

Public Financing of Pain Management: Leaky Umbrellas and Ragged Safety Nets

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The United States, unlike all other industrialized nations, does not have a comprehensive public system for financing health care. Nevertheless, the magnitude of America's public health care financing effort is remarkable. Of the one trillion dollars the United States spent on health care in 1996, almost half, \$483.1 billion, was spent by public programs.¹ In 1995, Medicare—our social insurance program for persons over sixty-five and the long-term disabled—covered 37.5 million Americans; Medicaid—our program for indigent elderly and disabled persons and indigent children and their families—covered 36.3 million.² In 1996, Medicare and Medicaid spent \$203.1 and \$147.7 billion, respectively.³ The payment policies of these massive public health care programs have a profound effect on the provision of health care.

Many of the recipients of Medicare and Medicaid suffer pain. In 1994, 376,200 Americans over age sixty-five died of cancer.⁴ Virtually all of these would have been Medicare recipients, and as many as 70 percent of them died in unrelieved pain.⁵ Nearly four million Americans over sixty-five endured the pain of inpatient surgery in 1995, again nearly all of whom were Medicare recipients.⁶ The Medicare hospice benefit provided palliative care to 266,000 suffering persons in 1994.⁷ In some states, Medicaid covers almost half of all persons with acquired immune deficiency syndrome (AIDS)—another very painful disease—and Medicaid's share of AIDS-related expenditures is increasing.⁸ Medicare and Medicaid, therefore, play a critical role in paying for pain management in the United States.

Although Medicare and Medicaid pay for a great deal of pain management, they often stand in the way of, or at

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

Second, even persons who are covered by Medicare and Medicaid face significant gaps in benefits. Medicare, for example, does not cover oral prescription pain medications for most noninstitutionalized beneficiaries. Though most states voluntarily cover prescription pain medications through their Medicaid programs, many do not cover over-the-counter (OTC) pain medications, and some programs impose significant restrictions on drug coverage.

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

Fourth, in recent years, aggressive utilization review and fraud and abuse surveillance and enforcement have, some believe, deterred the adequate provision of pain management services. In many states, for example, Medicaid prescribing is subject to both prospective and retrospective utilization review. Under federal law, state Medicaid drug utilization review (DUR) programs are responsible for assuring that drugs are not overused, abused, or misused.⁹

Though some state DUR programs have taken the lead in trying to educate physicians and pharmacists in pain management, inquiries sent by DUR programs to physicians questioning pain medication prescribing practices may deter physicians from prescribing adequately high dosages of medication in some situations. Highly publicized fraud and abuse prosecutions of health care professionals who prescribe controlled substances may also be a deterrent. As a society, we are uncomfortable with controlled substances. Our programs to control their use can, however, limit legitimate (as well as illegitimate) uses.

These gaps and deficiencies in public program coverage of pain management services should concern us for several reasons. First, the alleviation of pain is one of the most fundamental obligations of health care professionals. The ethical codes of both the medical and nursing professions recognize an obligation to "relieve suffering."¹⁰ Indeed, the Agency for Health Care Policy and Research (AHCPR) has opined that "The ethical obligation to manage pain and relieve the patient's suffering is at the core of a health care professional's commitment."¹¹ The obligations of beneficence and respect demand that health care professionals provide adequate treatment for pain.¹² Health care financing programs that pay for care for a wide variety of medical conditions but discourage adequate pain management threaten the ethical practice of health professionals.

Second, adequate pain management is necessary as an alternative to assisted suicide. Congress took a strong position opposing assisted suicide in the Assisted Suicide Funding Restriction Act of 1997.¹³ Research has consistently shown, however, that uncontrolled pain is an important contributing factor in suicide by cancer and AIDS patients, and one of the most common reasons for requests for euthanasia or physician-assisted suicide (PAS).¹⁴ An effective program for limiting euthanasia and PAS must provide for adequate pain management.

Third, funding of a full range of pain management modalities is cost effective. As is explored below, Medicare tends to cover expensive modalities for pain management, such as internal infusion pumps, but not less expensive modalities, such as oral medication. A patient may be covered for the \$4,000 cost of morphine delivered through an infusion pump, but not for the \$100 cost of an oral morphine solution.¹⁵ Medicaid programs cover prescription pain medications, but usually do not cover less expensive OTC preparations.

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

Medicare

Medicare is our nation's largest health care financing program, both in terms of expenditures and number of recipients. Medicare covers virtually all persons in the United States who are over sixty-five, as well as persons who have been disabled for more than two years and persons with end-stage renal disease. Medicare is in fact not one program, but two, or perhaps three, programs. First, Medicare Part A, the Hospital Insurance Program, pays for care received in hospitals or other health care institutions. Second, Part B, the Supplemental Medical Benefits Program, covers services provided by physicians and other health care professionals, as well as some medical devices and supplies. Third, the Balanced Budget Bill of 1997 created Part C, the Medicare+Choice managed care program, which essentially covers the benefits provided by Parts A and B in managed care settings.

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

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

The greatest limitation of Medicare financing of pain management is that it does not cover oral medications received in outpatient settings, including pain medication.¹⁶ This means that Medicare beneficiaries must either pay for their own pain medication or receive it through a more expensive modality or in a more expensive setting.

Another overarching problem with Medicare is the limitations of its payment for physicians' services for pain management. Medicare pays for physicians' services based on its resource-based relative value scale (RBRVS).¹⁷ A physician cannot bill for a service unless that service corresponds to a Current Procedure Terminology (CPT) code recognized in RBRVS. If a physician's service does not involve a procedure otherwise assigned a CPT code, the physician must use the CPT evaluation and management (E and M) or consultation codes to bill Medicare. The level at which physicians can bill for E and M and consultation CPT codes, however, is closely related to the amount of time they spend face-to-face with patients in outpatient settings or at the bedside or on the floor in inpatient settings.¹⁸ CPT Codes 99358 and 99359, which cover prolonged service without patient contact, are not covered by

Medicare. The only opportunity physicians have for billing for service time not involving face-to-face patient contact is the care management codes for hospice and home health patients, CPT Codes 99374 through 99378. These codes can only be billed once a month, however, and only then for management of hospice or home health care.

These coding rules create particular problems for physicians who practice pain management. Pain management tends to be heavily cognitive. For every hour that a physician spends face-to-face with a patient, he/she may spend several hours reviewing records of previous treatment and several more hours devising and writing a care plan report.¹⁹ Medicare does not adequately compensate doctors for this preservice and postservice time, and thus deters adequate treatment.²⁰

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

Injections

Medicare Part B covers drugs administered by a physician incident to the physician's professional services.²¹ The drugs must be of a type that cannot be self-administered and that is commonly furnished in a physician's office or clinic without charge or included in a physician's bill.²² Ordinarily, this means that the drug must be injected. Injected medication is not covered, however, if standard medical practice indicates oral administration.²³

The Medicare statute seems intended to discourage doctors from providing medication injections. Injections cannot be billed separately to Medicare unless no other physician fee schedule service is billed at the same time.²⁴ Moreover, payment for postoperative pain control medication may be included in the global fee paid for the surgery and thus may not be separately billable.²⁵ A doctor also can only be reimbursed for 95 percent of the wholesale price of a drug he/she provides.²⁶ For some pain patients, however, injections that their doctors are willing to provide are the only available relief that will be covered by Medicare.

Infusion pumps and electrical stimulation

Medicare covers some of the technologies used for pain management. Medicare covers external and internal infusion pumps used to deliver pain medication, and the pain medication provided through them.²⁷ Infusion pumps are covered under Medicare's Part B durable medical equipment (DME) benefit.²⁸ External infusion pumps are only

covered by the DME benefit under limited circumstances, but these include morphine infusion via an external infusion pump when necessitated by intractable pain caused by cancer, both in inpatient and in outpatient settings, including hospice.²⁹ The morphine necessary for the use of the infusion pump is also covered if reasonable and necessary.³⁰

Medicare also covers implantable infusion pumps to administer opioids intrathecally or epidurally for treating "severe chronic intractable pain of malignant or nonmalignant origin."³¹ To be eligible, patients (1) must be expected to live for at least three months; (2) must have proven unresponsive to less invasive medical therapy, such as systemic opioids, and (3) must have completed a preliminary trial of intraspinal opioid drug administration with acceptable pain relief, acceptable side-effects, and patient acceptance.³² Again, necessary drugs for infusion are also covered.³³ Infusion therapy is normally managed by a home health provider.³⁴ In cases where infusion pumps are covered, therefore, but less expensive and invasive therapies may also be effective, Medicare incurs additional expense because it must pay both for the pump and for the professional (usually home health care) staff to maintain it.

Medicare will cover electrical nerve stimulation under some circumstances.³⁵ Transcutaneous electrical nerve stimulators (TENS) units are covered under Medicare for acute postoperative pain as hospital supplies or supplies incident to a physician's services.³⁶ They are also covered for chronic intractable pain under the DME benefit.³⁷ Implanted electrical nerve stimulators are covered, but only as a last resort, after other modalities have failed and the patient has been evaluated by a multidisciplinary team.³⁸ Medicare presumes that patients can be trained to use stimulators, hence it does not cover electrical nerve stimulation provided by physicians or physical therapists in an office or clinic on an ongoing basis.³⁹

Hospital services

The hospital benefit is arguably the most basic Medicare benefit. Part A covers inpatient hospital care for up to ninety days for any "spell of illness," plus up to sixty "lifetime reserve" days available on a one-time basis.⁴⁰ Because about one-quarter of all persons between ages sixty-five and seventy-four and almost one-half of all persons over seventy-five are hospitalized each year,⁴¹ and about one-half of all deaths occur in hospital, a great deal of pain is treated under the Medicare hospital benefit.

Medicare hospital coverage includes the provision of drugs and biologicals.⁴² Under the Medicare regulations, drugs are only covered if (1) they represent a cost to the hospital, (2) they are ordinarily furnished for the care of inpatients, and (3) they are furnished to an inpatient for care within the hospital.⁴³

A hospital stay solely for the purpose of administering

a drug is not covered by Medicare.⁴⁴ Medicare will, however, cover inpatient hospitalization for pain rehabilitation where hospitalization is reasonable and necessary, the patient's condition is attributable to a physical cause, usual methods of treatment have not been successful in alleviating pain, and the pain has resulted in a significant loss of ability to function independently.⁴⁵ Medicare also covers outpatient treatment necessary for pain. The new hospital outpatient prospective payment scheme will have a special payment category for nerve blocks.

Medicare-participating hospitals must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), unless they are independently certified for Medicare participation.⁴⁶ JCAHO requires that hospitals address care at the end of life, including "managing pain aggressively and effectively."⁴⁷ Most Medicare participating hospitals should be addressing pain management under this requirement.

Though the Medicare hospital benefit facilitates the provision of pain relief services to Medicare beneficiaries, it has serious drawbacks. In part because of diagnostic-related group (DRG) reimbursement, hospital lengths of stay are very short. For instance, the average length of stay in 1995 for persons with malignant neoplasms, age sixty-five to seventy-four, was 7.3 days.⁴⁸ Issues of pain can only be addressed in the most transitory way during these short stays. Hospitals that keep patients for longer periods of time, however, begin to lose money dramatically. Medicare has introduced a new ICD-9 Code for palliative care, but, at this point, is only using it to test the feasibility of a special DRG reimbursement category for palliative care.⁴⁹ Until hospitals are compensated adequately for the costs of palliative care, they are unlikely to focus on pain management.

SNF services

Medicare Part A covers pain medication through the SNF benefit. Medicare covers up to 100 days per spell of illness of posthospital extended care for beneficiaries in a SNF.⁵⁰ Medicare covers the cost of drugs and biologicals provided to Medicare beneficiaries resident within the facility.⁵¹

The Medicare SNF benefit, again, plays a limited role in providing pain relief. The SNF benefit is intended as an extended care benefit, supplementing hospital care for acute episodes. It is ordinarily available only if the resident has been hospitalized for at least three days within the thirty days preceding admission.⁵² The average length of SNF Medicare coverage per admission is quite short, 27.4 days.⁵³

The articulated goal of SNF services under Medicare is to "attain or maintain the highest practicable physical, mental, and psychosocial well-being for each resident," and each resident must have a plan of care to this end.⁵⁴ Although Medicare criteria governing the need for skilled services recognize that not every SNF resident has "resto-

ration potential"—for example, that "terminal cancer patients may need some ... skilled services"⁵⁵—the orientation of the SNF benefit, the SNF participation requirements, and the SNF survey process are geared toward restorative rather than palliative care. This regulatory neglect of pain within SNFs is, not surprisingly, reflected in poor performance of nursing facilities in pain management.⁵⁶

Regulations governing the SNF survey process in particular pay little attention to pain management.⁵⁷ The Health Care Financing Administration's (HCFA) survey procedure guidelines, for example, lists sixteen issues on which surveyors are supposed to focus in assessing the extent to which the physical, emotional, psychosocial, or spiritual needs of residents are being met, but pain management is not on that list.⁵⁸ Pain management is not even listed among the 141 issues of concern that a surveyor can check on the observation/interview worksheet provided on HCFA's SNF inspection form.⁵⁹ Nor is pain mentioned in HCFA's care guidelines for SNF inspections, which come to 136 pages in the *Code of Federal Regulations*—not even under the section dealing with observation of terminally ill residents.⁶⁰

Pain is beginning to appear in subregulatory guidelines and manual provisions related to the SNF survey process and certification. One of the items that facilities must report on a HCFA resident census form is the number of patients in pain management programs.⁶¹ Surveyors are supposed to identify hospice patients and interview them in the survey process.⁶² Pain is also addressed incidentally in the process of reviewing other care issues.⁶³ Though HCFA is interested in addressing pain more expressly in its guidelines and protocols, pain is still largely ignored in the survey process.

Pain is noted in the SNF patient assessment process and in the most recent iteration of the minimum data set (MDS). MDS is a computer-reported resident assessment tool, which since 1995 has tracked, among other factors, pain symptoms, frequency, and site. Final rules for resident assessment in long-term care facilities, published on December 23, 1997, in the *Federal Register*, require resident assessment based on MDS.⁶⁴ Though the regulation does not list pain as one of the eighteen items that states must consider in resident assessment instruments or as one of the eighteen items that states must address through resident assessment protocols (RAPs), pain is discussed in the preamble of the regulation. Specifically, the preamble, in the context of discussing comments on the proposed regulations, notes the pain items in MDS and suggests that these items might be considered in evaluating special populations.⁶⁵

Most important, the preamble seems to acknowledge the inappropriateness of the rehabilitation-oriented "aggressive work-up to determine causal factors" that contribute to lack of functioning (which is normally required for SNF residents) for SNF hospice patients receiving palliative care.⁶⁶ The preamble encourages states to focus on

RAPs appropriate for the special needs of hospice patients, that is, to focus on increasing residents' comfort level and on helping patients to die with dignity.⁶⁷ It also recognizes that more work needs to be done to devise appropriate regulatory tools for addressing the needs of hospice patients in SNFs.⁶⁸ In the end, however, HCFA's regulatory scheme for nursing facilities under Medicare and Medicaid still largely ignores pain management. Nursing facilities, which are largely financed by Medicaid and to an increasing degree by Medicare, have, therefore, faced few regulatory incentives to improve pain management, or even to attend to pain. This may be changing, but further change needs to be encouraged.

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

Hospice benefit services

The Medicare hospice benefit is the primary Medicare pain management benefit, at least for the terminally ill. The benefit was created in 1983, in part to save money for the Medicare program by moving beneficiaries requiring end-of-life care out of more expensive treatment settings.⁶⁹ It has been estimated that about 77 percent of hospice patients are covered by Medicare nationally.⁷⁰ Though the Medicare hospice benefit has made hospice services available to many who might not otherwise have obtained them, it has also made hospices heavily dependent on Medicare and subservient to Medicare requirements.

Because the hospice benefit was designed to reduce costs, eligibility has always been strictly limited, specifically to Medicare beneficiaries who are "terminally ill."⁷¹ Medicare considers a beneficiary to be terminally ill if the beneficiary's attending physician certifies that the beneficiary has a life expectancy of six months or less.⁷² A beneficiary who elects hospice care must waive his/her right to Medicare coverage of any other treatment of the terminal condition (other than physician's services), though the beneficiary may subsequently revoke the waiver and leave hospice care.⁷³ Hospices are paid on a per diem rate, based on four different payment levels, subject to a cap in all cases.⁷⁴ Though the Medicare hospice and SNF benefits are mutually exclusive, hospices do provide services to dually eligible (Medicare and Medicaid) beneficiaries receiving Medicaid-funded nursing facility care.⁷⁵

For a number of years after its introduction, the Medi-

care hospice benefit was fiscally insignificant. In 1986, the program paid out \$77 million.⁷⁶ In recent years, however, the program has grown rapidly. During 1995, program expenditures reached \$1.85 billion, a 36 percent increase from the preceding year.⁷⁷ The program has begun to attract more attention from government, including attention from the Department of Health and Human Services Office of Inspector General (OIG), which polices fraud and abuse.⁷⁸

The hospice program was significantly revised by the Balanced Budget Act of 1997 (BBA),⁷⁹ which addressed many problems that affected the hospice program, but difficulties remain. Perhaps the most important is the short and rapidly declining length of hospice stays. Although the hospice benefit is available to persons in their last six months of life, most patients remain in hospices for a much shorter time. A study using 1990 Medicare claims data found that the median hospice patient survived thirty-six days after enrollment in a hospice.⁸⁰ The study found that 28.5 percent of patients died within two weeks after entering hospice.⁸¹ A more recent, as yet unpublished, study has found a decline in median length of stay, using 1995 data, to twenty-nine days.⁸² One hospice director asserted that, in the last quarter of 1996, the median length of stay had declined to twenty-one days.⁸³

A number of factors may contribute to the declining length of stay.⁸⁴ One, as discussed below, is the increased pressure being placed on doctors both through regulation and enforcement to refrain from referring patients to hospices until death is almost certain. A second is Medicare DRG hospital reimbursement, which both discourages hospitals from admitting patients until their condition is grave and encourages hospitals to discharge patients as rapidly as possible, making it tempting for discharge planners to make a quick home health referral rather than a more time-consuming hospice referral.⁸⁵ A third might be changing trajectories of dying, brought on by new treatments that often permit patients to remain in the community with symptoms controlled for a much longer time than previously, followed by a precipitous death when the treatments finally fail.⁸⁶ A final reason, also discussed below, may be the reluctance of other Medicare providers, such as SNFs or home health agencies, to refer patients to hospices until the patient is in the last stages of dying because of the exclusivity of the hospice benefit.

Whatever the cause of the decline, its implications for hospices are very serious. Hospices are paid on a per diem basis, but most of their expenses are incurred during the first week of care—when the plan of care is being established and resources are marshalled for the patient—and the final week—when death is being managed.⁸⁷ Hospices can survive because their income may be greater than their costs in the intervening weeks. If there are no intervening weeks, however, hospices face serious financial problems.

As noted above, one reason why patients come to hospices late in the dying process is the Medicare requirement that a physician must certify that a patient has only six months to live before the patient can receive the hospice benefit. The "death sentence" requirement imposes an immediate barrier to hospice entry because it requires that before the patient can receive hospice benefits—and the pain management hospice affords—(1) the patient must come to terms with his/her own mortality and (2) the treating doctor must essentially admit defeat in curing the patient.⁸⁸ The Medicare requirement that patients waive curative treatment for their terminal condition reinforces the relinquishment of hope that the certification requirement documents.

As hospices increasingly move beyond simply caring for cancer patients, and take on patients with other diagnoses, and as new treatments for cancer emerge, prediction of death trajectories becomes more difficult.⁸⁹ A particular problem arises when physician certifications for patients who did not die as early as predicted are reviewed retroactively by investigative agencies.⁹⁰ Prognoses are always easier to make retrospectively. Reviews are especially problematic for noncancer hospice patients, where certification standards have only recently been clarified.⁹¹ When earlier physician certifications are reviewed under recently promulgated standards, documentation deficiencies may be found which could be interpreted by a reviewer as demonstrating an inappropriate referral.⁹² With the encouragement of OIG, fiscal intermediaries have become more aggressive in retrospectively reviewing hospice certifications.⁹³ This review may be deterring doctors from making appropriate referrals to hospices, because no doctor wants trouble with OIG.

Hospices are also facing increasing problems in functioning within Medicare payment rates. Hospices are responsible for all costs related to terminal illnesses and must cover them within their Medicare per diem rate. It is not always clear, however, whether costs are related to a terminal illness. Hospices are clearly responsible for the costs of opioids required by a dually eligible Medicaid patient for pain management; but Medicaid should have to pay independently for that patient's insulin if the patient is a diabetic, because the diabetes is unrelated to the patient's terminal condition and insulin is not palliative care.⁹⁴ Some Medicaid DUR programs, however, have reportedly taken the position that hospices must pay for all medications hospice patients receive.⁹⁵ Hospices are also arguably responsible for the costs of chemotherapy for cancer or immunosuppressive medication for AIDS therapy, which relieve the pain and other symptoms caused by incurable conditions. Antiretroviral therapy medication for AIDS therapy can cost more than \$10,000 a year, however.⁹⁶ The ever-increasing costs of these therapies severely taxes the ability of hospices to deliver care within the per diem rates granted by Medicare.

Another area of concern is coordination between hospice and other Medicare or Medicaid providers. Though a patient receiving the Medicare hospice benefit is not eligible for the Medicare SNF benefit, dually eligible Medicare and Medicaid recipients may receive the Medicare hospice benefit and Medicaid payment for their nursing facility care.⁹⁷ The state Medicaid agency must pay the hospice at least 95 percent of the rate the agency would pay for nursing facility services, and the hospice in turn must contract to pay the nursing facility for board and care services.⁹⁸ Many hospices, however, pay nursing facilities at least 100 percent of the Medicaid rate the facility would otherwise get from the state, with the difference coming from the hospice.⁹⁹ Over 17 percent of Medicare hospice patients lived in a SNF in 1995, and many of them were dually eligible.¹⁰⁰

The hospice/nursing facility benefit has met with increasing suspicion in recent years. In 1997 and 1998, OIG issued two reports examining the hospice/nursing facility benefit and a fraud alert, suggesting that the benefit is resulting in excess payments, duplicative coverage of services, underservice by each provider, and inappropriate referrals.¹⁰¹ Further clarification of responsibilities, at the very least, seems necessary.

Coordination between Medicare managed care and hospices is problematic as well. When a Medicare beneficiary enrolled in managed care elects hospice, the beneficiary's managed care enrollment ceases. The attending physician with the MCO can still treat the patient and the MCO can provide services unrelated to the terminal condition; but the MCO must now bill Medicare on a fee-for-service (FFS) basis.¹⁰² Although many MCOs are quite willing to refer to hospices dying patients, whose care is usually very expensive, MCOs in some parts of the United States where Medicare rates are very favorable, as well as MCOs that do not understand the hospice benefit, are reluctant to refer patients.¹⁰³

Hospices must meet Medicare certification requirements, and must be audited by the states to assure compliance with these requirements. States also audit hospices to assure compliance with licensure requirements.¹⁰⁴ Few states have sufficient hospices, however, to maintain a substantial hospice certification or licensure program. Many rely on nursing facility surveyors.¹⁰⁵ These surveyors may not, however, understand sufficiently well the philosophy and practices of hospices, or even the nature of prescribing medications in hospices. Not only can this result in misunderstandings in the survey process, but it also deprives hospices of the guidance that knowledgeable surveyors might bring to them.

Medicare managed care

Over 18 percent of Medicare beneficiaries are currently

enrolled in Medicare managed care.¹⁰⁶ The BBA created Medicare Part C, which is intended to increase dramatically enrollment in Medicare managed care. Under both the traditional Medicare risk-sharing health maintenance organizations (HMOs) and competitive medical plan benefit, and the new Part C benefit, contracting MCOs are responsible for providing their members with services beyond those that Medicare covers on the FFS side, to the extent that the payment the organization receives from Medicare exceeds the cost of Medicare-covered services.¹⁰⁷ This provision requires that economies achieved by Medicare MCOs be passed on to beneficiaries. Among the additional services that Medicare MCOs may offer are coverage of prescription drugs and biologicals.¹⁰⁸

Coverage of prescription drugs (including oral pain medication) is one of the most popular benefits offered by Medicare managed care. In December 1998, 226 of the 338 risk-based Medicare plans reported that their benefits covered outpatient drugs.¹⁰⁹ If Medicare managed care expands, therefore, it is likely that more Medicare beneficiaries will have their pain medication covered. Although this is generally a positive factor, grounds for concern arise here.

First, MCOs generally have been more aggressive in managing pharmaceutical benefits than public programs have been.¹¹⁰ Insofar as MCOs have experience with pain management, it might well be with a younger population and with musculoskeletal pain, where pain management approaches are quite different. Some education and adjustment, and perhaps ultimately regulation, may be necessary to assure adequate protection for the elderly, as the current HCFA regulations leave MCOs considerable discretion to "determine the level and scope" of this benefit.¹¹¹ There is also concern that, as MCO payment rates are tightened under the payment methodology of the BBA, MCOs may begin dropping the drug benefit. Moreover, insofar as Medicare policy-makers are primarily focused on the task of moving Medicare beneficiaries into managed care, they may slight the problems of the vast majority of beneficiaries left behind in FFS Medicare, who currently do not have adequate access to pain medication.

Recommendations

First, Medicare Part B should be expanded to cover oral outpatient pain medication.¹¹² Part B has been expanded to cover other medications, including oral anticancer chemotherapeutic agents and antiemetics used as part of a chemotherapy regime, prescription drugs for immunosuppressive therapy for organ transplant recipients, and erythropoietin for dialysis patients.¹¹³ Oral pain medications are relatively inexpensive compared with many of these medications, and are just as necessary for those for whom they are indicated.

Second, E and M and care planning CPT codes used

under RBRVS physician reimbursement should be reviewed and revised as necessary to assure that they adequately reflect the resource use necessary for pain management.

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

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

Fifth, oral anticancer chemotherapeutic agents should be covered by Medicare Part B for hospice patients when needed for palliative care. As noted, oral anticancer chemotherapeutic agents are normally covered by Medicare Part B. Hospice patients, however, must generally waive Medicare coverage for treatment of their terminal illness. When hospice patients require anticancer treatment for symptom control not for curative reasons, the oral anticancer agents must currently be paid for by the hospice from its per diem rate. These medications are very expensive, and strain hospice resources.

Medicaid

Medicaid is a joint federal-state program that pays for health care for the poor. Although most Medicaid recipients (about 70%) are children and their parents, most Medicaid expenditures are for the elderly (30.4%) and disabled (41.1%).¹¹⁴ Many elderly persons who are dually eligible for Medicare and Medicaid receive prescription drug benefits through Medicaid. Many disabled persons who have not yet been disabled for two years or who otherwise do not meet Medicare eligibility requirements also receive Medicaid benefits. Many poor persons in pain, therefore, depend heavily on Medicaid for payment for pain relief.

Medicaid programs must cover inpatient and outpatient hospital care, nursing facility care, and physicians' services.¹¹⁵ Although the state and territorial Medicaid programs are not required by federal law to cover prescription drug services, all in fact do.¹¹⁶ Twenty-eight programs also cover hospice services.¹¹⁷ Medicaid programs, therefore, pay for a significant range and volume of pain relief services. Because Medicare does not cover most outpatient medication, the most significant Medicaid benefit with respect to pain management is probably prescription drug

coverage. I will focus, therefore, on the prescription drug benefit.

Medicaid prescription drug coverage limitations

In 1995, prescription drugs accounted for about \$9.7 billion in Medicaid vendor payments, 8.1 percent of all Medicaid payments.¹¹⁸ The role of Medicaid in financing pain management medication cannot be overemphasized. One of the few studies of access to pain medication by patient payer status reported that Medicaid cancer patients received more pain medication—and more effective pain medication—than did patients covered by any other type of payer.¹¹⁹

There are, however, important limits to Medicaid coverage of pain medication. Prescription pain medication is, in most instances, included in Medicaid drug coverage. In fact, ten states cover aspirin, acetaminophen, or other specified OTC drugs when prescribed by a physician.¹²⁰ Many states, however, place limits on prescription drug coverage that affect pain management. For example, federal law permits state Medicaid programs to impose nominal cost-sharing requirements on Medicaid recipients, as long as children, pregnant women, patients in hospitals or residents in nursing facilities, emergency services, HMO services, hospice services and family planning services are excepted.¹²¹ Twenty-seven states currently impose copayments on prescriptions, ranging from \$.50 to \$3.00 per prescription.¹²² Most states charge variable copays, with lower copays for less expensive drugs or generics and higher copays for more expensive or brand-name drugs.¹²³

The Medicaid statute also permits states to limit the minimum or maximum quantities per prescription or the maximum number of refills to discourage waste.¹²⁴ About half of the states impose limits on the amount of drugs that can be dispensed under one prescription (usually a thirty- or thirty-four-day supply or 100 units) and/or on the number of refills per prescription (usually five in six months).¹²⁵ More significant, eight states limit the number of prescriptions or refills a recipient may obtain in one month (between three and seven), while a few others limit the number of dispensing fees that a pharmacist may receive in a month for filling a particular recipient's prescriptions.¹²⁶ Given that pain management patients often require frequent dosages of medication (sometimes thirty to fifty pills a day), these limitations may become a real barrier to adequate treatment.¹²⁷ In most states, quantity limits can be exceeded with prior authorization, but this still poses a deterrent to adequate pain management.

A number of studies have examined the impact of state Medicaid drug reimbursement policies on Medicaid recipients.¹²⁸ One looked at the effect of New Hampshire's imposing a limit of three paid prescriptions per month on Medicaid recipients, which was replaced a year later by a

\$1.00 per prescription copayment.¹²⁹ The study found that prescriptions filled for multiple drug users (with three or more prescriptions per month) dropped from 5.2 per month before the cap to 2.8 during the eleven-month cap period, climbing back to 4.7 when the copayment was introduced.¹³⁰ The use of prescription analgesics declined 31 percent from 28.3 to 17.5 prescriptions per hundred patients per month after the introduction of the cap.¹³¹

Attempts to limit Medicaid coverage of prescriptions, including pain medication, through the use of caps in particular is likely to have an adverse effect on pain management. Studies have also shown that copayments of as little as \$1.00 per prescription have led to 5 to 10 percent declines in drug use, including essential as well as nonessential drugs.¹³²

Medicaid prescription drug use control programs

Medicaid prescription drug coverage is also subject to administrative controls. These grow, by and large, out of the Omnibus Budget Reconciliation Act of 1990 (OBRA), which contained extensive provisions intended to control the cost of the Medicaid prescription drug benefit, while also assuring more appropriate prescribing for Medicaid recipients.¹³³ Most important for our purposes, OBRA required states to establish prospective and retrospective DUR programs.¹³⁴ These programs, which were to have been established by January 1, 1993, are supposed to review prescriptions for outpatient drugs to assure that the drugs are appropriate, medically necessary, and not likely to cause adverse results.¹³⁵ More specifically, the program must be:

designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.¹³⁶

DUR programs must cover all outpatient prescribing and may cover drugs dispensed in nursing facilities as well.¹³⁷ Where DUR programs identify problems in prescribing, they are authorized to issue written, oral, or electronic reminder notices; to initiate face-to-face discussions with providers; or to initiate intensified review or monitoring.¹³⁸ When necessary, DUR programs also refer providers or recipients to state surveillance and utilization review (SUR)

programs for further investigation, including possible fraud and abuse investigations.¹³⁹

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

Because of the potential impact of Medicaid DUR programs on pain management prescribing, Leonard Tomlin, Sheryl Ingram, and I surveyed state Medicaid DUR programs with respect to their policies and practices.¹⁴⁰ Twenty-seven states completed and returned the forms, including states from all regions of the United States. Of the states surveyed, twenty-one conducted both prospective and retrospective DUR; six conducted only retrospective. Twenty-three of the DUR programs reviewed drugs dispensed to nursing facility residents.

Ten of the twenty-one programs that conducted prospective DUR stated that they had developed standards and criteria specifically for prospective review of pain management prescribing.¹⁴¹ Twelve of the twenty-seven states stated that they had standards and criteria that specifically addressed retrospective review of pain management prescribing. Several of the states that responded negatively to the question of whether they had standards or criteria addressing pain relief, however, noted that their DUR contractors applied their own criteria or guidelines.

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

A major focus of our study was to determine which interventions state DUR programs pursued when they identified either inappropriate or potentially abusive prescribing of pain management medication.¹⁴² The DUR programs were first queried about what interventions they use to address these issues. The intervention used by the most

prospective utilization review programs both for inappropriate and abusive prescribing was an electronic notification to the dispensing pharmacist.¹⁴³ The second most common was notification of denial of Medicaid payment for the prescription, subject to an override by the pharmacist.¹⁴⁴ Other interventions pursued included denial of Medicaid coverage, written or oral notification to the prescribing physician or dispensing pharmacist, or referral to the SUR program.

With respect to retrospective utilization review, the intervention used by most programs for both inappropriate and abusive prescribing was a written notification to the prescribing physician;¹⁴⁵ the second most common a written notification to the dispensing pharmacist.¹⁴⁶ In situations of suspected abuse, about half of the states identified as a possible intervention locking the patient into a particular physician¹⁴⁷ or a particular pharmacist.¹⁴⁸ Several of these programs noted that the lock-in would have to be effected through the SUR program.

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

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

Notice letters always invited responses from the providers to whom they were addressed. The articulated purpose of the request for response was normally to improve DUR criteria or otherwise to adjust the program. The re-

sponse forms provided by some programs seemed genuinely oriented toward ascertaining whether information was useful to the provider. On the other hand, some notice letters seemed to demand rather than request a response, and some requested providers to specify the actions that they have taken in response to the notice. A doctor otherwise skittish about pain management prescribing may well find a DUR written notice to be threatening, but the samples we received did not seem on their face to be easily interpreted as threats.

Interventions other than written or electronic notices were far less common. Only eight programs had had face-to-face discussions regarding prescribing of pain medication with physicians in 1996, and all had had fewer than twenty such discussions. Nine programs had had face-to-face discussions regarding pain management prescribing with pharmacists in 1996, and all but two had had fewer than twenty.¹⁴⁹ Ten programs had had some physicians under intensified review regarding pain management prescribing at some point during 1996, seven of these in fewer than twenty instances.¹⁵⁰

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

Several reporting DUR units seemed aware of and/or sensitive to concerns regarding pain management.¹⁵¹ Seven reported either excluding from review or otherwise treating specially cases involving the prescribing of pain medication for conditions with intractable pain, such as cancer or AIDS. This usually involved suppressing DUR messages regarding the chronicity, dosage, or duration of prescribing of controlled substances for cancer patients. A couple of other states mentioned that they were unable to do this because they lacked sufficient diagnostic information to identify such patients, suggesting that they had considered this measure.¹⁵²

DUR programs are required by federal law to provide educational programs to "educate practitioners on com-

mon drug therapy problems with the aim of improving prescribing and dispensing practices."¹⁵³ Three of the surveyed programs had conducted special studies of prescribing pain medication. Twelve reported sponsoring educational outreach programs or providing informational material regarding appropriate pain management prescribing.¹⁵⁴ Several supplied us with educational materials they had generated or information on studies they had conducted. Three states sent program newsletters addressing pain management prescribing. Two of these articles included underprescribing pain medication. DUR programs should play a more active role in educating providers with respect to undertreatment of pain. To the extent that providers fear, rightly or wrongly, that aggressive pain management prescribing will get them in trouble with the DUR program, DUR's emphasis on the risks of underprescribing in educational programs, newsletters, or informational mailings could serve as a healthy antidote.

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

Medicaid managed care

Enrollment in Medicaid managed care programs jumped 37 percent, from 9.8 million recipients in 1995 to 13.3 million in 1996. Currently, 40 percent of all Medicaid recipients are in managed care.¹⁵⁵ Although the greatest and fastest movement to managed care involves programs for families and children, state Medicaid programs are also beginning to move their disabled and elderly populations into managed care systems.¹⁵⁶ The BBA generally encourages this move.¹⁵⁷

Little information is currently available concerning how pain management is being addressed by Medicaid managed care. A recent study of Medicaid managed care contracts found that thirty of the thirty-seven general Medicaid managed care contracts or requests for purchase studied required "pharmacy" or "prescription drug" coverage.¹⁵⁸ Most state contracts do not set out specific limitations or exclusions in their contracts for prescription drug coverage, though some limit coverage to "medically necessary" drugs, and others address the use of mail order pharmacy.¹⁵⁹ There is no evidence that access to prescription drug coverage is either expanding or contracting under managed care.

One particular concern here may be the approach that Medicaid managed care plans take to DUR. Medicaid

managed care plans generally use their own pharmaceutical benefits management policies and procedures in lieu of the state DUR program.¹⁶⁰ Some speculate that these programs may be more rigorous than the DUR programs have been in controlling access to prescription drugs for Medicaid recipients.¹⁶¹ If this turns out to be true, the result could be more undertreated pain.

Medicaid nursing facility coverage

One of the most important functions of Medicaid is to finance nursing facility care. The Medicaid statutes require states to cover skilled nursing benefits.¹⁶² In 1996, Medicaid spent \$37.5 billion on nursing facility care, 47.7 percent of total national expenditures on nursing facility care, and 26.8 percent of all Medicaid expenditures.¹⁶³ Many of the 1.4 million Medicaid recipients who live in nursing facilities are in pain, thus the Medicaid nursing facility benefit is critical when studying pain management financing.

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

A final pervasive problem with Medicaid is the barrier that low payment rates, payment delays, and bureaucracy pose to Medicaid provider participation. In many states, Medicaid pays physicians a fraction of what they make from treating their private, or even Medicare, patients. Delays in payments to pharmacies, exceeding 100 days in some states, threaten program participation.¹⁶⁴ An undetermined, but certainly significant, number of Medicaid recipients probably lack adequate pain management because they cannot get access to professionals who will provide them with adequate pain management under the Medicaid program.

Recommendations

First, states should exclude pain management medication from limitations imposed on the number of prescriptions they will cover per month. Recipients in intractable pain should also be excused from copayment obligations, as are

several other categories of recipients (children, nursing facility residents, and so forth).

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

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

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

Fraud and abuse law

It is odd that the fraud and abuse laws should appear as a component of a study of the influence of public health care financing programs on pain management practices. The fraud and abuse laws, and there are many of them, are intended to deter and punish fraud against and abuse of public health care financing programs.¹⁶⁵ An important subsidiary function of the fraud and abuse laws, however, is to police compliance with federal and state program requirements, especially with billing requirements.¹⁶⁶ Filing a claim for payment for a service that was not provided in compliance with program requirements, or that was not medically necessary, or even that did not meet acceptable quality standards might be characterized as fraud and abuse.¹⁶⁷ The fraud and abuse laws, therefore, pervasively affect every federal and state health program benefit, including pain management. Some have perceived them as having a particularly negative effect on pain management.

The federal and state governments have available a host of tools for addressing fraud and abuse involving Medicare and Medicaid, including criminal, civil, and administrative sanctions.¹⁶⁸ Physicians who prescribe large quantities of controlled substances for pain relief have long risked the attention of state and federal authorities who enforce the narcotics control laws. Increasingly, however, providers also worry that they could also be charged with violating fraud and abuse laws, with all of the calamitous consequences such charges entail.

A variety of fraud and abuse claims can in theory be brought for inappropriate prescribing or dispensing of controlled substances. In fact, in the past few years, health care fraud and abuse claims have increasingly been joined with controlled substance violation claims in federal crimi-

nal prosecutions.¹⁶⁹ Violations of the Racketeer Influenced and Corrupt Organizations Act and mail fraud are occasionally joined as well.

Pharmacists who dispense drugs and bill a federal or state health care program for payment knowing that the drugs are not dispensed for legitimate medical purposes can be found liable under various federal and state statutes prohibiting false claims and mail fraud.¹⁷⁰ This is particularly true if pharmacists dispense without a prescription or forge prescriptions.¹⁷¹ Physicians who dispense medication for illegitimate purposes and then bill a federal or state health care program may also face false claims charges.

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

- participating in “scheme or artifice to defraud” a health care benefits program;¹⁷²
- making a materially false statement or making or using a “materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry” in a health benefits program;¹⁷³
- making a false or fraudulent statement to the federal government;¹⁷⁴ or
- “causing” a false claim or statement of material fact to be made in a federal or state health benefits program.¹⁷⁵

Physicians may also face civil liability for making a false statement,¹⁷⁶ or an administrative penalty for causing a false claim to be presented.¹⁷⁷ In sum, any physician who issues an illegitimate prescription could be prosecuted under a variety of federal criminal, civil, and administrative laws either for making a false statement or for causing a subsequent false claim filed by a pharmacist.

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

- a physician fraudulently billed for physician visits related to the prescriptions;¹⁷⁸
- a physician fraudulently billed for diagnostic testing related to the prescriptions;¹⁷⁹
- a physician received a kickback related to the prescriptions;¹⁸⁰ or
- a physician permitted unlicensed persons to examine patients and billed for their services.¹⁸¹

In a typical case, a physician sees large number of patients, all or most of whom receive prescriptions for narcotics.¹⁸² Often, the patients travel long distance to get to a particular doctor, bypassing other doctors who provide legitimate pain management.¹⁸³ The physician bills Medicaid for office visits and for diagnostic tests, but there is no evidence that the physician actually examined the patient or that the tests given were necessary or used in any way.¹⁸⁴ Prescriptions may be written by receptionists or other untrained personnel. In some cases, the physician also receives a kickback from the pharmacy or clinical laboratory. Some cases include additional indicia of the absence of legitimate treatment, such as the exchange of drug prescriptions for sex¹⁸⁵ or, in one case, the provision of psychotherapy for patients who were dead.¹⁸⁶

Although it is possible that some of the reported cases involved legitimate prescribing for pain management, it is hard to perceive this in the facts as reported. In one case, the physician admitted to illegitimate prescribing.¹⁸⁷ In others, the facts seem to point overwhelmingly against legitimate prescribing, as in cases that involve drug for sex exchanges. The few reported cases that actually involve pain management were marginal, such as one involving a dentist.¹⁸⁸

To determine the extent to which doctors who prescribe large quantities of opioids for pain management are at risk for fraud prosecutions, I interviewed prosecutors and attempted to interview potential defendants and their attorneys. I interviewed a variety of experts, including the heads of the MFCUs of three states who have been active in prosecuting narcotics fraud cases, a regional administrator of the MFCU of another active state, an assistant U.S. attorney who works with narcotics fraud cases, the director of the national MFCU organization, an attorney from the American Medical Association, an attorney with OIG, two attorneys who represent physicians charged with Medicaid fraud, and a physician who had been involved in a Medicaid fraud investigation. I also attempted to identify other doctors who had allegedly been charged with fraud claims.

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

said that they were most likely to pursue physicians if their medical records did not document that patient visits billed to Medicaid had actually occurred or that tests billed to Medicaid were appropriately ordered.

One attorney had represented several physicians in recent years in health care fraud cases based on prescribing of controlled substances.¹⁸⁹ He stated that cases which several years ago would have been brought as narcotics cases are increasingly being brought as both narcotics and health care fraud cases. None of the cases he defended had been brought exclusively as fraud cases. All had been brought as criminal rather than civil or administrative fraud cases—one had been a false statements case based on the prescriptions themselves, and the remainder had been false claims cases based on charges that services billed by the doctor had not been provided or were unnecessary.

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

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

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

As noted in the discussion of the Medicare hospice benefit, OIG has released a series of reports in recent years based on investigations of hospices, focusing particularly on the hospice-nursing facility relationship and on hospice eligibility certifications. More significant, OIG has recently released a fraud alert addressing hospice relationships with nursing facilities.¹⁹⁰ Fraud alerts are high profile signals of the intention of the federal fraud oversight agencies to pursue enforcement aggressively in particular areas.

They are intended to have an effect on provider conduct, and usually do. Some of those I interviewed believe that doctors are already being deterred from certifying patients for hospice because of a fear that they will face fraud investigations if their patients fail to die in six months. To the extent that this results in patients being denied palliative care, this effect is very unfortunate.

Similarly, one doctor interviewed commented that it is, from time to time, necessary in treating patients with complex pain problems to provide medical procedures at a rate in excess of those recognized as appropriate under Medicare-carrier local medical review policies. When these aberrations show up in audits (often conducted years later), the carrier may threaten fraud and abuse prosecutions if the provider does not agree to drop or pay back the claims.¹⁹¹

As is often true with enforcement of the criminal laws, the reality perceived by law enforcers is very different from the reality perceived by defendants and those who fear that they may become defendants. Law enforcers, who are acutely aware of the scope and seriousness of health care fraud,¹⁹² reject the suggestion that they would consume their limited resources persecuting conscientious doctors engaged in legitimate pain management. Doctors, on the other hand—who have heard of a case in which federal agents have invaded a doctor's office with guns drawn¹⁹³—become nervous when they receive a routine DUR inquiry regarding their prescribing.

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

Conclusion

We do not have a coordinated approach in the United States to pay for health care for those who do not have private or employment-related insurance. Rather, we have an odd and tattered assortment of leaky umbrellas and ragged safety nets. Not surprisingly, we do not have a coordinated approach to paying for pain relief either. Some programs cover

some pain modalities for some recipients or beneficiaries under some circumstances. I have identified some of the gaps and deficiencies in the federal and state health care programs that play the largest role in paying for pain management.

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

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

Third, health care professionals and legislators need to think creatively about health care financing and provision programs that will provide comprehensive approaches to pain management provision, that will transcend our present limited and compartmentalized approaches. Several such approaches are described in the 1998 Report to Congress of the Medicare Payment Advisory Commission.¹⁹⁴ Included among the approaches mentioned in the Commission report are the Hospital Palliative Care Initiative of the United Hospital Fund of New York, which will create a palliative care position at Brooklyn Hospital Center to coordinate palliative care, including care for discharged patients receiving home care, and a palliative care consultation team at Saint Vincent's Hospital; the OPTIONS program of HealthCare Partners Medical Group of Los Angeles, which provides multidisciplinary care emphasizing symptom management, pain control, and quality of life for the terminally ill; and the Medicaring Project proposed by George Washington University's Center to Improve Care for the Dying, to provide extended hospice-style services for those in the last phase of life.

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

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22. 42 C.F.R. § 410.26(a). Even if drugs meet these criteria, Medicare will not cover them if they are under a proposed Food and Drug Administration order to withdraw approval because of suspected lack of efficacy. See 42 C.F.R. § 410.29(b).

23. See *Medicare Carriers Manual*, *supra* note 21, ¶ 2049.4.

24. See *id.* ¶ 15010, modified by transmittal no. 1566, [1997-1 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 45,258 (May 1, 1997). See Office of Payment Policy, Bureau of Program Development, Health Care Financing Administration, Memorandum, "Policy Issues Flowing from the Carrier Medical Directors' Meeting," [1992-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 40,375 (May 29, 1992) (discussing billing for injections).

25. See Office of Payment Policy, *supra* note 24.

26. See Balanced Budget Act, Pub. L. No. 105-33, § 4556(a), 111 Stat. 462-63 (1997) (to be codified at 42 U.S.C. § 1395u(o)). This provision was added as a cost-cutting measure by the 1997 Budget Act, and was effective January 1, 1998.

27. See K.B. Pace, "The Medicare Reimbursement Puzzle," *CARING*, May 1995, at 10-12. See also M.S. Uram, "A New Delivery System Makes Pain Control Easier," *RN*, 55 (1992): 46-50 (describing the operation of morphine infusion pumps).

28. Durable medical equipment is covered under 42 C.F.R. § 410.38(a) (1998), although infusion pumps are not explicitly mentioned in these provisions.

29. See Health Care Financing Administration, *Coverage Issues Manual*, ¶ 60-14.A.4 (HCFA Pub. 6, Aug. 1996) (hereinafter *Coverage Issues Manual*).

30. See *id.*; and *Medicare Carriers Manual*, *supra* note 21, ¶ 2100.5.

31. *Coverage Issues Manual*, *supra* note 29, ¶ 60-14.B.3.

32. See *id.*

33. See *id.* ¶ 60-14.B; and *Medicare Carriers Manual*, *supra* note 21, ¶ 2100.5.

34. See S. Masoorli, "Home IV Therapy Comes of Age," *RN*, 59 (1996): 22-26 (describing the administration of the home infusion therapy Medicare benefit).

35. See 42 C.F.R. § 410.38(f) (1998).

36. See *Coverage Issues Manual*, *supra* note 29, ¶ 45-19.

37. See *id.* ¶ 60-20.

38. See *id.* ¶ 65-8.

39. See *id.* ¶ 35-46.

40. See 42 U.S.C. § 1395d(a)(1) (1994).

41. See *Health United States*, *supra* note 4, tbl. 88 (citing 1995 data).

42. See 42 U.S.C. § 1395x(b)(2); and 42 C.F.R. § 409.10(a)(5) (1998). Proposed regulations establishing prospective payment for outpatient hospital services would also permit hospitals to provide self-administered drugs, including pain medication, to patients being treated on an outpatient basis if the service is not advertised. See "Proposed Rule, Medicare Program; Prospective Payment for Hospital Services," 63 Fed. Reg. 47,552, 47,563-64 (proposed Sept. 8, 1998).

43. See 42 C.F.R. § 409.13(a).

44. See Health Care Financing Administration, *Medicare Intermediary Manual*, ¶ 3101.3 (HCFA Pub. 13, Aug. 1996).

45. See *Coverage Issues Manual*, *supra* note 29, ¶ 35.21.

46. See 42 U.S.C. § 1395x(e). See 42 C.F.R. § 482.25 (1998) for hospital certification regulations regarding pharmaceuticals.

47. Joint Commission on Accreditation of Healthcare Organizations, *Comprehensive Accreditation Manual for Hospitals* (Oakbrook Terrace: Joint Commission on Accreditation of Healthcare Organizations, 1996): at R.1.1.2.7.

48. See *Health United States*, *supra* note 4, tbl. 89.

49. See "Final Rule: Medicare Program; Changes to Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates," 63 Fed. Reg. 40,962-63 (July 31, 1998); C.K. Cassel and B.C. Vladeck, Sounding Board, "ICD-9 Code for Palliative or Terminal Care," *New Engl. J. Med.*, 335 (1996): 1232; and Committee on Care at the End of Life, *supra* note 20, at 165 (citing letter from Christine Cassel, M.D., Milbank Memorial Fund, dated July 20, 1996).

50. See 42 U.S.C. §§ 1395d(a)(2), (f), 1395x(i).

51. See *id.* § 1395x(h).

52. See *id.* § 1395x(i). If admission within thirty days of hospital discharge is not medically appropriate, but the need for further medical care at a later point is predictable, the thirty-day period may be extended. See *id.* See also 42 C.F.R. § 409.30(b) (1994); and Health Care Financing Administration, *Medicare Skilled Nurse Facility Manual*, ¶ 212.3(B)(2) (HCFA Pub. 12, Aug. 1996).

53. See Department of Health and Human Services, *supra* note 7, tbl. 37.

54. 42 U.S.C. § 1395i-3(b)(2), (4)(A)(i).

55. 42 C.F.R. § 409.32(c).

56. See, for example, R. Bernabei et al., "Management of Pain in Elderly Patients with Cancer," *JAMA*, 279 (1988): at 1879 (more than a quarter of patients in sample nursing facilities who were in daily pain did not receive analgesia).

57. See 42 C.F.R. § 488.305 (1998).

58. See *id.* § 488.110(e)(3).

59. See *id.* § 488.105.

60. See *id.* § 488.115.

61. See Health Care Financing Administration, Resident Census and Conditions of Residents Form (HCFA Form 672, July 1995).

62. See Health Care Financing Administration, "Survey Procedures for Long Term Care Facilities," *State Operations Manual* (Transmittal 274, June 1995), at P-9.

63. Pain is one of the factors listed under the activities, incontinence, dental, and pressure sore resident assessment protocols, for example. See RAI 2.0 User's Manual, at C-30, C-58, C-71, C-73, C-76 (Oct. 1997).

64. See 62 Fed. Reg. 67,174, 67,194 (1997) (codified at 42 C.F.R. §§ 483.20, .315 (1998)).

65. See *id.* at 67,194.

66. *Id.*

67. See *id.*

68. See *id.* at 67,195.

69. See Committee on Care at the End of Life, *supra* note 20, at 168; and V. Bower, "The Right Way to Die: Despite Good Intentions, Some Hospices End up Bullying Patients Who Won't Pass Away Gracefully," *Health*, 23 (June 1991): 39-43.

70. See Medicare Payment Advisory Commission, *Context for a Changing Medicare Program, Report to Congress* (Washington D.C.: U.S. Government Printing Office, 1998): at 158. One recent study found that 82 percent of the random sample of hospices surveyed were Medicare certified. See M.-A. Sontag, "A Comparison of Hospice Programs Based on Medicare Certification Status," *American Journal of Hospice and Palliative Care*, Mar./Apr. (1996): at 37.

71. See 42 U.S.C. § 1395x(dd) (1994).

72. See *id.* § 1395x(dd)(3); and 42 C.F.R. § 418.22 (1998).
73. See 42 U.S.C. § 1395d(a)(4), (d)(2), as amended by Pub. L. No. 105-33, § 4443, 111 Stat. 423 (1997); and 42 C.F.R. §§ 418.24, .28. The election is for two periods of ninety days each, and then for successive sixty-day periods. See 42 U.S.C. § 1395d(2)(B) (as amended by Pub. L. No. 105-33, § 4443, 111 Stat. 423).
74. See 42 U.S.C. § 1395f(i); and 42 C.F.R. §§ 418.302-.309 (1998).
75. See 42 U.S.C. § 1396a(a)(13)(B) (as amended by Pub. L. No. 105-33, § 4711(a)(1), 111 Stat. 507-08 (1997)). This financing is discussed *infra* notes 97-101.
76. See Department of Health and Human Services, *supra* note 7, at 84.
77. See D.M. Gianelli, "Hospice Bill Could Improve End-of-Life Care," *American Medical News*, Feb. 24, 1997, at 10.
78. See Office of Inspector General, Department of Health and Human Services, *Medicare Hospice Beneficiaries: Services and Eligibility* (Chicago: Department of Health and Human Services, OEI-04-93-00270, 1997) (hereinafter *Hospice Beneficiaries*); Office of Inspector General, Department of Health and Human Services, *Hospice Patients in Nursing Homes* (Chicago: Department of Health and Human Services, OEI-05-95-00250, 1997) (hereinafter *Hospice Patients*); Office of Inspector General, Department of Health and Human Services, *Hospice and Nursing Home Contractual Relationships* (Chicago: Department of Health and Human Services, OEI-05-95-00251, 1997) (hereinafter *Contractual Relationships*); Office of Inspector General, Department of Health and Human Services, *Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments* (Washington D.C.: Department of Health and Human Services, A-05-96-00023, 1997); and Office of Inspector General, Department of Health and Human Services, "Medicare Advisory Bulletin on Hospice Benefits," 60 Fed. Reg. 55,721 (Nov. 2, 1995).
79. Balanced Budget Act, Pub. L. No. 105-33, §§ 4441-4449, 111 Stat. 422-24 (1997). These provisions are discussed in Gianelli, *supra* note 77, at 10.
80. See N. Christakis and J.J. Escarce, "Survival of Medicare Patients After Enrollment in Hospice Programs," *New Engl. J. Med.*, 335 (1996): 172-77.
81. See *id.* at 174.
82. See S.G. Stolberg, "As Life Ebbs, So Does Time to Elect Comforts of Hospice," *New York Times*, Mar. 4, 1998, A1, A16; and Telephone Interview with Nicholas A. Christakis, M.D., Assistant Professor, University of Chicago School of Medicine, Department of Internal Medicine (Feb. 23, 1998).
83. See Interview with Bernice Wilson, Director, Ohio Hospice Association (Jan. 30, 1998). Another hospice director stated that, in some states, the median length of stay is down to eight days. See Interview with Samira Beckwith, President and Chief Operating Officer, Hope Hospice (Feb. 13, 1998).
84. This discussion is based largely on information provided by Bernice Wilson. See Interview with Bernice Wilson, *supra* note 83.
85. See *id.*
86. See Medicare Payment Advisory Commission, *supra* note 70, at 160.
87. See Interview with Bernice Wilson, *supra* note 83.
88. See P. Fish, "A Harder Better Death," *Health*, 11 (Nov.-Dec. 1997): 108-14; Stolberg, *supra* note 82, at A16; and Cassel and Vladeck, *supra* note 49, at 1232.
89. See Cassel and Vladeck, *supra* note 49, at 1232; and J. Lynn, Editorial, "Caring at the End of Our Lives," *New Engl. J. Med.*, 335 (1996): at 202.
90. See 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 34-35; and Fish, *supra* note 88.
91. See Office of Benefits Integrity, Department of Health and Human Services, Memorandum BPO-B12, "Instructions for Regional Home Health Intermediary Medical Review of Hospice Claims to Determine Terminal Illness for Non-Cancer Diagnoses—ACTION" (Nov. 27, 1995).
92. See Interview with Bernice Wilson, *supra* note 83.
93. See *id.*
94. The *State Medicaid Manual* only requires hospice patients to waive Medicaid payment for treatment related to the terminal condition for which hospice care was elected or a related condition. See Health Care Financing Administration, *State Medicaid Manual*, ¶ 4305.2 (HCFA Pub. 45, Aug. 1996).
95. See Interview with Cherry Meier, Director of Public Relations, VITAS HealthCare Corp. (Jan. 22, 1998); and Interview with Bernice Wilson, *supra* note 83.
96. See "Miracle' Drugs Tempt the Terminally Ill: Protease Inhibitors Complicate Hospice Guidelines," *AIDS Alert*, Dec. (1996): 137.
97. See 42 U.S.C. § 1396a(a)(13)(B) (as amended by Pub. L. No. 105-33, § 4711(a), 111 Stat. 507-08 (1997); and *State Medicaid Manual*, *supra* note 94, ¶ 4308.2.
98. See *Hospice Patients*, *supra* note 78, at 2.
99. See *Contractual Relationships*, *supra* note 78, at 4.
100. See *Hospice Patients*, *supra* note 78, at 9. A recent report from the Office of Inspector General (OIG) found that, in its sample of hospice patients in nursing homes, 29 percent were ineligible for the Medicare hospice benefit, compared with only 2 percent of hospice patients in the community. See *Hospice Beneficiaries*, *supra* note 78, at 4-5.
101. See *Hospice Patients*, *supra* note 78; *Contractual Relationships*, *supra* note 78; and "Special Fraud Alert: Fraud and Abuse in Nursing Homes Arrangements with Hospices," 63 Fed. Reg. 20,415 (1998).
102. See Interview with Sue Wells, Consultant, Wells Consulting Service, and Chair, National Hospice Organization's Managed Care Task Force (Jan. 28, 1998). See Pub. L. No. 105-33, § 4001, adding § 1853(h)(2), 111 Stat. 307-08, providing for payment to Medicare+Choice organizations for nonhospice services.
103. See Interview with Sue Wells, *supra* note 102.
104. See Health Care Financing Administration, *Medicare Hospice Manual*, ¶ 110 (HCFA Pub. 21, Aug. 1996); and Health Care Financing Administration, *State Operations Manual*, ¶¶ 2080-2087 (HCFA Pub. 7, Aug. 1996).
105. See Interview with Bernice Wilson, *supra* note 83.
106. See *Medicare Managed Care Contract Report* (visited Dec. 15, 1998) <<http://www.hcfa.gov/stats/mmcc1298.txt>> (noting that, as of December 1, 1998, nearly 6.76 million Medicare beneficiaries are currently enrolled in risk-based managed care plans).
107. See Pub. L. No. 105-33, § 4001, 111 Stat. 323 (1997). See Prospective Payment Assessment Commission, *Medicare and the American Health Care System: Report to Congress* (Washington, D.C.: ProPAC, 1997): at 44.
108. See 42 C.F.R. §§ 417.101(b), (d)(4), .102 (1998).
109. See *Medicare Managed Care Contract Report*, *supra* note 106 (noting that, as of December 1, 1998, 226, or over two-thirds, of Medicare risk-based health maintenance organizations and competitive medical plans covered outpatient drugs).
110. See M.R. Yessian and J.M. Greenleaf, "The Ebb and Flow of Federal Initiatives to Regulate Health Care Professionals," in T.S. Jost, ed., *Regulation of the Healthcare Professions*

(Chicago: Heath Administration Press, 1997): at 169-98.

111. See 42 C.F.R. § 417.102(b).
112. For the proposed legislation to accomplish this result, see S. 1345, § 8, 105th Cong. (1997).
113. See 42 U.S.C. §§ 1395x(s)(2)(J), (O), (Q), (T) (1994), as amended through 1997.
114. See *Health United States*, *supra* note 4, tbl. 140.
115. See 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a) (1994).
116. See 3 Medicare and Medicaid Guide (CCH) ¶¶ 15,505-15,507 (1996). See also 42 C.F.R. § 440.120 (1998).
117. See 3 Medicare and Medicaid Guide (CCH) ¶¶ 15,505-15,507.
118. See *Health United States*, *supra* note 4, tbl. 141.
119. See R.F. Holcombe and J. Griffin, "Effect of Insurance Status on Pain Medication Prescription in a Hematology/Oncology Practice," *Southern Medical Journal*, 86 (1993): 151-56.
120. See 3 Medicare and Medicaid Guide (CCH) ¶¶ 15,550-15,660. One state drug utilization review (DUR) director reported to me that the state's program had discovered that the most frequently prescribed Medicaid covered drug in nursing facilities in its state was Darvocet, which apparently was being used in place of over-the-counter pain-relievers not covered by Medicaid.
121. See 42 U.S.C. § 1396o(a)(2), (3) (1994); and 42 C.F.R. §§ 447.53-.54 (1998). See *Sweeney v. Bane*, 996 F.2d 1384 (2d Cir. 1993) (upholding a New York law requiring Medicaid recipients to pay copayments for prescriptions). Services cannot be denied to a recipient who is unable to pay a copayment. See 42 U.S.C. § 1396o(e).
122. For 1997 data from Medicaid state charts, see 3 Medicare and Medicaid Guide (CCH), ¶¶ 15,550-15,660.
123. See *id.*
124. See 42 U.S.C. § 1396r-8(d) (1994).
125. For 1997 data from Medicaid state charts, see 3 Medicare and Medicaid Guide (CCH), ¶¶ 15,550-15,660.
126. See *id.*
127. See D.E. Joranson and A.M. Gilson, "Controlled Substances, Medical Practice, and the Law," in H.I. Schwartz, ed., *Psychiatric Practice Under Fire* (Washington, D.C.: American Psychiatric Press, 1994): 183-85 (discussing the problems caused by state laws limiting the quantities of controlled substances that may be dispensed).
128. See, for example, S.B. Soumerai et al., "A Critical Analysis of Studies of State Drug Reimbursement Policies: Research in Need of a Discipline," *Milbank Quarterly*, 71 (1993): 217-52.
129. See S.B. Soumerai et al., "Payment Restrictions for Prescription Drugs under Medicaid," *New Engl. J. Med.*, 317 (1987): 550-56.
130. See *id.* at 552.
131. See *id.*
132. See S.B. Soumerai et al., "Determinants of Change in Pharmaceutical Cost Sharing: Does Evidence Affect Policy?," *Milbank Quarterly*, 75 (1997): at 12.
133. See General Accounting Office, *Prescription Drugs: Automated Prospective Review Systems Offer Potential Benefits for Medicaid* (Washington D.C.: General Accounting Office, GAO/AIMD-94-130, 1994): at 3.
134. See 42 U.S.C. § 1396r-8(g) (1994).
135. See *id.* § 1396r-8(g)(1)(A).
136. *Id.* See also 42 C.F.R. §§ 456.702, .703, .705, .709 (1998).
137. See 42 C.F.R. § 456.703.
138. See 42 U.S.C. § 1396r-8(g)(3)(C)(ii); and 42 C.F.R. § 456.711(b), (c), (d).
139. See 42 C.F.R. §§ 455.13-.16, .21; 456.3 (1998). See

E.E. Lipowski and T. Collins, *Medicaid DUR Programs, 1993* (Washington D.C.: American Pharmaceutical Association Foundation, 1993): at 7-8, 14-15.

140. A six-page survey was sent to all Medicaid DUR programs in early 1998, with the assistance of Leonard Tomlin of the Ohio Medicaid DUR Program and Sheryl Ingram of the Searle Group (which assists in surveying DUR programs). For purposes of the survey, pain medication was defined to include opiate agonists, opiate partial agonists, opiate antagonists, non-steroidal antiinflammatory agents (including aspirin and salicylate compounds), and miscellaneous analgesics (acetaminophen and Tramadol).
141. Among the drugs identified as receiving special attention were: Ultram; ketorolac tromethamine (Toradol) and acetaminophen; butorphanol (Stadol Nasal Spray); carisoprodol (Soma); and nonsteroidal antiinflammatory drugs used in combinations or in high dosages. Another factor that raised particular concern is patients who received pain medication from more than one doctor or early refills.
142. Inappropriate prescribing was identified on the questionnaire in terms of therapeutic duplication, drug-disease contraindication, adverse drug-drug interactions, incorrect drug dosage, incorrect duration of drug treatment, or drug-allergy interactions. Potentially abusive prescribing was defined in terms of clinical abuse/misuse, including abuse, gross overuse, overutilization, or underutilization.
143. Electronic notifications were used by 15 of 21 programs where inappropriate prescribing was suspected, and by 14 of 21 where abusive prescribing was suspected.
144. Denial notifications were used by 10 of 21 programs for inappropriate prescribing and by 8 of 21 for abusive prescribing.
145. Written notifications were used by 23 of 27 programs for inappropriate prescribing and by 20 of 27 programs for abusive prescribing.
146. Written notifications were used by fourteen of the retrospective review programs for both inappropriate and abusive prescribing.
147. Fourteen of twenty-seven states took this approach.
148. Twelve of twenty-seven states took this approach.
149. One of the remaining programs had between 20 and 50; the other, between 50 and 100.
150. One of the remaining programs had between 20 and 50; another, between 50 and 100.
151. These may have been the programs most interested in responding to our survey, so it would be inappropriate to project that these results also reflect the nonresponding programs.
152. Apparently, states differ as to whether they have diagnostic information when they conduct drug utilization review, and further vary as to whether this information is available for prospective review, retrospective review, or both.
153. 42 C.F.R. § 456.711 (1998).
154. Another program noted that educational seminars on pain management were readily available, suggesting that it was not necessary for DUR programs to provide such education.
155. See Physician Payment Assessment Commission, *supra* note 107, at 26.
156. Federal law, however, prohibits states from requiring persons receiving qualified Medicare beneficiary benefits to enroll in a managed care entity. See 42 U.S.C. § 1396u-2(a)(2)(B) (1994).
157. See Pub. L. No. 105-33, §§ 4701-4703, 111 Stat. 489-95 (1997).
158. See S. Rosenbaum et al., *Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Con-*

tracts (Washington D.C.: George Washington University, Center for Health Policy Research, Vol. 2, 1997): at 2-6, tbl. 2-1.

159. See *id.* at 2-6.

160. See Yessian and Greenleaf, *supra* note 110, at 179.

161. See *id.*

162. See 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a) (1994).

163. See K.R. Levit et al, "National Health Expenditures, 1996," *Health Care Financing Review*, 19, no. 1 (1997): at 199.

164. See Joranson, *supra* note 20, at 250 (citing T. Reutzel, "Hidden Costs: A Simulation for the Effect of a Public Aid Payment Lag on Community Pharmacies," *Illinois Pharmacist*, 53 (1991): 16-17, 23-25).

165. See T.S. Jost and S. Davies, *Medicare and Medicaid Fraud and Abuse* (St. Paul: West, 1998): §§ 1-1, 1-2.

166. See *id.* § 1-4.

167. See *id.* § 2-1.

168. See *id.* §§ 2-1 to -7. In particular, under an administrative sanction authority added in 1997, physicians and other providers must be excluded from participation in federal health care programs for at least five years if they are convicted of a felony "relating to the unlawful manufacture, distribution, prescription, or dispensing of controlled substances." Providers convicted of misdemeanor controlled substances violations may be excluded from federal health care programs. See 42 U.S.C. § 1320a-7(b)(3) (1994). Thus, even if a professional convicted of illegitimate prescribing of controlled substances is not convicted of health care fraud, he/she might be excluded from participation in government health care benefits programs.

169. See, for example, *United States v. Sims-Robertson*, Nos. 92-1076, 92-1080, 92-1082, 92-1090, 92-1094, 92-1096, 92-1115, 1994 WL 12212 (6th Cir. 1994); *United States v. Romano*, 970 F.2d 164 (6th Cir. 1992); and *United States v. Sblendorio*, 830 F.2d 1382 (7th Cir. 1987).

170. See *United States v. Hughes*, 895 F.2d 1135, 1143 (6th Cir. 1990) (conviction of pharmacist for mail fraud upheld); and "Medifraud Druggist Placed on Probation," *Chicago Tribune*, Apr. 9, 1986, at C5.

171. See B. Kilby, "Pharmacist Convicted," *Tulsa World*, May 10, 1995, at 9.

172. See 18 U.S.C. § 1347 (1994).

173. See *id.* § 1035.

174. See *id.* § 1001.

175. See 42 U.S.C. § 1320a-7b(a) (1994).

176. See 31 U.S.C. § 3729(a)(2) (1994).

177. See 42 U.S.C. § 1320a-7a.

178. See *United States v. Sidhu*, 130 F.3d 644 (5th Cir. 1997); *Sblendorio*, 830 F.2d at 1384; *Sims-Robertson*, 1994 WL 12212, at *2; "Medical Clinics, Michigan," *National Association of Attorneys General, Medicaid Fraud Report* (Washington, D.C.: National Association of Attorneys General, June 1995); and M. Lasalandra, "Docs Charged with Writing Prescriptions for Addicts," *Boston Herald*, Dec. 16, 1993, at 26.

179. See *Sims-Robertson*, 1994 WL 12212; and *Romano*, 970

F.2d at 165.

180. See *Sims-Robertson*, 1994 WL 12212, at *2, *4; and *Romano*, 970 F.2d at 165.

181. See *Sidhu*, 130 F.3d at 647-48; *Sims-Robertson*, 1994 WL 12212, at *2; and "Physicians, Michigan," *National Association of Attorneys General, Medicaid Fraud Report* (Washington, D.C.: National Association of Attorneys General, July/Aug. 1993): at 22.

182. See M. Possley, "Druggist Dispenses Medicaid Fraud Story," *Chicago Tribune*, Dec. 8, 1985, at 1. See also General Accounting Office, *Medicaid Drug Fraud: Federal Leadership Needed to Reduce Program Vulnerabilities* (Washington, D.C.: General Accounting Office, HRD-93-118, 1993) (describing drug fraud schemes.)

183. See Lasalandra, *supra* note 178.

184. See, authorities cited, *supra* note 178. In some cases, doctors have subsequently falsified records to support their prescribing. See "Physicians, California," *National Association of Attorneys General, Medicaid Fraud Report* (Washington, D.C.: National Association of Attorneys General, May 1994): at 14.

185. See M. Fuetsch, "Agents Say Mayfield Podiatrist Tried to Trade Drugs for Sex," *Cleveland Plain Dealer*, Jan. 26, 1995, at 48.

186. *Sidhu*, 130 F.3d. at 647.

187. See *id.* (admission of defendant Gifford on appeal).

188. See J. Irwin, "Dentist Faces Charges for Prescriptions: Patients Say He Ended Pain, Officials Disagree," *Cincinnati Enquirer*, July 12, 1997, at A1, A6.

189. Telephone Interview with Ben Bailey, Attorney, Bowles, Rice, McDavid, Graff, and Love (Mar. 17, 1998).

190. See Office of Inspector General, "Special Fraud Alert: Fraud and Abuse in Nursing Homes Arrangements with Hospices," 63 Fed. Reg. 20,415 (1998). The most recent OIG report on hospices, however, reveals that formal plans of care were found for 96 percent of hospice beneficiaries, and that, in 99 percent of the hospice records reviewed, documentation confirmed that the beneficiaries and their families were receiving care as indicated by the plans of care. See *Hospice Beneficiaries*, *supra* note 78, at 4.

191. Interview with Dr. Steven Waldman, Member, Society for Pain Practice Management (June 9, 1998).

192. See, for example, M.K. Sparrow, *License to Steal: Why Fraud Plagues America's Health Care System* (Boulder: Westview Press, 1996) (describing the seriousness of the health care fraud problem).

193. See L. Messina, "Judge Blasts Agents' Behavior During Raid," *Charleston Gazette*, Sept. 30, 1997, at 1 (noting one case in which federal agents ordered patients in a waiting room "up against the wall," holding the doctor's nine-year-old, pajama-clad son at gun point while they searched the doctor's home and office). OIG special agents and Federal Bureau of Investigation agents are authorized to carry firearms while on duty.

194. See Medicare Payment Advisory Commission, *supra* note 70, at 162-64.