of a criminal trial for a defendant, but a pattern of defense verdicts or jury nullifications may deter prosecutors from pursuing criminal cases against physicians.

The Naramore reversals and the requirement of direct evidence of intent to kill

In deciding Naramore's appeals of the Willt and Leach convictions, the Kansas Court of Appeals took the extraordinary step of reversing the jury verdicts on the ground that no reasonable jury could have found beyond a reasonable doubt that Naramore had acted with homicidal intent. The court noted that, although the cases were tried as conventional murder and attempted murder cases, the convictions raised important issues about the criminal liability of physicians for providing medical care to patients. There was no direct evidence that Naramore intended to kill either Leach or Willt. Instead, the state relied on circumstantial evidence: the drugs given to Leach and the withdrawal of life support from Willt. The court noted that there was "substantial competent medical opinion in support of the proposition that Dr. Naramore's actions were not only noncriminal, but were [also] medically appropriate." The state argued that the jury had heard conflicting testimony about Naramore's care of Leach and had believed the prosecution's evidence that the care was so unreasonable that it evinced intent to kill. The court disagreed, concluding that the evidence supporting a reasonable explanation for Naramore's treatment decisions was so "extremely strong" that a reasonable jury could not reject it. The court held that, absent direct evidence of criminal intent, the prosecution could not prove beyond a reasonable doubt that a physician had specific intent to kill so long as some expert medical testimony supports the physician's actions. In other words, there can never be sufficient evidence to convict a physician based on the medical care provided when some competent medical testimony supports the actions and the state produces no direct evidence of criminal intent. As a practical matter, the Naramore decision, if it is not modified or limited by the Kansas Supreme Court, will make it almost impossible to obtain a criminal conviction based on care given to patients that is neither clearly reckless nor purposely homicidal.

Recommendations

Even though physicians rarely face criminal investigations or prosecutions, they do occasionally happen, and any criminal matter has the potential to deter physicians from using sufficient opioids to manage pain

experienced by dying patients. Given the small number of cases, it seems unlikely that change in the criminal law will promote better care of dying patients. Therefore, these recommendations are practical suggestions for improved communication among health care providers and for institutional changes to improve pain management for the dying.

Keep accurate records

In several cases, nurses were troubled by requests that they enter false information in the patient's chart or by observations that the physician had written an inaccurate chart note. Prosecutors may also regard deliberate inaccuracies in the record as potential evidence of wrong-doing. High doses of morphine and other opioid analgesics or sedatives can be justified if they are titrated to the patient's symptoms. Accurate records of caregivers' assessments of pain, along with those of the patient and family, demonstrate the necessity of escalating doses and show that the purpose of the dose adjustments was to manage pain. If a patient receives an agent with no role in pain management, like a neuromuscular block or potassium chloride, that treatment should also be accurately reported in the chart. Physicians should not prescribe or administer drugs they are unwilling to record in the medical chart. Accurate records are also essential to advance another goal: improving institutional review and health care provider education in palliative care.

Hold team meetings

Decisions at the end of life can be painful for families and health care professionals. The course of terminal care will involve many individuals, including the patient, physicians, nurses, other members of the hospital staff, and the family. All these individuals should be informed that the goal of terminal care is to relieve pain and suffering through the dying process. The patient and family should understand that dying can take minutes, hours, or days. They should also be advised about the common symptoms like labored or rattled breathing that can accompany dying. The health care providers should agree on the paramount importance of patient comfort.

Institutional guidelines for pain management and for withdrawal of life support

Institutional guidelines that lay out a process for discontinuing intensive care, life-sustaining treatment, or other therapies that do not directly contribute to patient comfort (such as intravenous fluids, diagnostic procedures, and antibiotics) and that provide effective palliative care serve several useful functions. First, the process of writing and adopting these guidelines educates health care providers about the ethical and legal status of palliative care and withdrawal of life-sustaining treatment. Neither of these practices should be confused with euthanasia or inappropriate killing. Second, guidelines can provide procedures for observing, evaluating, and documenting patients' distress and increasing pain medication when appropriate. Thus, guidelines may improve pain management for dying patients. Third, the presence of guidelines may prevent mistakes like failure to stop neuromuscular blocking agents or misjudgments like the administration of potassium chloride.

Informed consent to palliative care and withdrawal

In law, ethics, and practice, the provision of palliative care and the withdrawal of life-sustaining treatment are characterized as appropriate responses to the autonomous wish of a dying patient who has accepted comfort as the primary goal of therapy. Informed consent is essential to ensure that a patient has made an informed and voluntary choice. However, conversations with a patient or family should not be requests that the family indemnify physicians or accept responsibility for causing the patient's death. At the same time that physicians refrain from asking families to authorize the death of a loved one, it is important that professional caregivers continue to work with families to make joint decisions. Even when the medical team agrees that continued treatment will not contribute to a meaningful recovery, physicians should guard against making unilateral decisions. As these cases illustrate, it is crucial that the surrogate, family, and other appropriate parties remain aware of the medical team's recommendations and informed about the team's intent to withdraw or withhold care.

Proper jury instructions

Should a case proceed to a criminal trial, the jury should be instructed about a physician's obligation to provide palliative care, and, if appropriate, proper efforts to resuscitate a patient. Physicians have unique responsibilities to dying patients about which there is a growing medical, legal, and ethics literature. However, certain legal and ethical agreements about care of the dying are not well understood by lay people. For example, the fact that it is permissible to administer high doses of opioids if necessary to treat severe pain even if the opioids may pose some risk of hastening death is well established in law and ethics, but may not be commonly appreciated by the general public. Potential treatments for dying patients will almost always carry risks, possibly fatal ones, as well as benefits. Weighing those risks and benefits will, of

necessity, involve the exercise of professional judgment. Physicians defending themselves against charges that include the requirement of a specific intent to kill should request that the jury be instructed regarding physicians' responsibility to make professional judgments concerning their patients' care. These instructions should include the particular standard of care appropriate to the facts of the case. For example, palliative care, withdrawal of care, or standards for resuscitation would have been appropriate for the cases considered above.

Conclusion

For two disturbing reasons, the criminal cases discussed are tragic. First, they represent bad deaths for the patients and families involved. Second, they represent wrenching ordeals for the physicians and nurses who underwent investigation, and sometimes indictment, trial, and incarceration. Detailed examination of these cases illustrates that fear of criminal liability or investigation should not deter physicians or nurses from aggressively using opioid analgesics to manage terminal pain, provided that pain has been carefully assessed and treated and communication with families and involved professional caregivers is thorough. The cases also illustrate, however, that patients' fears about dying in pain or suffering from lack of institutional sensitivity to the quality of dying are justified. Major initiatives in medical and public education regarding pain control should include the lessons learned here, distinguishing fact from fiction in the ethics and law of pain relief.

Acknowledgments

This project was supported by a grant from the Mayday Fund through the American Society of Law, Medicine & Ethics. Ann Alpers is also supported by the Program in Medical Ethics and the Division of General Internal Medicine in the Department of Medicine and by the Center for AIDS Prevention Studies (Grant No. MH42459-06 from the National Institute of Mental Health) at the University of California, San Francisco.

Ann M. Martino, "In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?"

Journal of Law, Medicine & Ethics, 26, no. 4 (1998): 332-49.

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A decade ago, conventional wisdom in the medical establishment was that physicians treating chronic pain with opioid analgesics were at a substantial risk of being sanctioned for overprescribing by state medical regulatory boards. Dozens of articles written since have alluded to this risk as an obstacle to effective pain relief. In the early 1990s, a number of high profile cases in which physicians were disciplined by regulatory boards for overprescribing to patients with chronic pain were reported in the press. Although the board actions in many of these cases were eventually overturned by state judiciaries, the publicity heightened practitioners' sensitivity to the regulatory risks associated with prescribing opioids.

A review of the available data on state medical board actions nationwide for the period from 1990 to 1996 reveals that the perception of regulatory risk far exceeds the reality. Indeed, relatively few (less than 5 percent) of the disciplinary actions taken for overprescribing by state medical boards in any given year directly concern the treatment of chronic pain--malignant or nonmalignant--in patients. Nonetheless, as the question of how to manage chronic pain more effectively received greater attention in the popular press and professional journals, many state policy-makers made efforts to institute policies that further reduce what is, despite perceptions to the contrary, already a minimal regulatory risk.

Between 1988 and 1997, thirty-three states enacted laws (intractable pain treatment acts (IPTAs)), adopted administrative rules, and/or established guidelines for the use of narcotic analgesics for the treatment of chronic pain. These mechanisms vary considerably in nature and substance, though all were designed to

provide physicians with some measure of regulatory relief by reducing the real and perceived risks of being subjected to regulatory sanctions for treating pain with opioids.

Most state IPTAs establish that opioid analgesics have legitimate, therapeutic uses for the treatment of chronic pain; some also provide physicians who prescribe these drugs for pain with immunity from disciplinary action as long as there is a legitimate, therapeutic reason for the prescription. By contrast, the administrative rules and/or regulations adopted by state medical boards take the form of a practice standard, or a set of requirements, that a physician who prescribes opioids for chronic pain should meet to avoid board sanctions or to comply with the provisions of a state's IPTA. Guidelines generally serve similar purposes, although they often allow more flexibility and provide fewer guarantees, because they do not have the legal force of statutes, rules, or regulations.

Initially, these efforts to achieve regulatory relief received high praise. But today, second-guessing has begun, particularly among those who study chronic pain management, and with good reason: the early data--both hard and anecdotal--strongly suggest that fear of regulatory reprisal continues to be the reason physicians most frequently cite for not providing adequate treatment for chronic pain.

Why has regulatory relief--the chronic pain laws, guidelines, and administrative rules instituted by state medical boards in the last decade--failed to alter significantly the perception of risk? It may be, as Sandra Johnson has observed, because there is at least a minimal risk of being disciplined by a state medical board for overprescribing and no risk for being sanctioned for underprescribing. Physicians are sometimes sanctioned, albeit in small numbers, for overprescribing. However, there are no cases on record, by any state or federal medical regulatory entity, in which a physician has been subject to medical board discipline for underprescribing.

The absence of disciplinary actions for underprescribing has not gone unnoticed. Last year, Kirk Robinson, president, and Kathryn Tucker, director of legal affairs, for the Oregon-based organization Compassion in Dying, sent a memorandum to every medical board in the United States arguing that dying patients have a right to adequate pain medication. Although the focus of the memorandum was end-of-life care, Compassion in Dying outlined a series of steps for each state medical board to follow to address the perceived risks for overprescribing and the absence of any risk--real or imagined--for underprescribing to any patient experiencing pain. For example, the memorandum urged that underprescribing be adopted as a ground for discipline. In addition, Compassion in Dying put the boards and the public on notice that it was willing to assist chronic pain patients and their families in making complaints and/or in filing suits against practitioners who fail to provide adequate pain relief by underprescribing.

As will be discussed in the final section of this article, Compassion in Dying has made good on this promise, but to no avail. Indeed, a year after it distributed the memorandum, not a single medical board has reported taking a disciplinary action against a licensee based on an allegation that a patient received inadequate treatment with opioid analgesics.

In short, the conventional wisdom still holds: the regulatory risks associated with overprescribing are perceived by most physicians to be real and far greater than those associated with underprescribing. Regulatory relief has not changed this perception and might have strengthened prevailing norms. As one physician noted in an interview:

Doctors are asking for reassurance, not more rules or laws. Even the best intentioned of them [laws and rules], create only more fears in the minds of doctors trying to do their best, and place more ammunition in the hands of lawyers and regulators! Doctors will avoid the treatment of pain, so as not to take the chance of "not being in compliance" with some minor detail in a law or guideline that is supposed to encourage the treatment of pain.

This view persists because it reflects what will be described later as an ethic of "underprescribing," an ethic that is multi-level, multifaceted, and remarkably resilient to change.

The causes of underprescribing

While these Drugs (opioids) are safe and effective if taken as directed, they can be misused beyond the level prescribed, if they are taken more frequently or for a longer period than recommended.

Misuse or abuse of these drugs can produce a variety of untoward health consequences including drug dependence, overdose and death.

The regulatory relief effort of the last ten years, although undeniably flawed, was built on the premise that undertreatment of pain is a public health problem. As an extension of this premise, there is growing consensus that the reluctance of health care practitioners to use narcotic analgesics fully for therapeutic purposes has exacerbated the scope and impact of the undertreatment problem.

So much has been written and said about the under-utilization of narcotic analgesics for the treatment of chronic pain that underuse is taken as a given. For example, a routine search of the holdings of a major state university library, conducted in conjunction with this study, located over 125 journal and periodical articles and eighteen books dealing with the topic. A content analysis of all the articles and fifteen of the books revealed a widely shared and growing consensus in the medical and scientific communities, the law, social sciences, and humanities, and the popular press that inadequate treatment of chronic pain is the rule in the United States and most developed nations. This view is so pervasive that professional journal articles supporting a more cautious/conservative approach to the use of narcotic analgesics--for example, law enforcement and addiction specialists--generally acknowledge that inadequate pain treatment is a problem, but the scope of the problem has been overstated.

There is also an impressive body of literature, which includes a significant number of clinical studies, that provides compelling evidence that opioid analgesics can and should be used to treat chronic pain. Though some disagreement exists about how liberally these drugs should be prescribed, studies now being published suggest that it is appropriate to prescribe opioid analgesics to most patients experiencing pain (malignant and nonmalignant), even if the patients have a history of drug abuse in some instances.

Given the overwhelming evidence in the literature that inadequate pain management is empirically verifiable, it would follow that the patterns of underprescribing opioid analgesics should be changing. Why opioids are not used more liberally to treat pain has thus become the focus of much of the recent work written. There is now an extensive list of the causes for underprescribing, covering a broad range of issues--from societal (for example, cultural values about pain); to institutional (for example, education, treatment, reimbursement, and regulatory policies related to pain management within the health care system); to professional (for example, practice patterns, standards, and the ethos of physicians, pharmacists, nurses, and allied health care practitioners); to the individual or personal preferences and biases of practitioners and patients (for example, fears of regulatory reprisal and drug addiction). Some work in this area focuses narrowly on a specific, concrete cause (for example, regulatory barriers and obstacles, health care reimbursement policies, or inadequate education in pain management/drug addiction), while other work emphasizes the more ethereal aspects of the human condition that affect the ability to cope effectively with pain (for example, how people express pain, prevailing conceptions of pain in medicine or the so-called "medical model" of pain, and cultural norms about pain relief and patients' rights, physician-assisted suicide (PAS), and end-of-life care). Most provide valid and reliable empirical data, illustrating how one cause or another has led or contributed to the inadequate treatment of pain.

Figure 1 summarizes the various reasons most often identified in the literature and by practitioners interviewed for this and several other studies for underprescribing opioid analgesics. They are organized according to the probable source, from individual to societal. The sheer number of causes in each category suggests why recent efforts at regulatory relief focusing on one or several of the alleged culprits for underprescribing may not be sufficient to change prevailing treatment practices for chronic pain patients. Indeed, when taken together, the causes set out in Figure 1 are an expression of a far more complex phenomenon: an ethic of underprescribing that sets the parameters of, and the rewards for, appropriate prescribing to pain patients. In order for medical boards to alter existing prescribing practices for the treatment of chronic pain, they must, first, develop an understanding of the role of the ethic of underprescribing and, second and more important, institute policies and procedures that will alter the system of rewards that reinforces its core principles. It is my view that, as long as the system rewards underprescribing, current practices in the treatment of chronic pain will probably endure.

The ethic of underprescribing

Undertreatment for pain in the medical setting has sources that run far deeper than a reluctance to provide adequate pain medication.

How is an ethic formed and what is the basis for its central principles? An *ethic* refers to a body of principles about what is appropriate, good, or just conduct. As defined here, a *practice* is any cooperative human activity that has its own ethic--or rules of conduct--that anyone engaged in the activity must uphold. In this case, the activity or practice is the management of chronic pain.

Applied ethicists argue that there are multiple duties or responsibilities in any given ethic. For example, physicians have an obligation to serve patients' interests, to uphold professional standards, to adhere to the rules of the institutions that deliver and finance health care, and to obey the laws of the jurisdiction that has granted the privilege or right to practice. Variations in the scope of responsibilities at each level may create conflicts as a matter of course. Again, using physicians as an example, it is not uncommon for a doctor to be confronted with the dilemma of undertaking a course of action that, although clearly in the patient's best interest, is inconsistent with the rules of a health insurer or some deeply held personal value. According to philosopher Alasdair MacIntyre, there is a complex set of internal and external rewards that significantly influences the choices members of a practice make when faced with these kinds of conflicting responsibilities.

The core principles of practice determine whether particular behaviors or acts are good for the practice (internal rewards) or good because of the consequences they bring (external rewards). Internal rewards are generally attained only by meeting the obligations central to a particular practice. The sense of accomplishment or inner satisfaction that follows from having done a job well, from fulfilling one's obligations to a patient, from upholding the principles of the practice, and/or from doing no harm typifies rewards internal to a practice. External rewards, such as money, prestige, and status, are derived from sources secondary to the practice, even though they may be essential for its perpetuation. Income, peer respect, and the ability to practice without restraint and to make choices about and have input into the work environment are some examples of the rewards external to a practice. MacIntyre contends that to understand the nature of an ethic, it is more important to focus on the nature of these rewards and how they are valued, than on the acts practitioners take or their eventual outcomes, both of which may be the same.

In chronic pain management, physicians may not prescribe opioids for patients because they adhere to the medical model that construes pain as a symptom of a condition rather than as one that warrants treatment. In this instance, eliminating or moderating the pain with drugs without first fulfilling the obligation to isolate its cause would be a breach of the standards of the practice and cause the denial of internal rewards--for example, the sense of having abdicated rather than having met one's obligation to the patient. By contrast, another physician may be unwilling to prescribe opioids, even though that physician believes he/she has an intrinsic obligation to treat a patient's pain, for fear that doing so would result in the loss of external rewards--for example, reimbursement from an insurer or a board investigation that will affect licensure status or practice privileges--necessary to perpetuate the practice.

MacIntyre notes that when faced with competing responsibilities in the practice setting, the preferred course of action is often the latter. Most practitioners will choose the course of action that preserves external rewards, even if the goods internal to the practice are sacrificed in the process. In other words, the probability that practitioners will abandon principles appears to increase in instances where the perceived risk of losing external rewards is high.

The ethic of underprescribing applied

The works of applied ethicists provide a useful framework for understanding how an ethic is formed. With this in mind, the goals in this section are twofold:

- to identify the key principles in the ethic of underprescribing; and
- assess to what extent the ethic of underprescribing has been altered by recent efforts at regulatory relief.

Meeting these goals requires taking a step inside the practice of chronic pain management and examining the experiences of both patients and health care professionals. To this end, the following analysis draws on the findings of several published studies as well as the statements of patients and health care practitioners who participated in focus groups or who were interviewed at length as part of this project. Comments made by a diverse group of health professionals in two different forums held in March 1998--a national forum on

chronic pain management held by the Federation of State Medical Boards (FSMB), in Dallas, Texas, and a symposium on chronic pain sponsored by the Mayday Foundation and the Iowa Board of Medical Examiners (IBME), in Ankeny, Iowa--are also incorporated.

The focus groups involved health care practitioners (physicians, nurses, and pharmacists), patients and their families, and various other stakeholders. The focus groups were conducted by an independent research firm in January 1998, in Des Moines, Iowa, as part of this project. Follow-up interviews with focus group participants took place over the next several months. Data from nationally based studies that support focus group and interview findings are cited, where appropriate.

The principles

The principles or rules of conduct that set the standards for judging behavior in a practice ethic, while unique to it, are not formed in a vacuum. They tend to develop slowly, over time from a variety of sources. The three principles to be discussed here are drawn from the causes for underprescribing presented in Figure 1 and from the statements of practitioners.

Each principle discussed concerns a facet of the practice of pain management. Because the principles at the root of an ethic are not tangible things, narrative statements made by those who participate in and are affected by the practice of chronic pain management are woven together throughout to help us interpret and understand what they mean. The first principle, Just Say No, pertains to narcotics and drug addiction; the second, Grin and Bear It, focuses on what society makes of pain; and the third, Avoid Risks, centers on issues in the practice setting. The simple slogans or labels assigned to the three principles are primarily rhetorical; they are commonplace sayings that evoke, in a two or three word phrase, an understanding of the complex set of beliefs at the core of the ethic of underprescribing. However, it is the narrative statements about how chronic pain is and should be treated that best explain the nature and purpose of the ethic of underprescribing.

Principle 1. Just Say No: drug addiction and abuse harm individuals and society

Among the barriers to effective pain relief most often cited in the literature is a generalized fear of narcotics, defined here loosely as mood-altering substances. In some respects, the entire system of U.S. laws that has been established to control access to and the distribution of drugs rests on two extensions of this fear: (1) any chemical substance that distorts reality has the potential to be abused; and (2) persons who abuse or are addicted to these substances are likely to engage in conduct that threatens the social order.

The fear of opioid addiction is so pervasive that a term--"opiophobia"--has been coined to distinguish it from concerns about illegal drug use. Opiophobia has been heightened in recent years by the rhetoric accompanying government's War on Drugs. One of the central tactics in the War on Drugs has been to focus broadly on the horrors of addiction in media campaigns and antidrug and prevention programs, without drawing distinctions between drug dependency and abuse or types of addictive drugs. It is thus not surprising that many patients fear that taking any drug in large doses for relatively long periods of time will cause addiction. Consider the following comment made by a woman who, by her own account, was dependent on opioid analgesics to control intractable low back pain:

When I realized that without the medication I could not function, I felt like a "druggie" ... no better than a crack-head. My husband pleaded with me to stop [taking the prescribed medication] for the sake of our family.... He harassed me and the doctor. I was forbidden to mention that I took the drugs even to my closest friends. After a while, I started to act like a drug addict. I hid my medications from him and from everyone else. I drove miles to have my prescriptions filled at drugstores where no one knew me. No one ever explained to me that it was "okay" to need my medications ... that needing drugs to take away pain is different [from] being a druggie. So I stopped and the pain nearly killed me. I wanted to start up again, but the doctor who treated me before said no, not after all the trouble, even though I got divorced.... He [the doctor] was afraid I'd lose him his prescribing [privileges].

Several studies examining patient concerns about narcotics suggest that the sentiments expressed above are not unique. What is most telling in this quotation, however, is how the patient's fears of addiction

influenced the practitioner's actions. Even for the physician who is willing to prescribe opioids, the possible loss of a valued external reward (prescribing privileges) may provide a strong incentive to say no.

The extent to which opiophobia has shaped and been reinforced by the ethic of underprescribing cannot be overstated, particularly as it relates to the norms of the health care professionals who treat pain patients. As one doctor notes:

From the minute I entered medical school to the day I finished my residency, I had it drilled into my head that narcotics should be used sparingly (if ever). We spent hours listening to professors describe how patients will do anything to get their doctors to prescribe narcotics and not more than a minute or two discussing their therapeutic uses. My experience as a resident confirmed this view. Most of the patients who came into the ER [emergency room] complaining about pain were addicts or drug seekers. Many a young resident got duped. It's not an experience you forget ... [it] probably affects my thinking still.

Reinforcing the idea that saying no is its own just reward is once again the very real concern that saying yes will draw the notice of the organizations that regulate prescribing, administering, dispensing, and ordering of narcotics--the Drug Enforcement Agency (DEA), state drug enforcement bureaus, and the boards of medicine and pharmacy. A physician assistant explains:

It took years for [physician assistants] to convince the legislature to give us prescribing privileges for Schedule IIs. Frankly, I don't need or want the responsibility. I worked with a doctor in a small town family practice for years. [He] was a good doc ... kept up with the research ... believed that he could manage chronic pain patients. He only had one or two chronic pain patients, both elderly gents. It was a small town, with only one pharmacy. He was reported by a pharmacist friend to both the pharmacy and medical boards because he [the pharmacist] thought the number of doses per [pre]script[ion] was supposedly too high. Next it was the DEA. Nothing happened, no action was taken. But, the investigation was enough. He took early retirement. It destroyed him, and for what? Two patients who were dying felt better for awhile and died anyway. Now the town is out one very good doc.

Although substantial empirical evidence indicates that regulators seldom take punitive action in cases like the one above, the likelihood that an investigation will be conducted on an allegation of overprescribing is high. Avoiding an investigation is yet another incentive to underprescribe.

The standards for prescribing drugs are not monolithic, however. In certain circumstances, prescribing high doses of drugs is generally considered to be legitimate. For example, the general public and health care practitioners accept that it is appropriate to prescribe drugs to curtail the symptoms of certain illnesses and injuries, as well as to comfort terminally-ill patients suffering in pain. As one physician noted about the latter:

Mood-altering drugs are reinforcing. Their chemical make-up creates a need for more, which is why addicts do anything to get their hands on them. Cancer patients are different.... With dying patients, even if they do become addicted and want more, there's no harm done. It's only a problem if you kill the patient before his time in the process. Then you cross the line into physician-assisted suicide or, worse, euthanasia.

Legitimate uses are largely confined, thus, to circumstances in which there is a marginal harm or no potential for "the continued craving to use an opioid and the need to use the opioid for effects other than pain relief." However, even when prescribing opioids to terminally ill patients, the potential arises for the loss of external rewards. Some of the opioid analgesics prescribed for dying patients can slow respiration and, in doing so, hasten death. In virtually every state in the United States, laws on the books impose stiff criminal sanctions on health care practitioners who are suspected of crossing what is generally agreed to be a very ambiguous line. The threat of prosecution, the possibility of being labeled another Kevorkian, and the risk of losing prescribing or practice privileges are all strong incentives to say no, even in instances where the use of high doses of opioids is not only the legitimate, but also the most humane course of action.

In sum, strong rewards, both internal and external to the practice of chronic pain management, reinforce the principle in the ethic of underprescribing to say no. A practitioner who accepts that addiction is harmful

and that assisting or hastening death is a wrong has a duty to prescribe drugs in a manner that will not result in either. Federal and state prescribing laws, societal norms about the dangers of drugs, and board rules and regulations reward practitioners who underprescribe by making saying yes a risky proposition--to practitioners' livelihood, reputation, and status in the practice community and under the law.

Principle II. Grin and Bear It: pain happens

The principles of the ethic of underprescribing derive from a wide array of sources, including religion, history, science, and popular culture. David Morris argues that the view of pain in the United States is one in which pain is often indistinguishable from suffering. Suffering, in turn, is conceived of as a moral good: pain builds character, reflects intelligence, adds strength, and enhances pleasure. Morris goes on to say that this conception of pain has greatly influenced thinking about how people in pain should deal with it. The comment of a young man, whose father has agonized with chronic headaches for over a decade, makes the point:

I couldn't understand why my father was so embarrassed by [his] inability to withstand his pain until I started to study religion and history in high school. Christians believe it was necessary for Jesus to suffer the physical pain of crucifixion to redeem mankind from sin. Because of this, people who bear lots of [physical] pain in the name of God are turned into saints and martyrs. People who take pain in the name of country are given medals.... The real heroes in our society know ... it's best to suffer in silence. And if Jesus is the standard, you know the bar is going to be set pretty high.

Implicit in the notion that it is ennobling to suffer is the idea that avoiding or attempting to relieve pain is a sign of weakness. This idea is reflected in norms about how chronic pain patients should be treated. As a pharmacist notes:

Drug control laws essentially say that pain ... is part of the natural order of things.... [W]hat we really should be worried about [are] the things that make pain go away. I agree. I am a [scientist]. I know that there are only a limited range of things anybody can do to make pain go away and there are so many things that can cause it. To borrow a phrase, "pain happens." We have to be careful not to make too much of pain. It's my job to alert the proper authorities [when a doctor] gets carried away with a patient's complaints and prescribes morphine or some other narcotic at levels that hurt more than help.... Some serious pain in life is just unavoidable. Morphine or hydrocodone or whatever other narcotic is de rigeur at a given moment might control pain, but they won't stop the fact that we'll all suffer harsh pain at some point. It is misleading, and probably unethical and illegal, for any [health care practitioner] to suggest otherwise.

As this quotation intimates, avoiding pain, while not inherently wrong, is suspect--so much so that society has adopted substance control laws, rules, and regulations that reward practitioners who uphold the principle Grin and Bear It by choosing to underprescribe.

In many respects, the principle Grin and Bear It reinforces the internal rewards that follow from the principle Just Say No. A physician suggests how the two principles may function in tandem:

We develop the drugs to take pain away and then we turn around and pass laws that stigmatize their use. This has nothing to do with controlling pain; it's about controlling drug [distribution] and the addicts who use them. In some ways, it makes sense to me. But I still resent it that the U.S.A. had to get to the point where we needed to pass laws that say it's okay to use opioids for therapeutic purposes. If it really were okay, we wouldn't [need] the laws. Chronic pain patients are difficult enough to treat without having to worry about "big brother" looking over your shoulder. The DEA, the boards ... [they] don't trust doctors to be able to distinguish between a patient who needs medication for pain and a patient who is seeking drugs. I resent it and I'm not about to jeopardize my livelihood because of it. I refer almost all of my chronic pain patients these days.

The important role both principles play in the ethic of underprescribing is clarified further in the statement of a pharmacist, who works for a large drugstore chain in the Midwest:

It would be total chaos if we gave [pre]script[ion]s to everyone suffering from chronic pain. America would grind to a halt. That's how powerful these drugs are. Everybody thinks the pain they're feeling at this moment is the worst pain ever. There's no guarantee that opioids will make the quality of life better for patients in pain. Sure, they reduce pain, but they dull [patients'] senses ... too. This is why CSAs [controlled substance acts] are necessary. We all have a stake in pain management too. Can you imagine what would happen to American productivity if everyone who claimed to have chronic pain was treated with [opioids]?

And last, the revealing sentiments of a registered nurse, who practices in a hospice setting:

The patients with metastatic cancer or HIV [human immunodeficiency virus] who suffer needlessly ... the people who don't want to get out of bed and face another day because of pain in the occipitocervical area [in the spine at the back of the neck] or the lumbar [lower back], we [health care professionals] make them heroes by forcing them to endure pain that is treatable. We do it supposedly because the risk of addiction ... is supposed to be so high. Every day each and everyone of us does things where the real risk of a bad outcome is much higher--crossing a busy city street, for example. The real reason we underprescribe for pain, though, is that we don't know any better. We don't learn about the pathophysiology of pain when we are trained. And we are afraid--afraid some board or narcotics agent will sweep down and accuse us of wrong-doing and we'll lose everything.

Despite the considerable range of opinions about whether it is appropriate to prescribe high doses of narcotics to chronic pain sufferers, practitioners agree that it is a risky venture to do so, which highlights once again what powerful inducements external rewards can be in influencing pain treatment.

In a practice dominated by an ethic of underprescribing--one that conceives of pain as an inevitable part of the human condition, of suffering as a moral good, and of drugs as harmful or bad--some patients say they have considered taking their own lives rather than endure the unrelenting pain and the social stigma of not being able to cope:

I'd had pain before, though not like this. No one I went to could figure out why. At first, I thought I'd die and then I wanted to [die]. I was actually relieved when the doctor finally found the tumor. At least then I knew it wasn't all in my head. Things are better now. Back then for awhile, I really did think about going the Kevorkian route though.

As the recent U.S. Supreme Court decision in *Vacco v. Quill* implies, the far less onerous option of treatment with opioid analgesics may not be any more viable or socially acceptable than PAS for some pain sufferers. Morris points out that it will require a revolution in what society makes of pain--in the values of what he describes as the culture of pain--to change the patterns of underprescribing that have made PAS an option even worth considering.

The external rewards reinforcing the principle Grin and Bear It are many and powerful. Indeed, although it is hard to imagine that anyone who regularly engages in the practice of chronic pain management would purposefully deny relief to a patient experiencing unrelenting pain, the available empirical evidence clearly shows that it happens all the time. The reason underprescribing persists may well be that many health care practitioners believe that their duty to comply with laws and societal norms allowing pain to happen outweighs their responsibility to provide relief to patients. Yet, a more likely explanation for continued patterns of underprescribing is that practitioners take a look at the legal landscape and seek out alternative methods for fulfilling their responsibility. It is ironic that, in a society where the consumer has access to literally hundreds of over-the-counter drugs that promise a quick fix to pain, those with a real need are left to endure. The fact of the matter is that, as wary as we are of pain, we are more leery of anyone or thing that takes it away.

Principle III. Avoid Risks: it ensures no harm done

As indicated in Figure 1, most of the major health care institutions reward underprescribing. According to organizational theorists, institutions are instrumental entities that, by their very nature, are geared toward achieving organizational goals and to perpetuating the status quo. As such, they tend to be risk averse. Inasmuch as the practice of pain management is taught, delivered, financed, and regulated by

organizations, it makes sense that avoiding risks is a guiding principle in the ethic of underprescribing. Avoiding risks is a means not only of ensuring that practitioners do no harm (internal reward), but also of securing income, power, prestige, job security, and status--these are all external rewards distributed by all the major organizations and institutions in the American health care system.

Insurance providers have become the central players in the drive to contain health care costs. One of the ways they attempt to minimize costs is by basing reimbursement policies on determinations of medical necessity and on analyses of the average cost of treating certain diseases or performing particular procedures within a patient population. Pain, because it is so subjective, and chronic pain treatment, because it is so case specific, do not lend themselves to such cost-control measures. A physician explains how the reimbursement policies of insurers may create disincentives for deviating from the status quo of underprescribing:

Unless you're in a pain clinic, it's an unbelievable ordeal to obtain third-party payment for pain treatment with [opioids]. Every time it's the same. I call; the patient calls. Then I ask for a review, if the plan hasn't already. After suffering that indignity, reimbursement is denied a third time. If, by the fourth appeal, the payment still isn't forthcoming, there's a decent chance that either or both of us will be kicked from the plan. How and what they [insurers] reimburse is another mystery. Same plan, same coverage, same pain, same treatment, different day ... different payment. What's always the same ... [is that on] every pain patient I take [on], I lose money.

In short, the procedures established by insurance providers to achieve cost control--an organizational goal--have skewed the distribution of external rewards in a manner that creates a financial risk for chronic use of opioids.

The goal of regulatory organizations also centers on avoiding risks. Regulators use a command and control--"do this or else"--approach that creates risks for engaging in particular kinds of behavior. The effectiveness of this approach hinges on whether the target population believes regulators have the legitimate authority to command compliance. Said one physician:

I follow the guidelines on prescribing narcotics because, as a licensed doctor, I have an obligation to play by the rules, whether they're set by the boards or the DEA ... whoever. I do it because I believe that they're [laws, regulations, rules, and so forth] there for a legitimate purpose, be it to protect patients from some harm or threat or some such. I have duty to respect that, even if I disagree.

In turn, the scope of compliance depends on how much the group regulated fears or values the "or else" to be denied. In the following, an investigator for a state medical board identifies the nature of the regulatory risks confronting a physician if investigated or disciplined for overprescribing:

Say the board investigates a doctor for possible overprescribing after a pharmacist reports the doctor was prescribing opioids at doses above the accepted standard. I investigate the case the same way I would any other alleging inappropriate prescribing. I can't assume that, because the patient has a chronic pain condition, the doctor's actions were right. That's for the board to decide. If the board decides to take a [disciplinary] action, even a minor slap, there will be lasting consequences. The action will be reported [to the National Practitioner Data Bank]. Insurance companies and hospitals will use that data bank report to keep a doctor from getting privileges and on [insurance] plans. The hospitals and insurers do what they're going to do, regardless of what the board says. I know of a case where the doctor lost his hospital privileges just because the board ordered him to take a course in appropriate prescribing. That is not fair. Still I don't think the board should be making decisions based on ... how discipline will affect practice privileges. That protects doctors and it's our job to protect the public.

The following comments, made by a nurse, consider the impact of the same regulatory risks from the vantage point of health care practitioners:

It doesn't take all that much to protect yourself [from licensure discipline] or an investigation by the [DEA]. Good documentation of why you prescribed the drugs, regular follow-up, that sort of thing ... things we should do when treating any patient. These days, the cost of being accused is nearly as

high as [that of being] convicted. Even when no discipline results, other docs who know about the investigation might think you were duped by a patient. And it only takes one case and, before you know it, everyone thinks you're a [pre]script[ion] doc.

As these statements suggest, failure to avoid the risks established by regulators may have a ripple effect on the distribution of the external rewards that make practice possible and profitable.

To be investigated or sanctioned by a board could result in a loss of stature, reputation, institutional privileges, or access to insurance panels, even if no restrictions or limitations are imposed on the license to practice. In fact, loss of these other external rewards--all of which are essential to maintain a successful practice--may have the same effect as the most onerous sanction a board can take: license revocation. Thus, the regulatory imperative to avoid risks strongly reinforces the ethic of underprescribing.

In some respects, the goal of the educational institutions that train health care professionals is to teach practitioners how to fit in or to become members of the health care establishment. As such, these institutions socialize practitioners to avoid risk-taking. Before a group of health care professionals concerned about chronic pain, an anesthesiologist specializing in pain management stated:

For the better part of the last century, schools of medicine especially, but all health professional schools, have taught a medical model of pain which presents pain as a neurobiological manifestation of a disease or illness rather than [as] a problem warranting treatment itself. [As a result], pain management just hasn't been part of the core curriculum in most professional schools until of late.

According to another physician, these institutions have, however, apparently gone to great lengths to teach the value of avoiding risks:

The training in the pathophysiology of pain and in the use of opioid analgesics when I was a resident was nil. Until recently, physicians and pharmacists who didn't adhere to the medical model had to train themselves, or keep moving, to get the training and experience needed. In the fifteen years since I finished my clinical training, I've met a few physicians from my generation who regularly use opioids to treat chronic pain, but only two I would call successful doctors ... who have lucrative practices and are respected in the community. Many of the rest are outcasts, who had to fight long to get privileges, reimbursements, and partners ... and even harder to shake the reputation for being soft on pain.

Studies show that for many mid-career physicians underprescribing of opioid analgesics is the status quo. This complacency likely will continue as long as health education institutions base clinical teaching on an outdated model of pain that creates internal rewards for avoiding risks and that emphasizes the potential loss of external rewards for prescribing opioids.

The risk avoidance principle also overlaps with the other two central principles of the ethic of underprescribing. In the words of one physician:

Any doctor worth his salt knows the research about the [therapeutic uses] of opioids for treating chronic pain. There is such ignorance out there about addiction ... such concern about the regulators, the narcs, the board--the [pre]script[ion] cops ... such misunderstanding about narcotics and what they can do for this kind of pain. All the talk isn't going to change the reality that most doctors and patients don't think of pain as the problem. Instead, it's drugs [that] are the problem or disease [that] is the problem. That kind of thinking will be around until we do something to make the professionals understand that there is nothing to be gained from thinking and acting as if chronic pain and patients who have it can be wished away.

The comment of a member of a state medical board suggests even more clearly why the ethic of underprescribing endures:

Are we talking about changing an entire way of doing things because doctors are afraid the board or DEA or patients will turn on them? The board only disciplines physicians in the most egregious cases ... the same is true for the other enforcement agencies. They're [the few physicians sanctioned for

overprescribing] the exception that proves the need for the rules. We just don't see cases in which allegations involve underprescribing. If it's as common as some of these docs and nurses say, why isn't [it] being reported to the board?

The answer to the question posed by this physician is, simply enough, that underprescribing is the norm or the prevailing standard rather than an aberration.

The impact of regulatory relief

There are essentially two ways of stripping an ethic of its relevance: to establish new principles or to alter the system of rewards supporting existing principles. Recent efforts at regulatory relief--IPTAs, chronic pain regulations, rules, and guidelines--although a step in the right direction, were not designed with either goal explicitly in mind. Moreover, as alluded to earlier, an ethic is a complex phenomenon. The system of principles or standards of conduct that are at its core evolves gradually, over time as the practice itself develops. Hence, enacting laws or implementing policies that liberalize the chronic use of opioids will not undermine the relevance of a practice ethic unless they also fundamentally change the nature of the practice itself. The following statement by a physician illustrates the point:

I am licensed to practice in five states. Everyone of them has adopted a chronic pain rule or law of some kind in the last couple of years. While I think these new laws are well intentioned, I don't expect them to change prescribing practices anytime soon. In the first place, hardly any physicians know about them and the physicians [who] do know about them [physicians who regularly treat pain patients] don't need them: they already know what to do. In the second place, you cannot undo what it took a generation to create just like that. Even my colleagues [who] know about the board's new rules have a wait and see attitude. They haven't let the fact the board hardly ever disciplines physicians for chronic pain prescribing dissuade them in the past. No reason to believe the new rules will change that. It's all in perception.

If this physician's thinking is correct, regulatory relief might change the actual standards or rules of the practice, but it will not alter the perception that there are few risks and fairly substantial external rewards for underprescribing.

Can the IPTAs, rules, and guidelines on chronic pain management become the basis of a new ethic for pain management? Several researchers argue that regulatory relief has created an implicit risk for underprescribing by establishing a new standard that legitimizes the long-term use of opioids for therapeutic purposes in the treatment of certain kinds of pain. But, as the comment above suggests, an implicit risk may not be enough to strip the ethic of underprescribing of its relevance. For the risk to become explicit, it is necessary to develop external rewards that directly reinforce the standard on appropriate prescribing at the center of regulatory relief. Ironically, the most immediate means of establishing these external rewards may not be regulatory relief, but more regulation.

Establishing a new ethic: the role of medical boards

It is illegal in all fifty states for a physician to practice without a license. A physician with a license that has been restricted or limited as a result of a board sanction, while legally authorized to practice, may find it difficult to do so. As noted in the section on avoiding risks, it is not uncommon for hospitals to curtail the privileges of physicians by placing their licenses on probationary status. Similarly, malpractice insurers may raise premiums or deny coverage to physicians who have been disciplined. Health insurers and managed care organizations (MCOs) frequently make it a policy to exclude or deselect physicians with encumbered licenses from health care plans. Limitations on prescribing privileges imposed by a board can result in sanctions by DEA and state pharmacy boards. Changes in licensure status can also affect less tangible rewards. Prestige and reputation in the health care community and within a specialty area are valued external rewards that vary in accordance with a physician's licensure status. To the point, as the entities that authorize physicians to practice, state medical boards are uniquely positioned to affect the distribution of external rewards throughout the health care system.

The options: what medical boards can do

As yet, no state medical board has created a risk for underprescribing that takes advantage of this unique position. This may be a function of the fact that medical boards tend to be reactive rather than proactive. However, medical boards can create risks in three ways, if only indirectly: by investigations, rule-making, and administrative adjudication.

Most boards only initiate investigations after receiving a complaint or a report of an allegation. Despite the fact that the majority of boards are authorized to initiate an investigation on their own--that is, without first receiving a complaint or report--doing so can render a board vulnerable to criticism for being overzealous or biased against a particular practitioner or area of practice. Also, boards generally do not have the financial and human resources required to conduct routine compliance checks of licensees or to survey patient satisfaction with particular treatments or procedures. Moreover, state medical board investigations and sanctions tend to be aimed at physicians who deviate from prevailing clinical practice and conduct standards. As the discussion on the ethic of underprescribing suggests, the undertreatment of chronic pain with opioids is the standard--the prevailing clinical practice.

In discussions with medical board executives conducted between November 1997 and January 1998, only one board (California) of the thirty-six represented had received a complaint or report explicitly alleging underprescribing in the treatment of chronic pain. Several executives indicated that they had received complaints from prison inmates alleging that certain medications had been denied by prison officials as a form of punishment, but they noted that most were generally not pursued as underprescribing cases. The data on board actions indicate that, even in states that have adopted IPTAs and/or chronic pain guidelines, investigations involving the treatment of chronic pain continue to focus broadly on patterns of inappropriate prescribing. This may be the case because the medical experts and consultants the boards rely on to review investigative materials and to serve as witnesses in prescribing cases seldom have training in chronic pain management. As well, there appears to be consensus among medical board administrators that it would be both improper and impolitic to seek out underprescribing cases without first adopting formal rules or standards establishing grounds for disciplinary action.

Second, medical boards set formal standards and related policies about such matters by rule. Rule-making often occurs in response to national trends (for example, chronic pain and regulatory relief), changes in the science or technology that have an impact on the profession (for example, telemedicine acts and rules), or problems that surface repeatedly in complaints under investigations or under prosecution (for example, scope of sexual misconduct). The process of adopting a rule or regulation in most states is a democratic one, in which all interested parties are invited to participate. Proposed regulations are generally published or noticed for public comment for a set period of time; public hearings may also be held at some point; and, in virtually every state, proposed regulations are reviewed by a standing committee of the legislature and/or an executive branch council before a board can move for final adoption. Active and intense opposition to a regulation by a single party or a coalition of opponents can effectively derail efforts to adopt a rule at any stage in this process. Consequently, a medical board may not be able to adopt a formal policy on underprescribing through a rule if licensees, the public, or their representatives deem it unnecessary or potentially burdensome.

To date, no state medical board has adopted a formal policy or standard that treats underprescribing as an explicit ground for disciplinary action, and only one is considering doing so--IBME. The persistence of the ethic of underprescribing may be one of the reasons why medical boards are so reluctant to invest the capital necessary to build support for a rule on underprescribing.

And, third, standards of practice and professional conduct are also set through the administrative adjudicative process when boards render final decisions. It is difficult to assess with any accuracy the extent to which any one factor is the major cause for discipline. As a practical matter, most of the cases that result in a disciplinary action involve many factors, categorized broadly under headings such as unprofessional conduct, professional incompetence, or substandard care. Depending on how the grounds for disciplinary action are defined in a state's medical practice act or a particular state board's administrative rules, sanctions imposed for underprescribing could be reported under one of these general grounds.

Final decisions in the adjudicative option would have to be made on a case-by-case basis in response to complaints made by patients alleging underprescribing. However, as noted earlier, state board executives report receiving few complaints specifically alleging underprescribing or undertreatment of pain. As the public becomes more aware of this issue over time, the number of complaints may increase. Even if they do, boards will still have several obstacles to overcome. For example, it may be difficult to convince prosecutors

to pursue charges in an area in which there is little legal precedent and the standards of practice are ambiguous and vulnerable to broad legal challenges. Similarly, boards may not be able to locate expert witnesses willing to support publicly a charge that underprescribing is substandard care, given prevailing practices among physicians in most states. In the short term, it is unlikely that boards will be able to establish a risk for underprescribing on a case-by-case basis through the administrative adjudication process. Again, the data bear this out: in interviews with state medical board administrators, not one of the thirty-six who participated could identify a pending case that could become the basis for a standard on underprescribing.

Making the transition to a new ethic of prescribing

The most direct way of creating an explicit risk is the second--rule-making or standard-setting--because it allows boards to affect directly the direction of external rewards. A review of the practice acts and administrative rules enforced by state medical boards reveals that all have a law or rule on the books establishing the parameters for appropriate prescribing that alludes to or implies that risks for overprescribing exist.

The following is a representative sample of provisions on appropriate prescribing now in effect across the states:

The promiscuous or indiscriminate prescribing, ordering, administering, or dispensing of controlled substances for other than therapeutic purposes.

Prescribing, selling administering, distributing, ordering or giving to an habitue or addict or any person currently or previously drug dependent any drug legally classified as a controlled substance or recognized as a dangerous, addictive or illegal drug unless indicated as part of a therapeutic regime for chronic pain management approved by the board.

Prescribing, dispensing, or administering any controlled substance, prescription-only drug, or an illegal drug, or controlled substance for other than accepted therapeutic purposes.

Prescribing, dispensing or furnishing any prescription drug without prior examination and medical indication therefor.

Possessing, using, prescribing for use, or distributing controlled substances or legend drugs [controlled substances] in any way other than for legitimate or therapeutic purposes, diverting controlled substances or legend drugs, violating any drug law, or self-prescribing controlled substances.

Altered to address underprescribing, a rule could take the following form in a state with an IPTA or chronic pain regulations or guidelines:

Option 1: Prescribing, ordering, administering, or dispensing of controlled substances in violation of the standard for chronic pain management established in [*IPTA or board rule*] unless good cause is shown for failure to adhere to the requirements set forth therein.

As a more direct approach, a medical board could adopt the following rule as a ground for disciplinary action:

Option 2: Failure to adequately prescribe, order, administer, or dispense controlled substances, including opioid analgesics, for the relief or modulation of chronic pain in accordance with accepted knowledge and prevailing clinical practice for pain treatment and the standard for chronic pain management established in [*IPTA or rule*].

A more cautious board would add the caveat:

Nothing in this subrule shall be construed to be an advocacy of the imprudent or improper use of opioid analgesics. Further, this subrule shall not relieve a licensee of the obligation to comply with state and federal laws governing the lawful prescribing, ordering, administering, or dispensing of controlled substances.

Adopting any of these rules would authorize a medical board to scrutinize vigilantly physician practices for evidence of both underprescribing and overprescribing opioids. A medical board would then have the authority to take a disciplinary action on the above rather than on some broader ground--be it substandard care, professional incompetence, unprofessional conduct, and so forth--if a physician were found to have failed to prescribe appropriately for pain relief. The true difficulty arises in attempting to determine what constitutes "appropriate" prescribing. As the public entities responsible for regulating the practice of physicians, state medical boards are obligated to do no less.

The environment in which most medical boards operate will make meeting this obligation difficult. Medical boards do not function in a vacuum. Proposing a rule establishing underprescribing as a ground for discipline does not ensure that it will be adopted or, if adopted, readily enforced.

First, embittered by both their experience with national health care reform and the restrictions imposed on physicians by MCOs, medical associations have been particularly wary of government rules or policies in the last several years that could in any way further encroach on the clinical decision-making authority of practitioners. The perceived regulatory risks associated with overprescribing are of concern to professional associations and societies. Yet, in the current political climate, state medical societies may well view regulations establishing a risk for underprescribing for what it is--more regulation. A statement made by the president of one state medical society exemplifies this way of thinking about regulations on underprescribing:

We will do whatever it takes to avoid another set of guidelines or rules that make physicians vulnerable to malpractice lawyers or board lawyers. Our goal is to get the board off doctors' backs, not to give the board another reason to look over our shoulders. A rule on underprescribing will go a long way toward assuring that no physician in their right mind ... who is not practicing in a pain center ... will go anywhere near a pain patient. What we need is less board regulation ... less looking over our shoulders ... not more. The medical society will look very carefully at anything else.

If this perspective represents medical associations nationwide, state medical boards will have an uphill battle when trying to adopt formal policies on underprescribing. Ultimately, success will hinge on boards' abilities to rally public support and to persuade a skeptical medical community that establishing a risk for underprescribing will serve the long-term interests of patients and professionals.

Second, enforcing a policy on underprescribing may require medical boards to change fundamentally the way they investigate prescribing cases. As noted earlier, boards initiate investigations in response to complaints and reports alleging inappropriate prescribing. Boards rely on expert consultants and peer reviewers to examine patient charts and prescribing data gathered from pharmacies during the investigation and to determine whether the appropriate standard has been met. Most often, these experts are board certified specialists in the same area of medicine as the physician under investigation.

Board executives indicate that the majority of complaints boards receive involve physicians in primary care (family practice, internal medical, obstetrics and gynecology, pediatrics, and so forth) and surgical specialties. Because studies show that training in pain management in these areas of medicine has not been widespread, one of the greatest challenges confronting boards will be locating consultants and reviewers with sufficient experience in pain management to serve as credible witnesses. Boards seeking to enforce a policy on underprescribing may have to work together and pool experts across state lines and specialties. In the short term, boards may have no option other than to ask experts explicitly to consider whether undertreatment of pain is a problem when they review cases.

Third, the effectiveness of a policy on underprescribing will also hinge on whether board members, licensees, and the public change how they think about prescribing issues. As one board member explains:

While the idea of establishing a policy against underprescribing makes good sense, guidelines or rules are not alone going to change behavior. Board members and licensees have to change the

way they think about prescribing to chronic pain patients. Eventually, the patients too will have to be more aware. The board just doesn't get complaints about underprescribing because most patients in serious pain, particularly those [who] are terminal, don't think about continuing pain as being a prescribing problem. Board members, like most doctors outside pain clinics, do the same ... by focusing on the underlying organic problem, rather than [on] pain management as a problem.

As this comment suggests, not only must board members alter how they approach prescribing for chronic pain, but patients will also have to be more aware of the therapeutic uses of opioids.

Can boards do anything to raise the consciousness of patients and physicians on this issue without undertaking a massive education campaign? The following suggests, perhaps so:

We [board members] could start the process today, even before a single complaint [is filed] or the regulation [is adopted]. When we review cases where pain is an issue ... we could ask ourselves and our [expert] reviewers to look at the prescribing of drugs from the vantage point of "was it appropriate" and mean [was it] enough instead of only [was it] too much. If we do this as a matter of course, we really wouldn't need the regulation. It's best still to have a policy in print or on the books so that doctors will know that we mean business if we find prescribing wasn't enough.

Again, the challenge a board faces in choosing this course is determining the parameters of appropriate prescribing.

Underprescribing as inappropriate prescribing: a tale of two boards

In the last several months, at least two state boards have confronted this challenge. I recount their experiences below. The state boards are referred to as State Board A and State Board B. I do not identify the boards to protect the patients and to hold confidential the investigative materials provided to me by the boards.

State A is generally considered to be one of the leaders in the regulatory relief movement. It was among the first to adopt an IPTA; and the chronic pain management guidelines adopted by State Board A have been used as a model by many other states. Despite the state's reputation for being progressive in chronic pain treatment, State Board A does not have a law or regulation specifically addressing underprescribing practices. It is thus not surprising that Compassion in Dying would find State A to be an appropriate test site for an underprescribing case.

According to Ms. Tucker, a decedent's daughter contacted Compassion in Dying to request help in pursuing a complaint against a physician who failed, in her view, to provide adequate pain relief medication to her father during his final days in home-hospice care. The patient was apparently dying from inoperable cancer; sources indicate that he left the hospital before a formal diagnosis of his condition was made. According to the daughter's account, the treating physician significantly reduced the level of opioid analgesics prescribed for her father once he left the hospital. Compassion in Dying sought out an independent review of the physician's prescribing practices from an oncologist practicing in the same community. After reviewing the medical records at length, the oncologist determined that the pain care provided by the treating physician was inadequate and substandard. On the basis of this review, the daughter, with the help of Compassion in Dying, sent a complaint to State Board A, alleging that her father had received inappropriate treatment.

As would most medical boards, State Board A investigated the complaint as an allegation of inappropriate prescribing. State laws prohibiting disclosure of investigative information make it difficult to ascertain how the complaint was investigated or what issues influenced the board's thinking when reviewing the results of the investigation. However, most board's conduct lengthy interviews with the physician and complainant at the investigative phase and then seek out a medical expert or consultant to review the relevant medical records and to render an opinion before the board makes a determination in quality of care/prescribing cases. Generally, medical consultants and reviewers are selected for their expertise in a particular specialty. For example, if the physician under investigation is an internist, then the board will seek consultants who are board certified in internal medicine to conduct reviews.

Although there is limited public information available about State Board A's reasoning in this case, this much is known. Sources familiar with the case report that, after reviewing the results of the investigation, State

Board A determined that the physician's actions, though negligent, did not rise to the level required by law to file a formal charge (or charges) for inappropriate prescribing. A representative of the decedent's daughter claims that State Board A issued the physician a letter, essentially warning him that any future reports of underprescribing opioid analgesics to a patient would likely result in the filing of formal charges.

The daughter made her dissatisfaction with State Board A's decision known to the media and interested public officials, to little effect. The board has no plans to revisit its decision, but remains firmly committed to pursuing any complaints alleging underprescribing that it receives. Indeed, in finding merit in a complaint alleging underprescribing, State Board A has taken a significant step in establishing a risk for inadequate pain treatment. As yet, State Board A has not found sufficient cause to carry out its threat or to make the risk a legal reality.

In contrast, chronic pain issues have not been high on the political or public policy agenda of State B. State Board B did adopt a rule establishing chronic pain treatment guidelines, but was otherwise inactive. Currently, only one or two organizations are active on chronic pain issues in State B, and neither anticipates any progressive changes in public policy in this area in the near future.

As in the case before State Board A, State Board B received a complaint from a family member who was deeply upset by the quality of care provided to a dying patient in home-hospice care. In this instance, there was a clear diagnosis that the patient was terminally ill. However, it is questionable whether the patient or his family had come to accept the diagnosis or that he was receiving noninterventionist, palliative care. When the patient began to fail at home from a lack of sustenance, his family sought to have him admitted to a hospital. The patient's family alleges that the treating physician was agitated when the patient was admitted and, as a consequence, was unwilling to honor wishes to initiate extraordinary life-saving measures. The family contends that the treating physician chose only, either out of incompetence or malice, to administer potassium chloride and at levels that may have actually hastened the patient's death. The family's outrage was compounded by the treating physician's decision to override the request to resuscitate the patient in the event that he arrested.

Public information on the investigation of this case by State Board B is limited. If handled in a routine manner, staff would have first conducted an in-depth investigation of the complaint; if the board found reason for concern in the investigative materials, the relevant medical records would have been referred to experts in the field. According to public statements made by the decedent's family, after considering the results of the investigation and the findings of the panel of expert reviewers, State Board B concluded that the physician's conduct met the prevailing standard of care. The board apparently determined that the decision to administer potassium chloride was appropriate. Sources familiar with the case indicate that at no time did State Board B or its panel of reviewers consider whether it was substandard for the physician not to prescribe opioid analgesics to the patient in sufficient doses to relieve his pain or to enhance his ability to take nourishment. State Board B reportedly also found that the physician had not adequately explained to the decedent's family the patient's status and his rationale for issuing a do-not-resuscitate order. As a result, a confidential letter was sent by the board advising the physician to pay more attention to the concerns of patients and their families. The decedent's family has repeatedly denounced the State Board B's decision in the press and in other public forums. By all accounts, State Board B remains confident that it made the right decision.

Yet, for State Board B, the conclusion of the case marked a new beginning. The controversy surrounding the final decision prompted members to question whether they had adopted the appropriate approach to the case. Of concern was the board's failure to consider the prescribing issues in greater detail. State Board B determined that the prudent course of action in future quality of care/prescribing cases is for investigators to obtain materials that allow consultants and peer reviewers to assess the adequacy of pain treatment. As a result of this decision, State Board B has actively sought out experts in chronic pain management to assist in evaluating inappropriate prescribing cases. Staff of the board has been directed to study the scope of the underprescribing problem and to develop strategies that will improve State Board B's ability to detect and deter inadequate pain treatment. Further, at least three underprescribing cases are now under review by State Board B, in which formal charges on the grounds of inappropriate prescribing are likely to be filed in the near future. To put licensees on notice of this change in approach, State Board B is preparing to notice an amended rule that explicitly includes underprescribing as a ground for discipline.

Conclusion

Although they have taken very different routes, State Board A and State Board B are both in a position to establish meaningful risks for underprescribing. In time, perhaps they will do so. At present, there is compelling evidence that the ethic of underprescribing, though wounded, has not fallen. For example, the U.S. Senate narrowly defeated the Lethal Drug Abuse Prevention Act, which would expand the grounds for the suspension or revocation of a physician's DEA certificate if it were determined that a prescription for controlled drugs had hastened a patient's death. The legislation is expected to resurface in the next session, however. Since May 1, 1998, the number of formal overprescribing charges issued by state medical boards has actually risen by 10 percent over the past six month period. Few of the states that have not participated in the regulatory relief efforts to this point report that they are planning to do so. And, as yet, not a single case is on record in which a medical board has taken a formal disciplinary action against a physician for underprescribing.

J. David Haddox, Gerald M. Aronoff, "Commentary: The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain"

Journal of Law, Medicine & Ethics, 26, no. 4 (1998): 350-52.

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Recently, due to a number of converging factors, there have been significant shifts in public policy regarding the legitimacy of treating chronic pain with opioids. Traditional tenets handed down in medical, dental, nursing, and pharmacy education created a distinct reluctance on the part of practitioners to prescribe opioids on a continual basis. Much has been written about the reasons for these attitudes. One of the barriers that is very consistently reported by prescribers is the fear of regulatory and legal repercussions to ongoing prescription of this class of medications. It is in this arena that sentinel changes have occurred, the most recent of which is the promulgation of a document prepared by the Federation of State Medical Boards (FSMB), which suggests a set of guidelines meant to be endorsed or adopted by individual medical licensing boards on how to approach this particular aspect of practice. These guidelines, representing a broad consensus from a wide constituency, were developed in a relatively open forum and detail a balanced approach to the prescription of opioids for chronic pain. Similar actions have occurred at the state level, such as intractable pain treatment acts (IPTAs) in multiple states and the recent California law, known as the Pain Patient's Bill of Rights. Even though these products, borne of rethinking the place of opioids and the treatment of chronic pain, are encouraging, there is with any law, rule, or policy the potential for unintended consequences. Here, we discuss some potential negative sequelae of these generally positive actions from the perspective of two pain physicians who were involved in the development of FSMB's guidelines.

Probably the most bothersome of these unintended consequences is the notion that some patients, with access to the Internet or other sources, will read about these documents without having the benefit of the medical or regulatory context under which they are meant to be interpreted. Therefore, patients could easily assume that they have a legal right to demand any type of treatment they see fit. This can be problematic, in a number of ways. Although patients should certainly be active participants in their care, including selecting options presented to them, they should not be in the position of demanding a specific treatment, because they do not have the medical education necessary to make those decisions without being informed of reasonable options. In many instances of chronic pain, a contributing problem is not undermedication, but overmedication or inappropriate medication, with adverse drug-drug or drug-disease interactions. Some patients may actually benefit from the careful tapering of medications. This might be done in the context of an intensive, and sometimes, expensive comprehensive pain rehabilitation program. It is, of course, much easier to take a few pain pills than to arrive promptly each day, participate in physical conditioning, physical therapy, psychological therapies, and be a part of a therapeutic milieu. Additionally, insurers, looking only at the bottom line, may opt for ongoing medication therapy in lieu of more definitive nonmedication therapies.

One can foresee the case of an individual wishing to have opioids for a nontherapeutic purpose who might, under the guise of being a legitimate patient, demand that opioids be prescribed and, armed with one of these documents, might persuade a physician to prescribe analgesia out of fear of regulatory repercussions. The California law mentioned above, as originally written, provided patients with the legal right to demand opioids. It further intended to state that if physicians were not willing to prescribe opioids for patients, they were obligated to refer patients to professionals who would. Had it passed in its original form, the law would have set two very dangerous precedents: (1) it would have legalized specific treatment on demand,

regardless of medical appropriateness; and (2) it would have allowed micromanagement of everyday medical practice on the part of the legislature. It is our belief that medical practice should be governed by broad parameters set forth in state medical practice acts and by the rules, policies, and guidelines put forth by medical licensing boards, which are in a much better position to react to changes in science and to operate in a somewhat less politically charged environment than do the legislatures that empowered them.

Another concern for unintended consequences of these positive efforts to remove various impediments involves the unintended message to the public, regulators, and prescribers that all pain is responsive to or requires opioid medications. In actual practice, this is not the case. For mild or moderate pain, over-the-counter medications such as aspirin, acetaminophen, or ibuprofen are often quite adequate. Likewise, for more vexing neuropathic pain problems, such as painful diabetic neuropathy, an opioid may not be the drug of choice in a given person. Rather, a prescription nonopioid, such as an anticonvulsant or antidepressant medicine, may be preferable in terms of efficacy and tolerability. One can often avoid unacceptable side-effects seen with the opioids, such as constipation, by choosing a different medication.

A correlate to this is the implied message that all pain can be treated satisfactorily. Although practitioners of the field of pain medicine are generally expert at treating difficult pain problems, all of us have patients in whom the outcomes are less than perfect. We assume that this must also be the case in all other medical specialties. It is true that we have the means, knowledge, and medications to manage all pain more effectively than it is presently being managed, on average. However, this does not equate to the concept that all pain can be relieved. This notion of total analgesia could, therefore, be a basis for patient or family dissatisfaction and could potentially serve as the basis for a lawsuit. One can even imagine a patient who is unsatisfied with a physician for a different reason, but claims to have unrelieved pain as the basis for a complaint to a medical board.

IPTAs themselves are potentially problematic in a number of ways. Our first objection to IPTAs, as presently worded, is that they institutionalize the mistrust that has developed in some states between medical licensing boards and their licensees. In essence, these laws allow physicians to make an "end run" around their medical licensing board, provided that they stay within the confines of their state's IPTA. We believe that this is, again, setting a potentially bad precedent of having legislative micromanagement over the practice of medicine. Second, the definition used in most IPTAs is terribly flawed. If intractable pain "cannot be removed or otherwise treated and no relief of the pain is possible," then a patient is treated with opioids and experiences relief. If this is the case, then, by definition, the pain was not intractable in the first place and hence the practitioner is not within the protection articulated by the IPTA. Likewise, many of the definitions include the clause "in the generally accepted course of medical practice" as part of the definition. This would suggest that treating a chronic pain problem with opioids is outside the generally accepted course of medical practice. We believe that the treatment of pain should be an integral part of any medical practice. Many state IPTAs have clauses requiring evaluation by at least one physician other than the treating or attending physician. This, of course, would raise health care costs, in many cases, unnecessarily. Last, many IPTAs contain wording that they do not apply to persons being treated by a physician for chemical dependency because of the use of drugs or controlled substances. This has a number of areas of ambiguity that require clarification. First, this wording blurs the distinction between addiction and physical dependence. Second, the wording may well preclude coverage by IPTAs for treatment of pain in addicts. This would seem to legislate the concept that addicts who suffer from pain have abrogated all future rights to treatment of their pain because of their addiction.

With the increased amount of attention these policy changes have received in medical media, it is likely that many physicians who were, heretofore, reluctant to prescribe opioids, now may feel that it is incumbent to do so. Unfortunately, with the exception of FSMB's document, not one state IPTA makes specific recommendations regarding education in the pharmacology of drugs, the appropriate indications, the contraindications, and the distinction between physical dependence and addiction that would allow these drugs to be prescribed appropriately. Therefore, practitioners who were unfamiliar with their use may begin using them more liberally and may contribute to increased diversion or create complications that could otherwise be foreseen and prevented.

Our experience suggests that many physicians will briefly scan guidelines and may come away with the wrong impression. Often, physician behavior is hard to modify. It is entirely possible that the promulgation of guidelines will make physicians perceive that prescribing opioids for chronic pain is under even greater scrutiny than they thought, causing them to be even less willing to prescribe opioids for any reason. This may have the unintended consequence of creating exactly the opposite effect intended by these documents.

Likewise, physicians may see the documentation requirements as onerous, even though most of us would suggest that they can be met with minimal additional effort.

Last, the potential always exists for the dishonest physician to hide behind policies and regulations. It has been reported by law enforcement officers that some physicians "doctor the chart" to make prosecution difficult, even though the officers are convinced that these physicians are engaging in illegal activities. One could argue the point in a specific case, however, there will certainly be instances of abuse of the rules, policies, and guidelines in this manner.

In summary, the public policy changes that have been occurring are not happening in a vacuum. There is valid reason that attitudes and behaviors of prescribing, administering, and dispensing health care providers should change to improve the quality of life of many patients. In general, as evidenced by our contributions to some of these documents, we support the efforts to reduce regulatory barriers to good care. We all must beware, however, that even the best laid plans may go awry. Care and thought must be directed to remediation of the unintended consequences of attempts to change providers' attitudes toward prescribing by regulatory clarification or relief.