Pain Management and Palliative Care in the Era of Managed Care: Issues for Health Insurers

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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 physi-cian's actions. Pain remains a symptom ... not a disease and I feel this hampers our collective efforts to deal with the issue(s).1 — Blue Cross Blue Shield Medical Director

he 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.² 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.⁴

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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;⁵ (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,7 and inadequate reimbursement more generally for pain management and palliative care.8 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.9

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." ¹⁰

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.¹¹

Cost as a focus

Some evidence exists that cost and effectiveness are significant issues in MCO coverage of pain management for specific problems. ¹² 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.¹³

The development of new technologies to treat pain has led to the creation of a new "health care business."14 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. 15 Moreover, as cancer patients live longer, these costs might be incurred over several years. 16 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."17 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.18

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); neuroblative 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 "pre-

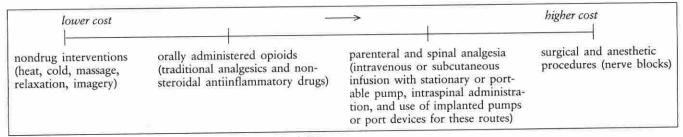


Figure 1. Relative Costs of Pain Management Modalities.

ferred 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.,21 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 PCA²² or epidural narcotic administration (ENA).²³ 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.²⁴

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."²⁵

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.²⁷

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.²⁹

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, postherpetic neuralgia, poststroke central or thalamic pain, and postamputation phantom limb pain. These pain syndromes do not respond as predictably as nociceptic 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.30

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 specialists³¹ 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."32

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. A 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.³⁸

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.39 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 costeffective 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.⁴⁰

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,"41 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."42 Furthermore, it "authorizes a physician who prescribes opioids to prescribe any dosage deemed necessary."43

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."44 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?"45 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."46 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 lifethreatening 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."⁴⁷

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.⁴⁹ According to a 1995 article on managed care and the provision of hospice care, approximately 80 percent of HMOs pay for hospice benefits.⁵⁰ 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."⁵¹ 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.⁵²

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.⁵³

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.⁵⁴

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.⁵⁵ 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."⁵⁶

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. 58

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.⁵⁹

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-five⁶³ separate companies (or plans)⁶⁴ 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.⁶⁵ 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, ⁶⁶ (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, 1997.⁶⁷ 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").68

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.⁶⁹

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

Priority Ranking	Pain Management for Terminally III (N = 11)	Management of Chronic Pain $(N = 14)$	Mental Health Issues $(N = 15)$	
Top 5 1 Plan (9%)		1 Plan (7%)	4 Plans (27%)	
Top 10	1 Plan (9%)	5 Plans (36%)	7 Plans (47%) 2 Plans (13%)	
Top 20	5 Plans (45%)	6 Plans (43%)		
Not in Top 20	4 Plans (36%)	2 Plans (14%)	2 Plans (13%)	

Table 1. Priority Given to Pain Management and Mental Health by BCBS Plan Medical Directors.

- "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").⁷³

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.⁷⁴

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 rehabili-

Question	Pain Management for Terminally Ill	Palliative Care	Management of Chronic Pain	Addiction to Opioids	
Identified issue as requiring special attention (<i>N</i> = 35)	37%	40%	67%	34%	
Developed a response 77% to the issue*		71%	87%	67%	
Planning to devote additional resources to issue*		57%	48%	17%	

Table 2. Summary of Results.

^{*} Percentage denotes those who identified issue as requiring special attention.

tation, headache, menstrual cramps, tennis elbow, fibromyalgia myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma.⁷⁷

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.⁷⁸

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.⁷⁹

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, 80 although some plans were reviewing their policies (the "benefit exclusion is being reevaluated by medical affairs"). 81

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"). Be 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."⁸⁴

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 ves. 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 parttime 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

Pain Management Modality	Acupuncture	Biofeedback	TENS Units	Implanted Pumps	Nerve Blocks
% of Plans	80%	63%	29%	17%	0%

Table 3. Plans that Do Not Cover Specific Pain Management Modalities.

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.⁸⁵

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.87 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,89 and 1992 when the American Pain Society (APS) published guidelines on analgesic medication for acute pain and cancer pain.90 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.91 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.92

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. ⁹³ 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."95 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."96

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. ⁹⁷ 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 notreatment group, there were generally no differences when biofeedback was compared with relaxation or behavioral therapy alone.⁹⁸

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." ⁹⁹

The recent evidence that acupuncture may be effective for some types of pain, as put forth in the November 1997 NIH consensus statement, ¹⁰⁰ 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 consis-

tent 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. 102 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 costeffective, despite higher initial costs."103 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."104

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. ¹⁰⁵ 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.¹⁰⁷

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. ¹⁰⁸ 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.¹⁰⁹

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."110 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."111

The traditional view results in withholding opioid therapy "for all but the most extreme cases of chronic non-malignant 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. ¹¹³

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 closetbig, 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 timeconsuming. 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.114

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."¹¹⁵

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. 116 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."117

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. 119 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" 120 or "a physician with an interest in pain who is attempting to treat chronic problems in the way that he knows best." 121 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. 122 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."123

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.¹²⁴ 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.¹²⁵

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." ¹²⁶

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.

Credentialed 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.

References

1. Email Comments of Michael Chamberlain, M.D., Medical Director, Blue Cross Blue Shield of Maine (July 15, 1998) (on file with author).

2. See, for example, AMA Department of Young Physicians Services, Pain Management: Resources for Physicians (visited Dec. 3, 1998) http://www.texnet.net/paincare/acute.htm (stating that "[d]espite good intentions and genuine concern for patients' comfort on the part of physicians, repeated evaluations of the state of pain therapy over the past 20 years suggest that many patients receive inadequate pain relief.").

3. Committee on Care at the End of Life, M.J. Field and C.K. Cassel, eds., Approaching Death: Improving Care at the End of Life (Washington, D.C.: National Academy Press, 1997): at 5.

4. See J.J. Bonica, Effective Pain Management for Cancer Patients (St. Paul: SIMS Deltec, Inc., 1994). According to John Bonica, "[d]ata contained in 11 reports, involving nearly 2,100 patients, published in the United States and several other countries reveals that in 70 percent of the patients managed with opioids and other drugs as well as anti-cancer therapy, the pain remained unrelieved in many instances until the death of the patient." Id. See also R. Bernabel, C. Gatsonis, and V. Mor, "Management of Pain in Elderly Patients with Cancer," JAMA, 279 (1998): 1877-82 (reporting on a study of over 10,000 nursing home residents with cancer which found that, although pain is common among such residents, it is often untreated).

5. See R.K. Portenoy, "Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective," Journal of Law, Medicine & Ethics, 24 (1996): 294-309; see also AGS Panel on Chronic Pain in Older Persons, "The Management of Chronic Pain in Older Persons," Journal of the American Geriatrics Society, 46 (1998): 635-51 (stating that opioids are often underprescribed for individuals with chronic nonmalignant pain in part because of "political and social pressures to control illicit drug use among people who take these medications for emotional rather than medical reasons" but that "addictive behavior among patients taking opioid drugs for medical indications appears to be very low").

6. See S.H. Johnson, "Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act," Journal of Law, Medicine

& Ethics, 24 (1996): 319-27.

7. See M. Sontag, "A Comparison of Hospice Programs Based on Medicare Certification Status," American Journal of Hospice & Palliative Care, Mar./Apr. (1996): at 32.

8. See J. Rhymes, "Hospice Care in America," JAMA, 264 (1990): 369-72; see also AMA Young Physicians, supra note 2: The AMA's Council on Scientific Affairs in its 1995 report "Aspects of Pain Management in Adults," identified the following barriers to optimal pain management:

Factors related to health care professionals

o inadequate knowledge of analgesic pharmacology and pain therapy

o poor pain assessment

o concern about regulatory oversight

o fear of patient addiction

o concern about the side effects of analgesics

o concern about development of tolerance to analgesics

o Factors related to patients o reluctance to report pain

- o reluctance to take pain medications
- o Factors related to the health care system

o low priority given to pain management

- o inadequate or inappropriate provisions for reimburse-
- o restrictive regulation of therapeutic agents that are controlled substances.
- 9. At the same time as we have become aware of the inadequacy of pain relief practices, our health care system is undergoing revolutionary changes. More and more of the insured population has moved into managed care. Over 70 percent of employees in medium and large organizations are enrolled in managed care plans, and the number of Medicare and Medicaid recipients in managed care is growing rapidly. See S. Findlay and W.J. Meyeroff, "Health Costs: Why Employers Won Another Round," Business & Health, 14 (Mar. 1996): at 49-51; see also Office of Managed Care, Health Care Finance Administration, National Summary of Medicaid Managed Care Programs and Enrollment (Washington, D.C.: HCFA Office of Managed Care, Sept. 20, 1996); and Health Care Finance Administration, Monthly Medicare Managed Care Contract Report (Washington, D.C.: HCFA Office of Managed Care, Sept. 1, 1996).

10. D.E. Joranson, "Are Health-Care Reimbursement Policies a Barrier to Acute and Cancer Pain Management?," Journal of Pain and Symptom Management, 9 (1994): 244-53

11. S.M. Wolf, "Physician-Assisted Suicide in the Context of Managed Care," Duquesne Law Review, 35 (1996): at 471 (footnotes omitted).

12. For example, a recent article regarding hospital-affiliated headache clinics stated that these facilities were often started before the managed care era and that, as managed care becomes more predominant, these clinics will have to document value in order to survive. See M.W. Green and D.W. Davis, "Hospital-Affiliated Headache Clinics in the Managed Care Era," Headache, 36 (1996): 503-05.

- 13. B.R. Ferrell and H. Griffith, "Cost Issues Related to Pain Management: Report from the Cancer Pain Panel of the Agency for Health Care Policy and Research," *Journal of Pain and Symptom Management*, 9 (1994): at 222.
 - 14. See id.
 - 15. See id.
 - 16. See id.
 - 17. Id. at 226.
- 18. See *id.* at 227. This figure is based on then current reimbursements for home nursing visits in California under Medicare.
 - 19. See id. at 228.
 - 20. See id. at 225.
- 21. Semmler v. Metropolitan Life Insurance Co., No. 119123/94, as reprinted in New York Law Journal, 25 (Nov. 17, 1997): at 25
- 22. Patient controlled analgesia is the "use of a pump, programmed and monitored under the supervision of anesthesiologists or other trained physicians, which permits a patient to press a button to obtain pain medication intravenously as needed, within limits set by the physician." Id.
- 23. Epidural narcotic administration is the "insertion of a catheter into the epidural space near the spine through which pain medication can be infused continuously and/or intermittently." Id.
 - 24. Id.
- 25. Id. The defendant's Claims Issues Committee, including four physicians, determined that "a benefit allowance for additional visits by an anesthesiologist" in such cases would be a payment for services that are not medically necessary. Id.
- 26. At issue in this case was whether the determination would be evaluated on a "de novo standard or a more lenient arbitrary and capricious standard," as desired by the defendant. The court ultimately applied the arbitrary and capricious standard. See *id*. Interestingly, an opinion by a federal district court regarding claimants governed by the Employment Retirement Income Security Act found that, under the same set of facts, the decision was not "arbitrary and capricious." *Semmler v. Metropolitan Life Insurance Co.*, 172 F.R.D. 86 (S.D.N.Y. Mar. 24, 1997), aff'd, 133 F.3d 907 (2d Cir.), cert. denied, 118 S. Ct. 2391 (1998).
 - 27. See New York Law Journal, supra note 21.
- 28. AGS Panel on Chronic Pain in Older Persons, *supra* note 5, at 636.
 - 29. Id. at 635.
 - 30. Id. at 635-36. (emphasis added) (endnotes omitted).
- 31. See M. Caudill et al., "Decreased Clinic Use by Chronic Pain Patients: Response to Behavioral Medicine Intervention," Clinical Journal on Pain, 7 (1991): 305–10 ("The treatment of chronic pain is costly and frustrating for the patient, health care provider and health care system. This is due, in part, to the complexity of pain symptoms which are influenced by behavior patterns, socioeconomic factors, belief systems, and family dynamics as well as by physiological and mechanical components.").
- 32. A. Zimm, "Tracking Elusive Sources of Pain More Difficult in Age of Cost Containment: Extensive Testing and Consultations with Specialists Often Required for Proper Diagnosis, Pain Experts Say," Warfields, Sept. 9, 1996, at 9. In response to this concern by insurers and managed care plans, some pain specialists argue that "when it comes to pain, providing more can actually cost less." This is especially true, advocates say, when costs are associated with obtaining a correct diagnosis. Id.
- 33. "Pain Control Innovations Abound, but Still no Voice of Authority: Report on Medical Guidelines and Outcomes Research," available in 1997 WL 8623976 (Apr. 3, 1997) (herein-

- after "Pain Control Innovations"); see also AGS Panel on Chronic Pain in Older Persons, *supra* note 5, at 637 (stating that "[a]mong those for whom the underlying cause [of pain] is not remediable or only partially treatable, a multidisciplinary assessment and treatment strategy is often indicated."). There are data to show that multidisciplinary treatments for chronic pain yield better functional outcomes in the long run and are more cost effective than single discipline treatments at least for chronic, nonmalignant pain. See, for example, H. Flor, T. Fydrich, and D. Turk, "Efficacy of Multidisciplinary Pain Treatment Centers: A Meta-Analytic Review," *Pain*, 49 (1992): 221–30. However, there has been little evaluation of the cost effectiveness of pain clinics "based on acute and postoperative models of care or cancer pain programs." See Ferrell and Griffith, *supra* note 13, at 230.
- 34. See "Finding the Right Care for Chronic Pain," Business & Health, 14 (Fall 1996): at 17, adapted from D.C. Turk and A. Okifuji, "Multidisciplinary Approach to Pain Management: Philosophy, Operations, and Efficiency," in M.A. Ashburn and L.J. Rice, eds., The Management of Pain (New York: Churchill Livingstone, 1998): 235–48.
- 35. Id.; see also "The Pain Coverage Conundrum," Business & Health, 14 (Fall 1996): at 22 (stating that "pain clinics are perceived in many instances to be composed of quacks who overcharge and offer unproven and expensive therapies that take advantage of the system").
- 36. "Pain Control Innovations," supra note 33 (quoting Dr. Kutaiba Tabbaa, director of pain management at MetroHealth Medical Center, in Cleveland, Ohio). Pain experts also argue that "primary care physicians may not be well trained to diagnose and treat pain.... For one thing, they may not realize that pain may still be persistent even though diagnostic tests reveal nothing abnormal. Primary care physicians may even question whether patients with no detectable abnormality are malingering or mentally unstable." "Finding the Right Care for Chronic Pain," supra note 34, at 17 (quoting Dr. J. David Haddox, medical director of the Pain Rehabilitation Program at the Emory University Clinic, in Atlanta). However, some pain experts admit that even though managed care plans may be reluctant to approve psychiatric evaluations or referral to some specialists, they have an easier time approving some types of interventions. For example, managed care plans appear to be more willing to approve implantable analgesic pumps because the primary care physicians understand the devices and the need for them. See "Pain Control Innovations," supra note 33 (quoting Dr. Tabbaa).
- 37. See "Pain Control Innovations," *supra* note 33. One pain provider asserts that plans do not understand that treatment of chronic pain requires a "package" approach. In his experience, plans approve "some elements of multidisciplinary care and disapprove others," which, he asserts, may not be effective in treating the patient. See "The Pain Coverage Conundrum, *supra* note 35.
- 38. A. Rutherford, ed., *The Anesthesia Answer Book* (Rockville: United Communications Group, 1997): at 16701.
- 39. See T.S. Carey et al., "The Outcomes and Costs of Care for Acute Low Back Pain Among Patients Seen by Primary Care Practitioners, Chiropractors, and Orthopedic Surgeons," N. Engl. J. Med., 333 (1997): 913–17.
- 40. See O.P. Friedlieb, "The Impact of Managed Care on the Diagnosis and Treatment of Low Back Pain: A Preliminary Report," American Journal of Medical Quality, 9 (Spring 1994): 24–29. Another argument for the benefit of clinical guidelines was made in a study of the impact of managed care on prescription drug use (not related to pain). Researchers found that members of health maintenance organizations (HMOs) were more likely to use prescription drugs at a greater rate than those

who were not HMO members. The study suggested that, in some cases, intensive drug intervention in the ambulatory setting may not only improve a patient's well-being but also may result in a decrease in overall health care costs by avoiding expensive hospital care or surgery. The researchers further hypothesize that HMOs, by establishing rational guidelines for prescription drug use, may increase "both the effectiveness and the efficiency of care." Specifically, they state that:

Studies have suggested that prescribing guidelines adopted by organized approaches used by HMOs are usually more appropriate than those implicitly followed by communitybased practitioners. Most current non-HMO prescribing practices are based on informal and often haphazard continuing education and, not infrequently, on information that

is colored by nonscientific considerations.

J.P. Weiner et al., DataWatch, "Impact of Managed Care on Prescription Drug Use," Health Affairs, 10, no. 1 (1991): at 53.

41. Hooper, Lundy & Bookman, Inc., "Senate Bills Introduced," California Health Law Monitor, 5 (Mar. 31, 1997): 4-16.

- 43. Id. Although California Senate Bill 687 was subsequently modified and the pain provisions deleted, Senate Bill 402 remained focused on pain treatment and was passed and signed into law in October 1997.
- 44. R. Pear, "HMO's Fight Plan to Pay for Some Emergency Care," New York Times, June 25, 1997, at A16.
 - 45. Id.

46. Id.

47. Id. (quoting Dr. Joel R. Saper, director of the Michigan Head Pain and Neurological Institute in Ann Arbor, Michigan).

48. Committee on Care at the End of Life, supra note 3, at 31. 49. See, for example, J. Randal, "Hospice Services Feel the Pinch of Managed Care," Journal of the National Cancer Insti-

tute, 13 (1996): 860-62.

- 50. See S. Becker and R.J. Pristave, "Managed Care and the Provision of Hospice Care," Managed Care Quarterly, 3 (1995): 39-43.
 - 51. Id.
 - 52. Wolf, supra note 11, at 471.
 - 53. Randal, supra note 49, at 869.
 - 54. Id.
 - 55. See id.
 - 56. Id.
- 57. "Study Hints HMOs' Dying Elderly Suffer Less," Baltimore Sun, Sept. 24, 1997, at C1 (discussing D.J. Cher and L.A. Lenert, "Method of Medicare Reimbursement and the Rate of Potentially Ineffective Care of Critically Ill Patients," JAMA, 278 (1997): 1001-07).
- 58. See J.R. Curtis and G.D. Rubenfeld, "Aggressive Medical Care at the End of Life: Does Capitated Reimbursement Encourage the Right Care for the Wrong Reason?," JAMA, 278 (1997): 1025-26 (casting doubt on the conclusions reached by Dr. Daniel Cher and Dr. Leslie Lenert, in part because of "systematic incentives for hospitals to minimize billing for managed care patients and maximize billing for fee-for-service patients").

59. See T.S. Jost, "Public Financing of Pain Management: Leaky Umbrellas and Ragged Safety Nets," Journal of Law,

Medicine & Ethics, 26 (1998): 290-307.

60. The senior medical director (SMD) was chosen because he/she would be most likely to have a sense of the importance of pain management and palliative care to the plan relative to other plan priorities, and to be knowledgeable about the plan's product lines. Other medical directors, although more likely to have detailed knowledge about pain management and palliative care, would be less likely to see the issue in the larger context of plan administration and plan products.

61. See Blue Brand Facts: The Blue Cross and Blue Shield System (updated Jan. 1998) http://www.bluecares.com/blue/ Blue Brand Facts/facts sheet.html>.

62. See id.

- 63. When we began our study in 1997, there were fiftyeight Blue Cross Blue Shield Plans (BCBS Plans). As of January 1998, due to ongoing mergers throughout the United States, there were fifty-five. Id. This trend is consistent with published reports regarding the status of BCBS Plans. See, for example, H.P. Cain II, "Proving the Policy Wonks Wrong," Health Affairs, 15, no. 4 (1996): at 105-06 (stating "[t]he Blues system is changing rapidly. Fifteen years ago there were eighty Blue Cross and Blue Shield plans. The number now is sixty and dropping. Mergers and consolidations are underway all over the country.").
- 64. BCBS refers to each of these fifty-five organizations as "Plans." Each BCBS Plan offers a variety of "insurance products," that is, HMOs, preferred provider organizations, traditional indemnity, and so forth.

65. See id.

- 66. Palliative care is distinguished from pain management for terminally ill patients because it is considered to be somewhat broader in scope, encompassing not simply pain management but also other approaches to comforting patients at the end of life and helping them to cope with an impending death. The survey form defined palliative care as "comfort care and other non-aggressive treatment for patients who are terminally
- 67. Prior to initiating interviews, an exemption from institutional review board approval was obtained by the University of Maryland, Baltimore Institutional Review Board.
- 68. In addition, one plan director, speaking as a Medicare carrier, said that the issue had come to him in response to uncertainty over coverage ("loading of pumps by home nurse is not provided by Medicare, so it becomes cost to patient. Turfed problem to Medicare.").

69. As regards the effort to develop guidelines or policies

on pain management, specific responses included:

· "working with local Institute exploring provision of guidelines, network of pain management centers as well as direct patient care";

· "developed policies on which pain management techniques are good and worthwhile and also on drug utilization tracking";

· "developed policies; ongoing monitoring of pain man-

agement programs"; and

· "reviewed hospice policy and procedure; reviewed infusion company's policy and procedure and persuaded the company to change their policies and procedures."

70. One SMD said it had come to his attention with regard to "off label use of neoplastic agents for supposedly palliative care."

- 71. Other reasons why or how the issue came to the attention of SMDs include the following:
 - · brought to our attention by "case managers and pharmacists with individual cases";

"increase in denial of individual claims";

- · "state legislative attention, pain provider in state putting pressure on legislators to establish centers of excellence for pain management";
- "hospice conference: after assuming charge of oncology, I went to conference and learned about issues of long term care and pain";
- "increasing number of requests/inquiries by physicians

seeking pain management programs for patients";

- "at a meeting of medical directors we discussed a concern about how we handle pain management";
- "patients who had outstripped medical community for getting services but still needed help; behavioral/mental health services were carved out and contracted to another company which required defining pain management—whether covered and where patient fits"; and
- "medical review on patient who requested benefits for pain management."

72. Other responses include:

 "developed case management 'catastrophic' program to deal with people with special needs";

· "on-going monitoring";

- conducted "internal research about what is covered and what is utilized";
- "established individual payment arrangements with [provider] groups, practices, centers, etc.";
- "threw problem back to case management; have tried to get addicted patients into pain programs but have had no success";
- "developed a response to abusers—some have been placed on automatic 100% review; pain clinic personnel seem to be a particular problem"; and
- "are looking at each case individually through case management—looked at and decided not to cover as routine benefit."
- 73. Additional specific responses include the following:

· "develop pain management provider network";

- "develop policies; e.g., three med[ication] injections for acute pain then reevaluate; are referring to center for excellence in pain management and specialists—evaluating outcomes";
- "develop policies—e.g., chiropractic care; development of pain management centers or at least guidelines specifying who, what and how to help; education of providers";
- "establish a working group; physician management groups which hold discussions of alternative methods of care";
- "create Centers of Excellence for chronic pain management, network of experts; educate oncologists about chronic pain management" [ideas of SMD, no plan agreement on this];
- "hire a consultant, develop policies; develop a pain management program for patients with chronic pain";
- "establish a working group; want to develop and establish guidelines and then policies";
- "education of patients, families, and physicians for undermedicating";
- "continue work of symposium and state experts to develop a comprehensive pain program";

· "maybe create a Center of Excellence"; and

- "right now [we] send out notices to all physicians the patient is getting prescriptions from, but feel a lot more education of physicians needs to be undertaken. Next step might be to start denying claims."
- 74. Specific responses include the following:
- "wrote letters to providers alerting them to the problem—response was positive";
- "reaching out to MDs, limiting members to one prescribing physician and one pharmacy; high users identified";
- · "track records and abuses; look for trends";
- "developed policies; quality management looked for stricter flags to alert us to developing problem";
- · "developed a policy that patient receive a certified letter

telling them how many narcotics the Plan will cover and that is all they receive";

- "addiction was included in Symposium discussion about the pain continuum";
- · "developed pain management program"; and
- "talked to pharmacy about monitoring prescribing patterns and notifying medical director; physician education."

75. Blue Cross Blue Shield of Massachusetts, Medical Policy (Boston: Blue Cross Blue Shield of Massachusetts, June 1996, reviewed Feb. 1998).

76. Id. To explain the difference between coverage for Medicare beneficiaries and non-Medicare beneficiaries, the policy states that "Medicare policy is developed separately from BCBSMA [Blue Cross Blue Shield of Massachusetts] policy. While BCBSMA policy is based upon scientific evidence, Medicare policy incorporates scientific evidence with local expert opinion, and governmental regulations from HCFA [Health Care Financing Administration] ... and the U.S. Congress." Id. According to a medical director at BCBSMA, local expert opinions are also used to develop medical policy for non-Medicare policies.

77. Id.

78. Blue Cross Blue Shield of Massachusetts, *Medical Policy* (Boston: Blue Cross Blue Shield of Massachusetts, Dec. 1996, reviewed Jan. 1998).

79. Specific responses include:

- · "epidurals except for cancer";
- · "physical therapy";
- "just about any alternative therapy";
- · "comprehensive pain management programs";
- "cupping; other exotic techniques; home electric stimulators like PENS [percutaneous electrical nerve stimulation]";
- · "questionable pain management centers";
- · "electrical stimuli to spinal cord";
- · "Aim 100 nerve stimulator";
- "implanted nerve stimulators—policy is being reviewed";
- · "hypnosis as anesthesia";
- "Porlou—an injection into spine; purposely irritating substance to create inflammation and formation of scar tissue which is supposed to relieve back pain";
- "magnet therapy devices";
- "trigger point therapy";
- · "neuro-musculoskeletal H-waves";
- · "chiropracty";
- · "hypnosis; massage therapy";
- · "chronic methadone usage";
- · "alternative medicine";
- · "hypnosis"; and
- · "none of the holistic alternatives".
- 80. For example, respondents stated:
- "cover for a few ICD9 codes, otherwise lack of scientific validation, policy decision in past";
- "policy developed after review of literature established a lack of scientific validation of effectiveness";
- "BCBS Association says experimental";
- "a medical review committee looked at the scientific efficacy and found that behavioral interventions failed the test";
- "no good evidence that biofeedback helps with pain";
 and
- "following recommendation of technology evaluation center of BCBS that does not recommend coverage."
- 81. Other responses include:
- "stress management is not a health or medical intervention"; and

· "do not have a credentialed network of providers."

82. Other similar responses include:

- "acupuncture is considered investigational, it's a standing policy; contracts written to not open up questionable practices":
- "never covered; no sufficient medical literature to show effectiveness";

· "unproved technology"; and

· "no scientific evidence of benefit."

83. For example:

• "given NIH [National Institutes of Health] report, will be re-reviewing acupuncture"; and

· "not requested; no proof of effectiveness; changing be-

cause of NIH study."

84. One respondent said that state law mandated coverage of pain management for a minimum of sixty days and because TENS units were not effective for chronic pain, the plan had made a decision not to cover it. A later conversation with this respondent indicated that the state law he was referring to did not explicitly mention pain management but had been interpreted to include pain management. More recently, he said, the plan's interpretation of the law had been revised.

85. Rutherford, supra note 38, at 16707.

86. "The Pain Coverage Conundrum," supra note 35.

87. Evidence indicates that persons with more severe and chronic pain use health care at rates substantially above population means. See M. Von Korff et al., "Chronic Pain and Use of Ambulatory Health Care," *Psychosomatic Medicine*, 53 (1991): 61–79.

88. For example, in Maryland, as of June 1998, only seventeen physicians were certified by the American Board of Hospice and Palliative Medicine.

89. See WHO, Cancer Pain Relief and Palliative Care

(Geneva: WHO Technical Report Series 804, 1990).

90. See M.B. Max et al., Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain (Skokie: American Pain

Society, 3rd ed. 1992).

91. See Agency for Health Care Policy and Research, Clinical Practice Guideline Number 1: Management of Acute Pain (Rockville: Department of Health and Human Services, AHCPR Pub. No. 92-0022, 1992); Agency for Health Care Policy and Research, Clinical Practice Guideline Number 9: Management of Cancer Pain (Rockville: Department of Health and Human Services, AHCPR Pub. No. 94-0592, 1994); and Agency for Health Care Policy and Research, Clinical Practice Guideline Number 14: Management of Acute Low Back Pain (Rockville: Department of Health and Human Services, AHCPR Pub. No. 95-00642, 1994).

92. See "Pain Control Innovations," supra note 33.

93. See R.N. Jamison, "Comprehensive Pretreatment and Outcome Assessment for Chronic Opioid Therapy in Nonmalignant Pain," Journal of Pain and Symptom Management, 11 (1996): at 231 (stating that guidelines currently exist on the use of opioid therapy for chronic nonmalignant pain but that "no empirical studies have been conducted to substantiate these guidelines"); and D. Justins, Book Review, "Pain Medicine: A Comprehensive Review," Lancet, 347 (1996): 814 (asserting that there is a lack of "reports of proper randomized controlled trials of a great many of the treatments currently used for chronic pain").

94. See AGS Panel on Chronic Pain in Older Persons, *supra* note 5. These include such interventions as educational programs, cognitive-behavioral therapy, exercise programs, acupuncture, TENS, chiropracty, and heat, cold massage, relaxation and

distraction techniques.

95. Id.

96. Id.

97. See also Technology Evaluation Center, Blue Cross Blue Shield Association, *Biofeedback* (Chicago: TEC Assessment Program, Vol. 10, No. 25, Jan. 1996). In its official statement, the panel defines "biofeedback" as "a procedure intended to train a patient to control a physiological process (e.g., blood pressure)." The Technology Evaluation Center's (TEC) criteria for review include the following:

1) The technology must have final approval from the ap-

propriate government regulatory bodies;

2) The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;

3) The technology must improve the net health outcome;4) The technology must be as beneficial as any established

alternatives; and

5) The improvement must be attainable outside the investigational settings.

See id. at 1-2.

98. Id.

99. Technology Evaluation Center, Blue Cross Blue Shield Association, *Acupuncture in the Treatment of Pain* (Chicago: TEC Assessment Program, Vol. 11, No. 22, Jan. 1977). The statement goes on to say that

The studies in which needles are inserted in places other than those prescribed by the meridian maps from Chinese medicine are the most consistent. Among these studies, there is little evidence that acupuncture, as it is traditionally prac-

ticed, is effective as a treatment of pain....

The remaining two control conditions, low- or noneedle insertion and low stimulation have findings that are more provocative. Five of the 9 studies that used low-or no-needle insertion controls reported positive findings. The only study using a low stimulation control reported positive findings even on a measure of catecholamine activity. There are at least two possible explanations for these findings. It is possible that certain components of acupuncture, in particular, the needle insertion to a specified depth followed by stimulation, are effective, but the location does not have to follow the meridian maps of energy flow from Chinese medicine. Alternatively, it is possible that subjects in pain trials are aware of whether or not a needle is inserted and, thus, needle insertion is a key component to unbinding the subject and stimulating effects based on expectancy or bias.

Those well-controlled trials that report efficacy were generally smaller than the studies reporting negative findings. None of the 4 studies with a study population of greater than 100 reported positive findings. The largest sample for a study with positive findings was 48. The fact that smaller studies are more likely to provide positive support for the efficacy of acupuncture, while larger studies do not, suggests that possible influences of weaknesses in the study design or random differences that do not hold up with more

data.

Id. at 1–2.
 100. See National Institutes of Health Consensus Development
 Statement, Acupuncture (Nov. 3–5, 1997) http://www.consensus.nih.gov (visited 14 Dec. 1998).

101. Technology Evaluation Center, Blue Cross Blue Shield Association, *Transcutaneous or Percutaneous Electrical Nerve Stimulation in the Treatment of Chronic and Postoperative Pain* (Chicago: TEC Assessment Program, Vol. 11, No. 21, Jan. 1997). The TEC Panel justified its conclusion as follows:

There is a large body of research on the efficacy of TENS

for a variety of pain conditions, but relatively few controlled studies. Four published studies compared TENS with a placebo (e.g., sham TENS), a known active intervention (e.g., exercise, splint), or no treatment in patients who had chronic pain. Eleven studies of similar design assessed the efficacy of TENS in the treatment of postoperative pain. Although there is a large body of uncontrolled research that describes favorable results using TENS for pain management, the majority of controlled studies reported that, compared to placebo, known active intervention, or no treatment, TENS had no significant benefit. With the exception of two studies that suggest that TENS might reduce postoperative pain through a placebo effect, each of the few studies that contradict this basic conclusion had either mixed results or important methodological shortcomings. No controlled study provided consistent findings across multiple outcomes that TENS reduced pain experiences compared to appropriate control conditions.

Id. at 1. However, the assessment further stated that, as it was going to press, "a major research project on TENS was being planned. The proposed project is to be conducted by the Health Outcomes Institute, with funding from EMPI, a manufacturer of TENS devices. Two phases are planned: an outcomes study using data from several Blue Cross and Blue Shield Plans and a prospective evaluation of efficacy." Id.

102. According to one report, "[t]he advantage of the pumps-which can cost \$25,000 to implant in the patient's abdomen-is that only 1/300th of the amount of morphine usually given orally is required when it's delivered directly into the spine." "Pain Control Innovations," supra note 33.

103. Id.

104. Rutherford, supra note 38, at 16705.

105. The American Geriatrics Society Panel on Chronic Pain in Older Persons made this point in the introduction to its recent clinical practice guideline on the management of chronic pain in older persons. The panel said, "Pain is an unpleasant sensory and emotional experience.... Unfortunately, there are no objective biological markers of pain. Therefore, the most accurate evidence of pain and its intensity is based on the patient's description and self-report." AGS Panel on Chronic Pain in Older Persons, supra note 5, at 635.

106. Rutherford, supra note 38, at 16701.

107. Ferrell and Griffith, supra note 13, at 222.

108. See V. Mor, "Hospice Fraud Alert," Brown University Long-Term Care Quality Letter, 8 (Apr. 15, 1996): 4.

109. Id. The Office of Inspector General's focus on hospice was motivated by rapid growth in the size of the Medicare budget going to hospice providers and evidence of abusive billing practices. See also J.P. Shapiro, "Death Be Not Swift Enough: Fraud Fighters Begin to Probe the Expense of Hospice Care." U.S. News & World Report, Mar. 24, 1997, at 34; and D. Franz, "Hospice Boom Is Giving Rise to New Fraud," New York Times, May 10, 1998, at 1. Supporters of hospice have argued that it is difficult to predict the life expectancy of many patients and it is unfair to penalize hospices for predicting wrong. Moreover, this type of scrutiny may discourage physicians from earlier referrals to hospices so that patients may benefit in their last months from the services hospices have to offer.

110. Portenoy, supra note 5, at 296.

111. Id.

113. Blue Cross & Blue Shield of Massachusetts, Medical

Policy (Boston: Blue Cross & Blue Shield of Massachusetts, Jan. 1997, reviewed Feb. 1998).

114. Letter from Carla Alexander, M.D., Assistant Professor of Medicine and Director of Palliative Care, University of Maryland Medical Systems, to Diane E. Hoffmann, J.D., M.S., Professor of Law, University of Maryland School of Law (July 24, 1998) (on file with author).

115. Id.

116. See Justins, supra note 93. In the year 2000, the American Board of Medical Specialties will also allow physicians board certified in psychiatry, neurology, and physical medicine and rehabilitation to subspecialize in pain management by meeting the requirements for the subspecialty established for anesthesiologists. However, the subspecialty is in pain management, not pain medicine, a significant difference according to pain treat-

ment experts.

117. Id. For example, in 1997, California went to court to ban doctors from advertising certification by the American Academy of Pain Management (AAPM). AAPM was formed in 1988 "to issue credentials to multidisciplinary practitioners, including physicians, nurses, counselors, priests and social workers." D. Walsh, "Judge Allows State Limits on Doctor Ads," Sacramento Bee, May 24, 1997, at B4. The ban applied only to physicians. The California Medical Board had previously denied AAPM's application for recognition on the grounds that, among other things: "the academy gives a two-hour test consisting of 100 multiple-choice questions, while the state wants the 16 hours of testing required by the national specialties board" and "of the 5,000 practitioners certified by the academy as of April 1996, only approximately 1,000 had taken the test." The judge who heard the case initially granted AAPM's request for a temporary restraining order (TRO) preventing the state from implementing the ban, but subsequently reversed his decision and refused to issue a preliminary injunction and dissolved the TRO. The decision was based in part on a 1990 statute that "sought to remedy situations in which 'a physician who takes a weekend course can advertise [him or herself] as board certified in that specialty." Id.

118. A. Dunkin, "When Pain Itself is the Disease," Business

Week, Jan. 27, 1992, at 104.

119. See id. In 1992, there were just over 100 such certified facilities. Today, according to the Commission on Accreditation of Rehabilitation Facilities, there are just over 200. Id. 120. Id. In 1992, there were over 1,000 such facilities. Id.

121. N. Hendler and S. Talo, "Role of the Pain Clinic," in K.M. Foley and R.M. Payne, eds., Current Therapy of Pain

(Toronto: B.C. Decker, 1989): at 23.

122. See "Pain Clinic Personalities," Fibromyalgia Network: A Newsletter for People with Fibromyalgia Syndrome/Chronic Fatigue Syndrome, Jan. (1998): at 8.

123. Id. (based on an interview with Dr. Alan Spanos, a pain

specialist in Chapel Hill, North Carolina). 124. See Bernabel, Gatsonis, and Mor, supra note 4.

125. See, for example, H.D. Hadjistavropoulos, M. Ross, and C.L. von Baeyer, "Are Physicians' Ratings of Pain Affected by Patients' Physical Attractiveness?," Social Science and Medicine, 31 (1990): 69-72. A significant body of information indicates that both provider and patient sensitivity to pain may be a result of cultural bias. See, for example, B.R. Ferrell, "When Culture Clashes with Pain Control," Nursing, 25 (1995): 90. These biases can enter into both treatment and coverage decisions.

126. Randal, supra note 49.

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