MURDER BY MEDICARE

THE DEMISE OF SOLO AND SMALL GROUP MEDICAL PRACTICES

by Jonathan W. Emord

PHYSICIANS IN SOLO AND SMALL GROUP medical practices are a dying breed. They find it increasingly difficult to bear the regulatory burdens imposed on them by government and thus to remain in business. The party largely responsible for their demise is Medicare.

Physicians find it difficult to discern what medical services are covered by Medicare. They face rising costs for services and equipment, yet also face caps on Medicare reimbursements. They must spend considerable time and money to satisfy complex and confusing Medicare regulations, that are traps for the unwary, and they fear costly inquiries, investigations, audits, and prosecutions by Medicare enforcement authorities. They find the transformations in the medical marketplace wrought by an increasingly intrusive federal regulatory establishment to interfere with their exercise of independent professional judgment and limit their freedom to serve the best interests of their patients.

Physicians intent on complying with Medicare regulations might prescribe a particular treatment not because they think it is best for a patient but because it is likely to be accepted by Medicare insurance carriers as "reasonable and necessary" for the diagnosis and thus be deemed compensable by Medicare. Medicare largely defines the kind of financial relationships physicians may have with other physicians and with vendors, suppliers, laboratories and other enterprises. Such restrictions preclude many joint business arrangements that would lower the costs of care.

In the past Medicare has imposed fines on and compelled reimbursements by physicians to help finance growing program costs. But since 1997 those funds have been placed in trust to finance more investigations of physicians in an effort to leave no stone unturned that may hide any evidence of fraud or abuse, whether real or presumed.

Medicare is transforming the way health care is delivered in the United States—away from individualized treatment, where successful patient care is the paramount objective, toward bureaucratized treatment, where strict adherence to uniform federal rules is the chief concern. Cost containment pressures necessarily discourage tailored care in favor of one-size-fits-all approaches. Medicare burdens are hastening the arrival of the day when physicians will be able to practice only if they are affiliated with large hospitals or managed care groups that can afford the risk managers, accountants, and lawyers needed to ensure compliance with Medicare regulations.

A BRIEF HISTORY OF MEDICARE

When federal financing of medical care was first considered in 1964, President Lyndon Johnson proposed a limited program of hospital insurance benefits for the aged and disabled. The American Medical Association and other public health organizations lobbied for an expanded program that would also pay for services delivered by physicians not associated directly with hospitals. In 1965 Congress enacted two health insurance programs: Medicare Part A, to cover hospitalization costs, and Medicare Part B, to cover the costs of physician services to the aged and disabled. The Health Care Finance Administration (HCFA) was created to administer the program.

In 1972 Congress expanded the program to cover nursing home residents in need of rehabilitation services in addition to skilled nursing care. In 1980 Congress eliminated the requirement that beneficiaries in need of home health services be hospitalized before they would be eligible for those services. Since 1980, Congress and the HCFA have amended Medicare Part B almost annually to cover, for example, comprehensive outpatient rehabilitation facility services and outpatient ambulatory surgical services. With this expansion has come more federal control over the provision of medical services to Medicare beneficiaries.

The Medicare program has grown substantially during its three-decade existence, with annual program costs mushrooming from $799 million in 1965 to $203.1 billion in 1997. The program now serves more than 38 million enrollees; it will serve many more as baby boomers enter their senior years.

Congress has consistently avoided the politically unpopular course of cutting benefits as a means of reducing the program's financial burden. It has endeavored to achieve program savings in part through regulatory strictures on coverage and through enhanced enforcement against Medicare providers. It

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has depended on the HCFA to cover, in part, growing program costs through financial penalties levied on Medicare providers for violating the program's myriad regulations. The HCFA maintains that approximately $90 billion is lost each year because health care consumers are defrauded. This figure includes, for example, charges to consumers for services not covered by Medicare that might be deemed inappropriate for the patients involved. The agency also asserts that some 14 percent of claims submitted to Medicare are fraudulent, a figure that amounted to $23 billion in 1997.

HEIGHTENED ENFORCEMENT

In May 1995, the Department of Health and Human Services (HHS) initiated Operation Restore Trust (ORT), a pilot program to demonstrate the effectiveness of enhanced antifraud and abuse investigations and prosecutions, coordinated among federal, state, and local governments. During the program's two-year test period, the HHS claimed that for every dollar spent on enforcement, twenty-three dollars were recovered. In the five pilot states, California, Florida, Illinois, New York, and Texas ORT produced $187.5 million in receipts from fines, recoveries, audit disallowances, and civil money penalties. Operation Restore Trust resulted in 210 case filings, 74 criminal convictions, 58 civil actions, 69 current indictments, and 218 provider exclusions.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) expanded the ORT pilot program nationwide. The act vastly expanded funding and authority to prosecute and punish fraud and abuse for the Department of Justice, the HHS, and the HHS Office of the Inspector General. It authorized $1 billion to be spent between 1996 and 2004 on enforcement actions, with $240 million spent in the last year. At a return rate of twenty-three dollars for every dollar spent on enforcement realized in the pilot program, Medicare could collect a total of $5.5 billion in 2004. Individual health care fraud settlements can also net the government huge sums. For example, the National Medical Enterprises Corporation paid $362.7 million in criminal fines, civil damages, and penalties, and paid the states another $16.3 million. Caremark, Inc., paid the federal government $161 million to settle a government health care fraud case. In 1977 alone, enforcement actions netted the federal government $1.2 billion in criminal fines, civil settlements, and fraud judgments.

One of the most significant changes made by HIPAA was the creation of a trust into which all monies recouped from health care fraud and abuse actions must be deposited. Those funds are earmarked for use in financing more federal fraud and abuse investigations, thus creating a self-perpetuating enforcement machine. Taking a chapter from the Drug Enforcement Administration's book, HIPAA grants federal authorities increased forfeiture powers by allowing it to seize equipment used in the commission of a health care offense, sell it, and apply the proceeds to finance additional enforcement actions.

Rewarding those who enforce Medicare fraud and abuse regulations with more program funds creates strong institutional incentives for those enforcers to pursue as many investigations and fraud and abuse prosecutions as possible, thus increasing the risk that the innocent as well as the guilty will suffer punishment. An analogy can be made with the Internal Revenue Service. Past years have brought to light IRS abuses that resulted from agents being rewarded for how much money they could extort from taxpayers. Thus, while the IRS is supposedly abandoning a system of perverse incentives, Congress has mandated such a system for Medicare.

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Diversion of fines and reimbursements from physicians is likely to place serious pressure on the Medicare system in the future. Because funds extorted from physicians will not be used to cover Medicare program costs but to extort more funds, Congress will not be able to disguise cost increases in Medicare.

Real fraud, of course, is something that should concern the government. But an actual intent by physicians to deceive is frequently absent. That intent is simply presumed, based, for example, on patterns of miscoding or on the mistaken assumption that a physician has received notice of some change in Medicare coverage. The lack of clarity in Medicare rules and in what is covered causes even well-intended practitioners to err from time to time. When those errors reveal a pattern, a physician may be accused of fraud or abuse, yet in actuality be an innocent dupe of a complex regulatory system that is difficult if not impossible to master. Indeed, for sole and small-group practitioners who lack the money to hire risk managers, accountants, and attorneys to assist them, knowing day to day what codes to use and when to bill can be extremely difficult. The nature of Medicare's fraud enforcement efforts suggests that much of its recent collections are not from providers who knowingly and intentionally bill for services not rendered but from those who billed or engaged in business practices they did not know ran afoul of government regulations.

The Medicare enforcement scheme is designed first to limit payments for Medicare-covered services performed by physicians. Second, it seeks to expand definitions of improper billing, fraud, and abuse as a means to help Medicare recoup funds from physicians. And third, it expands the size and scope of audits and investigations of physician practices. If physicians resist, Medicare can seek civil and criminal penalties. Thus physicians, once the pampered recipients of Medicare largess, are now the targets of aggressive bureaucrats.

The creation of the enforcement trust fund causes Medicare's fraud enforcement system to be akin to a city government that finances its expenses by pressuring the police to issue more traffic and parking tickets, whether the behavior of

"Oh, I see. I always thought 'under the counter' was a figure of speech."

drivers warrants them or not. Congress has been able to take credit for a broad array of seemingly ever-expanding federally funded benefits and for holding down costs, while not being held politically accountable for the program's adverse effects on medical practices and health care markets. Thus the fears of taxpayers about runaway costs to some extent have been allayed, even though the system might face bankruptcy in the first decade of the next century.

Under the current system, the HHS contracts with more than sixty insurance companies to implement the Medicare program. The companies are required to document for the HCFA a set minimum percentage of collections from providers and physicians allegedly paid Medicare fees for services the carrier deems in retrospect not medically "reasonable and necessary." A principal byproduct of HCFA requirements has been the creation of a complex, sometimes incomprehensible coding system for billing, fraught with traps for the unwary, a myriad of largely hidden requirements that punish even innocent errors. Each insurance carrier maintains a computerized claims evaluation system that presupposes wrongful billing conduct based on "suspect" billing patterns and claims submissions. Upon discovery of such a pattern an insurer can initiate inquiries, investigations, and audits of physician practices. Each of those processes place a heavy burden on physicians and requires them to hire legal counsel at considerable expense. In each case contemporaneous documentary evidence is the key to defending a particular billing decision. In a typically hurried practice, the failure to document all facts relevant to diagnosis and treatment can lead to a carrier's after the fact determination that a paid claim was not justified and must be reimbursed.

Moreover, the federal government maintains a database listing the names of physicians who have been found liable for wrongful conduct, even before all appeals are exhausted and an action becomes final. The database is used by federal, state, and local health care officials and insurance carriers to identify suspect parties. Thus even an innocent party accused of wrongdoing who settles rather than litigates, or who loses at one level in the review process, can be listed on the database before all appeals are exhausted. The arrangement makes those physicians subject to further inquiries, investigations and audits.

MEANS OF PAYMENT

Over the years Medicare has come to control every physician; none can completely extricate himself from program review or jurisdiction. The increasingly complex billing systems imposed on physicians, purportedly to ferret out fraud and abuse, themselves ensure more rule violations and, consequently, greater opportunities for Medicare to recoup funds.

Before 1982 physicians had the option of participating or not participating in Medicare. Participating physicians would

(and still do) bill Medicare insurance carriers for all covered services. Those physicians "accept assignment" of all claims for payment from Medicare beneficiaries to insurance carriers under contract with Medicare. Carriers reimburse participating physicians for 80 percent of what the carriers judge to be reasonable or necessary charges for a covered service, based on Medicare regulations. The beneficiary pays the remaining 20 percent. Physicians participating in Medicare also agree not to charge the beneficiary more than the 20 percent even if the total amount received does not cover the physicians' total charge. Thus, for example, if a carrier judges the medically reasonable and necessary cost of Medicare-covered treatment X to be $100, it would pay the physician $80 and the beneficiary would pay the physician $20. (That would be true even if the market rate for treatment X is in fact $200.)

WITH MEDICARE, CONGRESS HAS DONE MORE THAN REPLACE MARKET PRICES WITH GOVERNMENT-SET PRICES FOR PARTICULAR MEDICAL TREATMENTS.

Before 1984 physicians not accepting assignment could bill Medicare beneficiaries directly for a covered service but Medicare insurance carriers would pay the beneficiary only 80 percent of what they judged "medically reasonable and necessary." That amount could vary depending on living costs in the physicians' part of the country and other factors. The patient would have to pay any charges in excess of the Medicare-approved amount. Thus, a beneficiary might have sought treatment X from what he or she judged to be a superior but more expensive physician who charged $150 for the treatment. If the Medicare-approved cost for that treatment were $100, the beneficiary could collect $80 and thus would have to pay the physician $70 out of pocket ($150 minus $80).

In the 1984 Deficit Reduction Act and through subsequent acts, Congress sought to eliminate cost disparities between participating and nonparticipating providers. At first it imposed a price freeze on the amount Medicare would pay for physician services. The freeze also in effect capped what a nonparticipating physician could charge a beneficiary, even if the beneficiary were willing to pay a higher price.

In the 1986 Omnibus Budget Reconciliation Act, Congress replaced the freeze with a maximum allowable actual charge (MAAC) applicable only to nonparticipating physicians. The MAAC relied on a complex calculation of costs for each covered service. If a nonparticipating physician "knowingly and willfully" billed an amount in excess of the MAAC, that physician could be fined or suffer other sanctions.

Under the Omnibus Budget Reconciliation Act of 1989, which became fully effective 1 January 1992, Congress replaced the reasonable charge payment program for physician services with a national fee schedule, and replaced the MAAC with a new limiting charge. The formula for the national fee schedule, the Resource-Based Relative Value Scale (RBRVS), factors in practice expense, work value, and malpractice expenses, among other elements, to arrive at the fee total.

Over the past decade, the freedom of nonparticipating physicians to charge market prices has been whittled away, the difference between prices charged by participating and nonparticipating physicians has been reduced, and thus most physicians have been pressured into participating one way or another in Medicare.

With Medicare, Congress has done more than replace market prices with government-set prices for particular medical treatments; it also has decided what treatments it will cover for certain medical conditions. Covered services are ones that Medicare will pay in accordance with the fee schedule if deemed "medically reasonable and necessary" under the circumstances. Those payment limits apply both to physicians who participate and to those who do not participate in Medicare. Medicare insurance carriers are required to evaluate the nature, kind, and degree of services provided to beneficiaries in search of Medicare fraud or abuse and to supplement the HCFA list of covered and noncovered services with coverage determinations of their own. In that way physicians may not exercise independent professional judgment in the care of Medicare beneficiaries but must always be mindful that carriers and bureaucrats may second-guess every treatment and every charge.

Thus, perhaps a year or more after the physician has been paid, the insurer might find that the physician earlier had billed for an inappropriate treatment. The physician can be (and frequently is) ordered to return the funds. If the physician fails to make the reimbursement in full and in a timely manner, the HCFA can impose civil monetary penalties, exclude the physician from participation in the Medicare program, or both. In 1977, HCFA excluded over 1,000 individuals and businesses from participating in Medicare.

Also, in the name of preventing billing fraud, Medicare has become a major invader of personal privacy. As a condition for enrolling in Medicare, beneficiaries must waive any rights of privacy over physician-patient communication so Medicare has access to all of the beneficiaries' medical records. That practice might be causing some Medicare beneficiaries to conceal parts of their medical histories from their physicians, thus encouraging misdiagnosis or inappropriate prescriptions.

The Medicare program suffers from the same problems that befall all efforts at government planning. Medicare pays set fees for a catalog of ever-expanding medical services. Medicare has no control over demand for those services and has never employed politically unpopular rationing to limit demand arbitrarily. Thus Medicare lacks any means to reduce expenditures other than by restricting payments to providers and demanding repayment of funds previously expended. A market would set prices and allocate services based on supply and demand. Higher prices would attract more of the service and, perhaps, entrepreneurs who would discover less-costly ways to deliver the service. Medicare price controls distort markets, fail to control prices, and eliminate incentives for

delivering services more efficiently. Medicare price controls also suppress innovation and promote a one-size-fits-all approach to care for the elderly.

Almost all Americans sixty-five years or older are Medicare beneficiaries. That group most frequently visits physicians' offices for the obvious reason that senior citizens suffer illnesses more frequently than younger people. Except in very limited circumstances, physicians now find it legally impossible to contract privately with a Medicare beneficiary. Under Medicare, physicians effectively become agents of the federal government, supplying only those services deemed "medically reasonable and necessary" by the government and its contract insurance carriers.

SEVEN DEADLY SINS

Physicians are required to use specified diagnostic codes in billing for each item or service under Medicare Part B. Medicare will not reimburse a physician for a service that is not billed using ICD-9-CM codes. The program's administrators may impose monetary penalties or exclude a physician from the Medicare program for a consistent failure to use the coding system or the right code.

There are seven principal means by which Medicare officials or insurance carriers can challenge physician claims for reimbursement.

1. Program officials might claim that a physician coded a particular service that is simply "not covered" by Medicare (i.e., miscoding). That might include, for example, billing Medicare for a preventive nutrient IV when Medicare excludes such services from coverage.

2. Program officials might dispute the level of coding assigned by a physician for a patient service (i.e., upcoding). The same office visit, for example, might carry higher compensation if it is for a difficult diagnosis than for a relatively simple one.

3. Officials might dispute the medical reasonableness or necessity of a service based on inadequate documentation in the medical records.

4. Officials could dispute the medical reasonableness based on a perceived excess frequency of administration (i.e., overutilization).

5. They could challenge the propriety of the physician's judgment in supplying a particular service, given the diagnosed condition of the patient (i.e., abuse).

6. Medicare officials could challenge the propriety of physician billing for a service based on an evaluation that the service billed for is in fact ancillary to a service not covered by Medicare.

7. Officials could challenge the propriety of a physician issuing separate bills that Medicare believes should be "bundled" (i.e., submitted in a single, combined bill at a fee less than would apply for separate billings).

In addition, overt instances of fraud and abuse are bases for challenges: for example, physicians billing for services that they never performed.

Each of the seven challenges involves a post hoc second-guessing of a physician's judgment. Without the benefit of direct discussion with the physician or examination of the patient, and often based upon the evaluation of cryptic, hastily written physician notes in medical records, Medicare insurance carriers decide daily to investigate or audit physicians. Those decisions carry with them nonrecoverable costs of tens of thousands of dollars in legal fees for each physician concerned, even those innocent of any wrongdoing. Of course, all such costs must ultimately be recouped from patients in the form of higher-than-market fees for services to nonMedicare patients or from taxes.

One or more of the seven typical challenges to Medicare billings are normally brought to the attention of a physician by the HHS contract carrier a year or more after the bills in question have been paid by the carrier. The contract carriers use sophisticated computer programs to reveal irregular billing patterns. Irregularities include frequent billings at high (and thus more costly) code levels, and frequent billings on a code that is rarely used or appropriate for treatment of a particular condition, and duplicate billings.

When an insurance carrier discovers a billing irregularity, it often dispatches a letter to the physician requesting an explanation and the medical records of the patients concerned. If those records include sufficient documentation to justify the billing, the inquiry will end. If they do not, the carrier may commence a postpayment review that results in an investigation or audit of Medicare records in the physician's possession. Even if physicians perform services in accordance with federal regulations and the policies of the carrier, they may still be required to reimburse the carrier if the records fail to provide what the carrier deems adequate documentary support for treatments and billings. In short, the carrier will presume that the physician lacks an appropriate basis for the Medicare claim and will generally not accept after-the-fact rationalizations or explanations from the physician as a substitute for contemporaneous documentation.

DAMNED IF THEY DO, DAMNED IF THEY DON'T

On the assumption that random medical-record sampling methodology is statistically sound, the carrier will extrapolate from a small sample to all the claims submitted by the physician in calculating an amount required for Medicare reimbursement. In other words, the carrier will assume that if a physician violated one rule in one instance, he or she must have violated the rule in more, undiscovered, cases. Thus, evidence of overpayment in a random sampling often will be multiplied by a factor of 200 percent or 300 percent, and the carrier will demand immediate reimbursement of that multiple sum.

It is not uncommon for an insurance carrier to demand reimbursement of tens of thousands of dollars covering several years of billings, all previously paid by the carrier without question. Those demands must be paid promptly or above-market rates of interest are applied to the unpaid balance—recently rates as high as 13.50 percent. To avoid interest penalties, physicians must pay even if they challenge the carrier's judgment. If payments are not made, the carrier can withhold reimbursement for future claims until it recoups the "overpayment" and the interest penalty. Failure to adhere to the carrier's demands on billing can result in referral of the matter to the HCFA, the HHS Office of Inspector General, the Department of Justice, or the Internal Revenue Service for prosecution. Civil and criminal penalties can result and physicians will be required to pay not only reimbursements plus interest but substantial penalties as well.

Physicians wishing to contest the judgment of the insurance carrier must prepare for a long ordeal that may surpass in years the physician's time in practice or even the remainder of the physician's life. Typically they must first present the matter to a claims examiner for the insurance company. If the examiner insists on reimbursement, the physician can appeal the claim to the company's hearing officer. If the physician does not agree with that verdict, he or she can appeal to an administrative law judge and, after that, to an appeals council within the Social Security Administration, and then to the Secretary of HHS before the case can proceed to a U.S. District Court for an independent judicial review. Exhausting all appeals can take between ten to twenty years. The physician may expend hundreds of thousands of dollars in legal fees and costs. Consequently, most physicians often agree to pay reimbursement demands rather than contest them, even if they believe that the charges against them are unfounded.

The plethora of HCFA regulations and sanctions has made many physicians, particularly solo and small group practitioners, so wary that they avoid submitting bills to Medicare. This "underutilization" practice is regarded by the HCFA as health care abuse because physicians "guilty" of the practice are depriving Medicare beneficiaries of their statutory entitlement to reasonable and necessary care, and are circumventing the Medicare regulatory scheme. If physicians in good faith provide Medicare patients more of a particular treatment than is common, they might be subject to a fraud investigation or audit for "overutilization." If, on the other hand, physicians endeavor to avoid a charge of overutilization by providing the patient with less of a particular medical service than is commonly supplied, those physicians again may be subject to an "underutilization" investigation or audit. In other words, physicians are damned if they do and damned if they don't.

HCFA depends upon fifty-three Utilization and Quality Control Peer Review Organizations (PROs) to advise it on the existence of overutilization and underutilization in prepayment and postpayment audits of physician practices nationwide. The PROs provide insurance carriers with counsel designed to reduce the number and costs of "unnecessary services," ensure that services are provided efficiently, and ensure that services satisfy generally recognized standards of care.

THE HIGH COST OF MEDICARE

For a physician who sees some twenty patients per day, satisfying Medicare's documentation requirements takes approximately two to three hours per day. To minimize the risk of violating the Medicare requirements, physicians have depended heavily on evaluation and management guidelines developed by the American Medical Association in conjunction with the HCFA. The guidelines are, in effect, the industry standard against which the HCFA evaluates the appropriateness of medical recordkeeping. Physicians are thus forced to regard their medical records as correspondence with Medicare. The recording requirements compel physicians to spend time away from patient care to develop written entries in medical records to support every medical decision made in the provision of services to Medicare beneficiaries. According to Jonathan Krantz, author of "Taming the New E&M Guidelines," in the March 1998 *Physician's Management*, one group practice of 284 physicians pays between $130,000 and $195,000 per month simply for dictation and transcription costs associated with Medicare's documentation requirements.

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According to George Witterschein in his article, "Why You're Guilty of Fraud and Abuse" in the March 1998 *Physician's Management*, physicians are subject to "so many regulations applying to every aspect of [their] practice today, [that] it's fairly certain [every one of them is] in violation of something, regardless of how honest [they] are." He adds that a technical violation in the past "wouldn't have mattered very much" but "[t]oday it does."

The extraordinary cost of noncompliance with Medicare regulations is illustrated by the case of Dr. John Lorenzo, DDS. Dr. Lorenzo was accused of fraudulently billing Medicare for $130,719 over a three-year period. Under the False Claims Act of 1986, those damages were trebled to $392,157. That act also requires the court to assess a fine of a minimum of $5,000 per false claim. Dr. Lorenzo was alleged to have submitted 3,683 false claims. The court entered a judgment against Dr. Lorenzo for a total of $18.8 million to satisfy the $130,719 overcharge to Medicare.

In the end, the bureaucratic morass created by Medicare is forcing an ever-greater number of solo and small group practitioners into managed care organizations. Large group practices can afford the copious monitoring of daily coverage determinations, enforcement actions, carrier reports, HCFA orders and announcements, proposed rules, new regulations, and new laws needed to understand and remain abreast of Medicare requirements. Large group practices can also afford to train billing personnel and hire risk managers and accountants to work under the guidance of billing experts and attorneys. Solo and small group practitioners obviously cannot and are thus easier targets.

The regulations are also producing "safe billing" practices based on "safe service" practices that drastically limit freedom of choice in health care for Medicare beneficiaries. Steering between charges of overutilization and underutilization, physicians are increasingly applying a one-size-fits-all approach to Medicare beneficiaries. Recognizing that treatment regimens of a particular frequency and duration are covered without costly inquiries, investigations, and audits, physicians are apt to follow that regimen even if they believe the patient would be better served by a different treatment. Although that practice would be deemed a Medicare abuse or Medicare fraud, it nonetheless goes easily undetected because, by definition, it is the treatment that Medicare bureaucrats expect.

TIGHT ENFORCEMENT

The massive new system for enforcement invites extraordinary abuse. There are no procedural safeguards in the law to protect innocent parties from being wrongly accused or to provide those wrongly accused and penalized with a statutory right to recoup the money they have lost as a result of the investigations, audits, and enforcement actions. Under HIPAA, health care practitioners may be forced to spend tens of thousands of dollars, lose financial opportunities and their reputations, and yet not be able to recover damages when they are finally proven innocent of wrongdoing.

Federal prosecutors typically regard four kinds of activities as instances of health care fraud: (1) fraudulent billing; (2) fraudulently acquiring, prescribing, or distributing prescription drugs; (3) kickbacks; and (4) quackery. Whether authorities pursue a criminal or civil charge depends upon the level of intent that the government believes it can prove. The precise level of intent depends upon which statute is used to bring a case against a practitioner. Under 18 U.S.C. § 287 the United States must prove that the practitioner submitted the false claim "knowing" that it was false. Under 18 U.S.C. § 1001 the United States must prove that the practitioner "knowingly and willfully" made the statement or concealed material information. And 18 U.S.C. §§ 1341 and 1343, concerning mail and wire fraud, do not specify an intent requirement, but the case law has deemed that proof that the practitioner acted "willfully" or "unlawfully" is required.

Under the civil health care fraud provisions a lesser level of intent is required. The most common statute relied upon for civil fraud prosecution is the federal False Claims Act, 31 U.S.C. § 3729 et seq. Under that act, the federal government must prove that the practitioner acted "knowingly." To satisfy that requirement, the government need only prove one of the following kinds of actions:

1. evidence of actual knowledge of the falsity of the claim;
2. evidence that the practitioner acted in deliberate ignorance of the truth or falsity of the information; or
3. evidence that the practitioner acted in reckless disregard of the truth or falsity of the information. No specific intent to defraud is required.

Physicians guilty of criminal fraud and abuse can be barred from Medicare and all other federal health benefit programs and fined $5,000 to $10,000 for each claim submitted that is deemed false and charged treble damages. The penalties imposed for civil wrongful billings include fines of $2,000 to $10,000 per wrongful claim and treble the physician's fee for the services in question.

MEDICARE'S REGULATORY MINE FIELD

Rep. Fortney "Pete" Stark (D-Calif.) is a primary author of two amendments to the Social Security Act that have dramatically restructured the health care marketplace. Unwary physicians, by merely engaging in financial relationships that are completely lawful in all other lines of business, can face substantial financial penalties and exclusion from the Medicare program.

Stark I was passed as part of the Omnibus Budget Reconciliation Act of 1989 (Sec. 6204). It prohibits a physician or an immediate family member of a physician from referring a Medicare patient to a clinical lab that may receive Medicare payments if that physician or family member has a financial relationship with the lab. It also prohibits an enterprise in which a physician has a financial relationship from billing Medicare or a Medicare beneficiary for a clinical laboratory service based on a referral from that physician. Despite frequent difficulties encountered in applying the law to specific cases, the law carries the draconian civil penalty of $15,000 per violation for those who break the law by accident, without intent, and, in cases where intent is present, a $100,000 penalty per violation and exclusion from collecting for treatment of Medicare patients.

Stark II was passed as part of the Omnibus Budget Reconciliation Act of 1993 (Sec. 13562). It expanded the prohibition on so-called self-referrals to include:

1. physical therapist;
2. occupational therapies;
3. radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
4. radiation therapy services and supplies;
5. durable medical equipment and supplies;
6. parenteral and enteral nutrients, equipment, and supplies;
7. prosthetics, orthotics, and prosthetic devices;
8. home health services and supplies;
9. outpatient prescription drugs; and
10. inpatient and outpatient hospital services.

The theory behind the Stark amendments is that physicians might refer patients for treatments or therapies that the patients do not need but that profit the physicians. But the Stark amendments have generated a thick patchwork of complex, intricate regulations. It is virtually impossible for anybody but lawyers experienced in Medicare law to know what relationships between health care providers are legal. Before entering into any financial relationship, regardless of how innocuous it may seem, a physician must seek legal counsel and expend considerable sums of money attempting to determine if it will violate the Stark amendments. When the answer is not apparent, counsel will be forced to solicit an opinion from the Office of Inspector General at HHS. That process requires the soliciting party to pay his or her own legal fees and the fees of counsel in the government. Even then the answer is not considered binding on the agency.

> UNWARY PHYSICIANS, BY MERELY ENGAGING IN FINANCIAL RELATIONSHIPS THAT ARE COMPLETELY LAWFUL IN ALL OTHER LINES OF BUSINESS, CAN FACE SUBSTANTIAL FINANCIAL PENALTIES AND EXCLUSION FROM THE MEDICARE PROGRAM.

If the Stark amendments were applied strictly to every seemingly prohibited relationship, they would destroy much of the medical marketplace while providing no additional protection for Medicare beneficiaries. Thus Medicare has become a major impediment to joint business arrangements that reduce patient care costs as a result of economies of scope and scale.

STIFLING INNOVATION IN MEDICINE

Medicare's bureaucracy and regulations, and the one-size-fits-all treatment regimens they promote, are stifling medical innovation. Historically, advances in medicine spring from off-label uses of medications approved by the Food and Drug Administration, from other forms of clinical experimentation, and from innovative treatments. Physician experience with off-label uses of the heart drug minoxidal, for example, led to the discovery that the drug promoted hair growth by suppressing production of testosterone.

It has often been said that the practice of medicine is as much an art as a science because so much is still unknown about human physiology and chemistry. The bureaucratization of medicine, the transformation of the physician from an artisan and scientist into an administrator of federally approved treatments divorces medicine from that dynamic discovery process that offers the best hope for finding new cures. Medicare discourages physicians from using their discretion in treating patients sixty-five years or older. Customized and innovative treatment would likely yield discoveries that would help physicians better treat older patients in the future.

Ironically, the loss of innovation and personalized care is viewed by many in and out of government to be the fault of market forces. But as the history of Medicare reveals, a free market in medical care for the aged and disabled does not exist and has not existed for decades.

RESUSCITATING MARKETS FOR MEDICAL CARE

There has been some recognition among policymakers of the destructive effects of current Medicare policies. Sen. Jon Kyl (R-Ariz.), for example, sponsored an amendment to the 1997 Balanced Budget Act that would have permitted physicians to opt out of Medicare on a case-by-case basis and privately con-

tract with Medicare beneficiaries for a mutually agreed-upon fee. Unfortunately, under pressure from Rep. Henry Waxman (D-Calif.), the final form of the amendment permitted physicians to opt out of Medicare provided that they not submit any bill to Medicare for any service to any patient for two years. That two-year exclusion neutered a meaningful option for most practitioners. (Sen. Kyl has introduced a bill to remove that exclusion.)

The Kyl amendment does at least focus on the need for a private market for the supply of medical services. Until the Kyl amendment became law the HCFA took the position that any effort by a physician to contract privately with a Medicare beneficiary constituted an act of coercion, a form of Medicare abuse. HCFA vowed to refer physicians who engaged in private contracting to the Department of Justice for prosecution.

But Medicare regulations continue to push solo and small-group medical practitioners into extinction and into large, heavily bureaucratized managed care groups. In the end, Medicare beneficiaries will pay the price. They will lose the customized care, freedom of choice, innovative treatment, and sensitive case management characteristic of the attentive private practitioner of old. Ironically, the medical practices Congress condones in the Medicare program are the very same centralized practices that it vociferously rejected when it repudiated President Clinton's health care initiative.

The underlying problem is that the entire Medicare system is based on the mistaken premise that government funding and management can provide cost-effective and adequate health care, and that bureaucrats far removed from the physicians' offices and the patients can define better in particular cases what is medically "reasonable and necessary" than can attending physicians.

The history of Medicare is one of budgets escalating wildly and one-size-fits-all care that falls far short of the best and highest use of medical resources. To reverse that course and prevent the demise of solo and small-group practices, Congress must wean the nation of Medicare and favor the substitution of private medical insurance, tax-free medical savings accounts, and private contracting between physicians and patients.

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