

## The feds and regulatory abuse

### The Wonkonians strike back

Considering the recent doings of the Gekkonians, by now we might feel quite sympathetic toward the Wonkonian notion that our healthcare problems would best be resolved not by free market economics, but by new and better regulations. We might even be cheered by the fact that the Wonkonians have not just been sitting idly by these past few years, wringing their hands in despair and wishing things had turned out differently. Indeed, this time has been very busy and fruitful for them.

Unfortunately, in practice the Wonkonians threaten to do at least as much damage to our healthcare system, to the doctor-patient relationship, and to fundamental American principles as the Gekkonians. In the service of covert rationing the regulatory imperative, like the profit imperative, takes on a life of its own, and completely overwhelms the healthcare system's mission to operate for the public good. The anti-fraud imperative

In his 1994 State of the Union Address, President Clinton, still fighting hard for passage of his healthcare reform initiative, declared dramatically that that our healthcare system "is riddled with inefficiency, with abuse, with fraud, and everybody knows it." This line gained him a huge bipartisan round of applause. And why shouldn't it? Everybody hates abuse and fraud in healthcare.

The mandate to root out fraud in the healthcare system is an extraordinarily powerful one. Everyone agrees that healthcare fraud is an inexcusable crime, and believes that perpetrators of real fraud should be tracked down vigorously and prosecuted fully.

Until the mid-1990s, however, federal programs like Medicare were very lax about fraud detection, and did not have the will or the systems in place to look for fraud. Thus, it was relatively easy for unscrupulous individuals to get away with even the most obvious fraudulent practices. Many scam artists, organized crime syndicates, and drug-related money launders saw the \$250-billion-a-year doled out by Medicare as a huge pot of unguarded money. This historic laxity with public funds is inexcusable, and efforts to get tough with fraud should be and are a priority.

Unfortunately, the anti-fraud imperative also presents an irresistible opportunity for the Wonkonians to gain control of physicians' behavior, and thus of the healthcare system, through the regulatory process. The anti-fraud program that is being put into place today is virtually guaranteed to prevent doctors, whether they're committing fraud or not, from making the patient's needs their paramount concern. Physicians who don't keep the wishes of the regulators at the top of their list of priorities are risking everything. Why fraud sells

Even aside from the simple fact that fraud is dishonest, deceitful and illegal, there are good reasons that the very idea of healthcare fraud provokes such a visceral reaction in most of us. For one, fraud is expensive. The government traditionally argues that of all the hundreds of billions of dollars they spend each year on healthcare, 10% is siphoned off by fraud. (This oft-quoted figure, despite its now-iconic status, is highly suspect. It originated with a 1992 General Accounting Office report, which clearly identifies the 10% estimate as deriving from an average of the educated guesses of an undisclosed number of unnamed individuals. But at least the guesses are said to be educated, so we will go with it.) Especially at a time when the costs of healthcare are skyrocketing, anything that inappropriately diverts money out of the healthcare system is particularly reprehensible.

Finally, there's an even more compelling reason for much of the angry talk about fraud - namely, the idea that if we don't root out this fraud, we may have to ration healthcare. This notion follows directly from the fact that, as we saw earlier, there are only two ways of reducing the amount of money we spend on healthcare; eliminating waste and inefficiency (e.g., eliminating fraud), or rationing. So if we don't want to ration, we'd better find lots of fraud to eliminate.

In fact, because finding fraud and rationing are inversely proportional (i.e., the more fraud we find, the less rationing we'll have to do), we have a deep and abiding need to find fraud under every rock. We are more than ready to believe there is a lot of fraud out there, and more than ready to use drastic measures to find and punish it.

The Wonkonians, of course, are ready to match our zeal ounce for ounce. Accordingly, fraud has become their focal point for instituting aggressive regulatory action in healthcare.

For physicians like myself, this scene has some very ugly overtones. For there's a substantial difference between trying to identify and root out real fraud, and defining fraud in such a way as to be able to find as much as you can (because the more fraud you find the better off society is). Unfortunately, the Wonkonians' anti-fraud efforts are shaping up to look more like the latter than the former.

Interpreting the anti-fraud activities of the government over the past several years will inevitably be colored by one's own outlook and prejudices. An individual who is inclined to view government as essentially benign and well-meaning can look at the sum total of those anti-fraud activities and conclude that in general they have been reasonably constrained. One who is inclined toward the opposite view of government can look at those same activities and see things that are deeply disturbing.

I am going to argue that, even if you are inclined toward the former view, you need to begin taking into account the fact that covert rationing corrupts everything it touches. The anti-fraud imperative presents to the Wonkonians opportunities for abuse that, under a covert rationing paradigm, become irresistible. The clearest and most common technique employed by Wonkonians in abusing the anti-fraud imperative is one I call the Regulatory Speed Trap.

Note: My view of the Wonkonians' anti-fraud activities has been deeply influenced - though, I submit, not invalidated - by my own personal experience. For those of you who may be interested, I offer my own story - How DrRich Got Radicalized - here . I do this partly to show one example of how the Wonkonians are capable of behaving, and partly in the interest of full disclosure - to give you some indication of my frame of mind as we explore together the ultimate implications of their anti-fraud imperative.

## The Regulatory Speed Trap

Wonkonian methodology is not exclusively embraced by liberals and Democrats. The first easily recognizable application of Wonkonian anti-fraud techniques, in fact, occurred during the Reagan administration, in its crack-down on the defense industry.

When the Reagan Justice Department began its attack on fraud in the defense industry, that industry was slow to realize what was happening to it. The industry did not understand for a year or two that the government had suddenly become deadly serious about regulations it had always treated quite benignly. "Business as usual" had suddenly become felonious behavior. Formerly tolerated activities were pursued relentlessly by federal prosecutors, who liberally applied sweeping new federal statutes - such as mail fraud and money laundering statutes - that were originally aimed at stopping racketeers and drug pushers. By the time the defense industry had fully awakened to the danger - and began protecting itself by instituting expensive "compliance programs," and spending billions on lawyers, consultants and accountants - the government had gained criminal convictions on more than 60 firms and individuals in the defense industry.

In this effort the government recovered a lot of money in fines and penalties that, it said, had been misused. But the defense industry simultaneously began spending huge amounts of new money on regulatory compliance, and that cost was quickly passed on to the consumers (i.e., to that same government). How much the feds actually "saved" at the end of the day is questionable.

Clearly there was fraud in the defense industry, and clearly it needed to be investigated and prosecuted. Is there less corruption now? Perhaps. But it's instructive to note that the famous \$450 hammer incident that set the whole thing off resulted from a silly accounting practice rather than graft. The Army actually paid only \$5 for that hammer. The other \$445 was a standard unit charge for administrative overhead that the Army bookkeepers added to every item they purchased, whether a \$5 hammer or a fifty million dollar tank. Likewise, a good bit of the fraud and abuse that was uncovered during the government's crackdown on the defense industry was not fraud in the classic sense, but rather was misinterpretation of, ignorance of, or simply ignoring regulations that didn't make much sense in the first place.

The methods used by the government in their crackdown on the defense industry suggests a pattern. I call this pattern the Regulatory Speed Trap: The Regulatory Speed Trap: 1) Over a long period of time, regulators promulgate a confusing array of vague, disparate, poorly worded, obscure, and mutually incompatible rules, regulations and guidelines. 2) Individuals or industry, faced with the necessity of having to provide a service despite difficult to-interpret regulations, necessarily render their own interpretations (usually with assistance from attorneys, consultants, and the regulators themselves), and act according to those interpretations. 3) By their apparent concurrence with (or at least by their failure to object to) the providers' interpretation of the rules, over time regulators allow de facto standards of behavior to become established. 4) After substantial time passes, regulators reinterpret (or "clarify") the ambiguous regulations in such a way that the de facto standards now constitute grievous violations. 5) Regulators aggressively prosecute the newly felonious service providers.

It is my contention that this five-step Regulatory Speed Trap represents an easily recognizable blueprint, a virtual modus operandi, for Wonkonians (whatever their political party). At the moment, it is the chief methodology by which they are attempting to wrest back control of the healthcare system.

Basic to the Regulatory Speed Trap is an underlying set of complicated and often contradictory rules and regulations. This requirement, of course, is virtually a given, since regulations over time naturally evolve away from clarity and toward

complexity. Societies have functioned reasonably well despite complex regulations only because traditionally, bureaucrats allow de facto standards to form under their purview, thus preventing paralysis and allowing society to function within the bounds of normalcy.

Fundamentally, what the Wonkonians have discovered is that the tangle of vague regulations underlying this "business as usual" provides them with an ample opportunity to achieve an end that otherwise might be unachievable. By suddenly enforcing strict new interpretations of inherently confusing and traditionally ignored rules ("here is what we meant all along, and you should have known it"), they have found a powerful means of pressing their own agenda - and a means of doing it without all the inconvenience of having to advance a platform, pass a legislative program, or engage in public discourse.

The Wonkonians know that when people have learned to survive within a system of complex and contradictory regulations, then everyone is always guilty of something. All they have to decide is whom they would like to be guilty, then go get them. Whether you're a solid citizen or a felon, therefore, depends largely on whether the controllers of bureaucratic arbitrariness have decided to look in your direction.

## HIPAA tales

One of the things that frightened doctors the most about the Clintons' failed Health Care Reform Act was the Draconian program it proposed for combating healthcare fraud. It offered a very broad definition of fraud, arguably broad enough to include almost every practitioner. And the punishment it offered for perpetrators of fraud ranged from massive monetary penalties to hard time. So the largest sigh of relief when that bill was defeated emanated from doctors, who now thought the threat of overzealous punishment for innocent mistakes had passed.

Many physicians remain unaware to this day that the Health Insurance Portability and Accountability Act of 1996 (HIPAA, otherwise known as the Kassebaum-Kennedy Bill), resurrected many of those same anti-fraud measures, lifting large blocks of language from the Clinton's original plan and making them the law of the land.

The laws themselves are accompanied by a clear mandate for the Department of Justice (DOJ) to make healthcare fraud a top priority. This the DOJ has done; indeed, only violent crime has a higher priority today. Further, in their zealous pursuit of fraudulent physicians, the DOJ has the strong support of the American people. Some of the more notable provisions of HIPAA follow.

HIPAA creates a new series of federal crimes, together called "healthcare fraud." These offenses make it a federal crime to defraud healthcare benefit programs - any benefit program, not just Medicare.

Defrauding health benefit programs may be accomplished by theft or embezzlement, obstructing a criminal investigation of healthcare offenses, making false statements or misrepresentations relating to healthcare matters, using the mail in the act of doing any of the above (mail fraud), or processing the proceeds gained from doing any of the above (money laundering). These crimes are punishable by up to 10 years in prison, or even life in prison if a patient dies as a result of fraudulent activity.

These new statutes give the Feds some very sharp teeth for rooting out real healthcare fraud, such as running phony medical clinics or laundering drug money through medical facilities. Prosecutors will have tremendous leverage in investigating and prosecuting criminals, thanks to the severe penalties mandated by sentencing guidelines for federal crimes, and by their new ability to immediately paralyze suspected violators by freezing their assets.

On the other hand, these new statutes also mean that, potentially, any doctor who makes a simple misstatement to an HMO can land in jail. New monetary penalties for civil offenses

It is likely that pursuing felony charges against doctors will only rarely serve the purpose of the feds. Instead, the feds more likely will be interested in extracting monetary penalties for the violation of civil prohibitions. HIPAA provides for such penalties in spades.

For instance, HIPAA prohibits billing for medical services "that a person knows or should know are not medically necessary." Anyone vaguely familiar with the practice of medicine understands that there are many gray areas in which experts will disagree about what is or is not medically necessary. Ordering a mammogram in a healthy 38 year old woman who thinks she perceives a new breast lump that the physician cannot really feel, for instance, would be considered prudent by some, entirely wasteful by others. HIPAA apparently invites the feds to become the final arbiters of such disagreements, and provides for severe monetary penalties for those who wind up on the wrong side of the decision.

Such penalties include up to a \$10,000 fine plus up to three times the dollar amount of the overpayment for each item. Any more than a handful of violations will be prohibitively expensive for most physicians, thus creating a powerful incentive to "settle" with the feds at the first sign of an investigation. Creation of a coordinated anti-fraud program and account

HIPAA creates a new anti-fraud program that has its own trust fund, the Health Care Fraud and Abuse Control Account, within the Medicare Trust Fund. This provision in effect establishes a powerful new anti-fraud bureaucracy from units of the OIG and FBI, and provides it with all the money it needs to fund its efforts. The fraud trust fund will receive appropriations of up to \$2.5 billion over the first few years, but this is only seed money. The anti-fraud units will be allowed to receive into this account the penalties, fines and settlements they collect as a result of the anti-fraud activities. In other words, what they collect, they keep. Encouraging qui tam suits - The False Claims Act

Qui tam provisions, more commonly known as whistleblower provisions, empower private parties to sue in the name of the United States for "false claims." These provisions were originally enacted during the Civil War to protect the government from bad horse trades, and were largely forgotten until the 1980s. At that time, qui tam provisions were resurrected, strengthened and given new emphasis in the False Claims Act to bolster the DOJ's crack down on the defense industry. Whistleblower suits are now being actively encouraged as a way of finding healthcare fraud. The False Claims Act provides powerful incentives for suing providers - in qui tam suits, the whistleblower gets to keep up to 15% of whatever is collected. As one might expect, whistleblowers often turn out to be disgruntled employees, ex-spouses, or competitors seeking either revenge or to get rich quick. An entire industry has developed to encourage such suits - a simple search on the Internet readily turns up a host of law firms that now specialize in qui tam actions. Establishment of an anti-fraud bureaucracy

Nothing captures the true spirit of the HIPAA anti-fraud provisions more than the creation of a coordinated anti-fraud bureaucracy which gets to keep the penalties, fines and other recovered monies it collects, in order to fund ever greater enforcement activities.

In considering the implications of such an arrangement, one needs first to consider the nature of any bureaucracy. A bureaucracy is an organism that utterly depends on growth to sustain life. Every individual within a bureaucracy, whatever else she may be doing, strives every day to increase the number of people reporting to her. She must do this; it is how her worth is measured, and therefore it is her lifeblood. This growth is accomplished by expanding work roles, or better yet, by subdividing work roles into ever more specialized components, each of which requires its own staff. Bureaucracies accumulate layers as naturally as trees; you can age them by taking core samples.

The anti-fraud program creates a new federal bureaucracy with a unique new twist. Since it keeps what it collects, its rate of growth (i.e., its life-force) will be determined not by how much funding it can wheedle out of Congress, but by how much fraud it can uncover. This arrangement virtually guarantees that its fundamental motivation will not be to root out fraud, but to identify as much fraud as possible. Stamping out fraud, in fact, would be to commit bureaucratic suicide.

Descriptions of how success will be measured within this new bureaucracy reflect this fundamental reality. While lip service is given to wiping out healthcare fraud, the real enthusiasm within the anti-fraud units comes from their projections of the expected rate of return from their anti-fraud efforts, which is expected to be between \$10 and \$23 for every dollar spent. One suspects they will do whatever is necessary to achieve and maintain these projections.

If further incentive were needed, the anti-fraud bureaucracy can expect to enjoy significant public support for a long time. Especially in light of the notion that the more fraud we uncover, the less rationing we'll have to do, it will be exceedingly difficult to incur the wrath of the people by uncovering too much healthcare fraud.

To go along with these powerful motivating influences, the anti-fraud bureaucracy has been granted sweeping investigative and enforcement powers. It has been given broad subpoena powers. It can acquire virtually any and all financial and medical records in existence, and can immunize those supplying the records (to assuage their fear of breaching physicians' or patients' confidentiality). It has the ability to freeze the assets of individuals suspected of healthcare fraud. Providers suspected of fraud can now be threatened with tough new federal sentencing guidelines for "white-collar" crimes. Federal prosecutors will routinely add to their list of charges such white-collar crimes as mail fraud and money laundering, both of which carry extraordinary sentences and have extremely broad applicability. Both of these charges could apply, for instance, if a provider mails to an HMO a bill containing a misstatement, then deposits the resultant check in a bank.

The anti-fraud bureaucracy will not really want to send very many doctors to jail, since jailing perpetrators will not directly benefit their anti-fraud account and thus will not contribute to their continued growth. They'll want to send just enough to jail to make their point, then they'll be happy to negotiate settlements with most of the other doctors who come under their scrutiny. (Most doctors who find themselves under the spotlight will be strongly incented to settle since, given the

confused state of the regulations, it is almost inconceivable that the feds would come up entirely empty-handed after a reasonably thorough audit of any physician's records.) The settlements themselves are likely to be astronomical in magnitude, given the extraordinarily high fines and penalties stipulated for healthcare abuse.

Meanwhile, the False Claims Act will assure that the anti-fraud bureaucracy has many leads to pursue for a long time to come.

How are the anti-fraud regulations being used?

Anyone, such as your author, who may be inclined to criticize the anti-fraud activities of the government as overzealous, runs into a problem right away; namely, the existence of healthcare fraud is undeniable, it is inexcusable, and vigorous efforts to eliminate it are appropriate. The provisions of HIPAA and the FCA can easily be viewed as simply giving prosecutors the weapons they need to go after the criminals that are robbing all of us.

One way to examine whether the anti-fraud imperative is doing good or doing evil is simply to look at how these regulations are applied. Are they being used to seek out and destroy those providers who are truly guilty of fraud in the classic sense (that is, the intentional and willful effort to procure funds illegally)? Or are they being used as a Regulatory Speed Trap, to hound and intimidate the more typical, generally honest practitioner who is confused about the regulations but who dearly wants to avoid even the appearance of impropriety? If our healthcare system was operating anywhere but in the LLQ, where covert rationing is king, and where controlling physician behavior is Job One, the former behavior is almost certainly the one we would see. As it is, however, we are indeed operating in the LLQ, and all too often we see the latter. Lack of clarity, and lack of desire for clarity

If the objective of an anti-fraud campaign were truly to eliminate fraud from the system, then the enforcers would want the rules and regulations to be simple and clear enough that honest, well-intended people would know how to behave.

Admittedly, this is easier said than done. It is the nature of regulations to become constantly more complex over time. "Thou shalt not kill," for instance, is a pretty straightforward regulation, but civilization cannot leave it alone. Within a few thousand years we find ourselves factoring in issues such as warfare, capital punishment, late-term (or early-term) abortion, frozen embryos, withdrawal of life-support, physician-assisted suicide, the insanity plea, the definition of "brain-dead," and cloning. Pretty soon deciding (in a regulatory sense) whether it's okay to kill, or whether one is even killing, becomes next to impossible.

So it is certainly unfair to indict the Wonkonians for failing to provide us with a simple code that immediately clarifies all healthcare regulations. Insisting on the impossible is never very useful. Health care is inherently a muddy field of endeavor, and the regulations that have evolved to govern healthcare are necessarily even murkier than, say, banking regulations.

On the other hand, especially when they're talking about punishing violators with massive financial penalties or jail, it is fair to expect the Wonkonians to clarify specific areas of regulatory confusion. They should act as if they are interested in helping the essentially honest to stay on the straight and narrow, not in entrapping them.

In this light, it is instructive to note that when Congress was deliberating on HIPAA in the mid-1990s, the only fraud-related provision that produced any significant debate whatsoever was the stipulation that the government should provide "guidance" to providers regarding the legality of certain proposed activities. Under this contentious provision, providers could seek advice prospectively from the OIG on, for instance, what constitutes prohibited remuneration, or whether a proposed partnership structure meets safe harbor provisions under the anti-kickback law. Providers would be saying, in other words, "We don't want to break the law, we want to be solid citizens. Here's what we propose to do. If we do this, will we be in compliance with the law?"

The Clinton administration, the DOJ, and the OIG vociferously opposed this seemingly reasonable proposal. Their objections were based on the fear that issuing opinions before the fact would impinge on their ability to subsequently prosecute cases. This argument seems to complain (revealingly) that clarifying the regulations would lead to more compliance and therefore less fraud to uncover. In the end, the advisory opinion requirement became part of HIPAA. But even then, President Clinton himself called for rapid repeal of these provisions just a few days after signing the bill into law. It thus seems apparent that the Wonkonians do not consider the clarification of healthcare regulations to be a worthwhile endeavor. Instead it appears that any requirement to do so is seen as being burdensome and counterproductive to their true goal.

In any case, providers counting on these advisory opinions to keep them out of trouble are likely to be disappointed. In actual practice, submitting a question for an advisory opinion to the OIG is time-consuming and expensive, and when the reply is finally obtained it can be less than helpful. The OIG routinely stipulates, for instance, that its opinions are binding only for the individual entities requesting the particular opinion in question, and cannot be relied upon by any other individual or entity; that its opinions are stipulated to be strictly limited to the facts described therein, and apply only as

long as all of the material facts have been fully, completely and accurately presented and the arrangement in practice fully comports with the information provided; that no other party may introduce any advisory opinion into evidence in a legal proceedings; that no other federal or state agency is bound by these opinions; and that an advisory opinion cannot be applied to any other arrangements which appear similar in nature or scope. Finally, as the kicker, the OIG reserves the right to "reconsider" the questions and issues raised in its advisory opinions at any time, and modify or terminate those opinions retrospectively.

This is not exactly clarity at its best. In fact, the only thing that seems clear is that the regulators are failing to display much interest in giving providers a line of sight to regulatory compliance. How effective is the new anti-fraud bureaucracy?

This is a very difficult question to answer, as there are no metrics by which to judge its efficacy. There are ways to estimate the number of fraud cases brought, and the amount of money collected, by the fraud control activities. But since we really don't have any idea of the true baseline level of fraud, judging the impact on the overall amount of healthcare fraud is not possible. Effectiveness of HIPAA anti-fraud measures

The number of civil filings and criminal indictments more than doubled (from approximately 300 cases to nearly 700 cases) in the first five years after HIPAA became law.

Periodically and in accordance with federal regulations, the General Accounting Office (GAO) will perform an audit of the Health Care Fraud and Abuse Control Program (HCFAC). In its most recent report, which covers fiscal years 2002 and 2003, the GAO notes that HCFAC had given themselves credit for saving the healthcare system \$19.9 billion in 2002 and \$20.8 billion 2003 as a result of their anti-fraud activities. However, the GAO's audit could only account for savings of \$1.5 billion (2002) and \$3.9 billion (2003). Thus, HCFAC had exaggerated its own efficacy by more-or-less a factor of 10. Further, the GAO notes in its report (more than somewhat disapprovingly), that while it had previously asked both the HHS and the DOJ to formally notify Congress of the fact that HCFAC's own reports have not been entirely accurate or timely, HHS and DOJ had thus far declined to do so. (It is worth noting that if physicians had taken accounting liberties anything like those taken by the regulators themselves, they would be paying triple damages, huge fines, and negotiating plea bargains to stay out of jail.)

So, in summary, it appears that the HCFAC effort has resulted in a doubling of legal filings against providers, and in the recovery of an additional few billion dollars a year. Is this good? Sure it is. Is it a resounding success? It is very hard to say, of course, but given that, officially, 10% of the \$1.2 trillion we spend on healthcare is said to be wasted on fraud, recovering a couple of billion here or there does not seem all that impressive. If it were sufficiently impressive, perhaps the HCFAC folks might not have felt compelled to inflate tenfold the savings they actually generate. Effectiveness of the False Claims Act

It is even more difficult to estimate the amount of "savings" to the healthcare system that the FCA has produced. Since many FCA actions take the form of lawsuits brought by private citizens and are litigated by private law firms, a lot of the "winnings" are not returned to the healthcare system. The FCA industry, however, has seen robust growth. While in 1991 only \$70 million was recovered in qui tam lawsuits, by 2001 \$1.6 billion was recovered; the majority of this recovery came from suits related to healthcare fraud.

The FCA appears to have become the government's vehicle of choice for prosecuting healthcare fraud cases, either by initiating actions themselves, or joining qui tam suits brought by individuals. The most notorious and possibly most illustrative of FCA actions brought by the feds is the Physicians at Teaching Hospitals (PATH) audit. The methods the feds are willing to use and the "attitude" they display as they pursue fraud claims are nicely illustrated by this example. The PATH audit - a case study

In mid-1996, the feds adopted a new set of regulations governing how physicians should bill Medicare for services performed in conjunction with medical residents (i.e., medical trainees) in teaching hospitals. These new regulations stipulated that, in order to legally bill Medicare for a service provided to a patient, an attending physician must either provide that service directly, or must be physically present when the resident physician performs the service. Furthermore, the new regulations spelled out strict requirements for how the attending physician must document in writing that such physical presence had occurred.

Almost at the same time, the OIG announced a series of nationwide audits of how well physicians at teaching hospitals complied with those rules - the Physicians at Teaching Hospitals (PATH) audit. The PATH audit would cover the six-year period (i.e., the entire statute of limitation period) from 1990 through 1995.

Alert readers will spot the problem right away - the audit was to be conducted to check compliance with rules that had not yet been promulgated.

Prior to 1996, the rules governing when a teaching physician could bill Medicare for patient services were extremely ambiguous. The most authoritative document prior to the new rules was Intermediary Letter 372 (IL372), written in 1969.

IL372 appeared to require the physical presence of the attending physician for billable services only "when a major surgical procedure or a complex or dangerous medical procedure is performed." Regarding the required documentation of billable services, IL372 was ambiguous. One paragraph states that adequate notes documenting these billable services could be "either written or countersigned by the supervising physician." However a different paragraph in the same letter says that billable services must be "substantiated by appropriate and adequate recordings entered personally by the physician. . . ." (This apparent discrepancy is just one example of how even a single regulatory document can give conflicting advice on a key issue.)

Over the years the ambiguous nature of these documentation requirements was acknowledged by teaching physicians, medical schools, and the government, all of which talked about (some day) initiating clarification efforts. But life must go on, so a de facto standard of behavior was established. In most teaching institutions that standard was as follows: for routine (i.e., non-surgical and non-complex) services performed by residents, it was okay to bill as long as those services were clearly overseen by an attending physician. Further, the attending physician's countersignature of the resident's note was considered adequate evidence of such oversight (and of acceptance of legal responsibility for the resident's actions).

This de facto standard was adopted not only as a matter of convenience, but also as a vital part of the teaching process. In training good physicians, it is important to allow trainees some degree of independence - with oversight, of course, by an experienced clinician. A resident must learn to assess patients' problems and to reach tentative clinical decisions on his own. Committing those assessments and decisions to writing (in the form of a "progress note" in the patient's medical record) forces him to carefully consider all the important clinical parameters, and to concisely summarize the patient's clinical problems, the objective findings, the assessment, and the plan for diagnosis and therapy. The attending physician, after performing her own assessment of the patient, then discusses the case with the resident and reviews the resident's progress note. If there is a deficiency in the resident's analysis, it is corrected. If there is a discrepancy of opinion regarding the diagnosis or the management of the patient, the discrepancy is discussed and a resolution negotiated (keeping in mind that the attending physician has the last word). The attending physician's countersignature of the resident's note (most often with an addendum that makes corrections or underscores issues of importance) indicates that all of the above has occurred.

For decades this had proved to be an effective method for both patient care and for optimizing the training of physicians. Thus, the de facto standard was adopted not only because it appeared to comply with IL372, but also because it was philosophically the right thing to do.

When the new "clarified" regulations became effective in June, 1996, the resident's independence was significantly reduced. Under the new guidelines, the attending physician now has to be present for even routine patient services. Further, only the attending physician's own progress note can legally describe those services. The need for the attending physician to write her own extensive progress note (essentially duplicating the resident's note) automatically devalues the efforts of the resident, and also reduces the attending physician's motivation (and time) to carefully critique the resident's efforts. This requirement dilutes the opportunity for teaching and learning. But rules are rules, especially when violating them constitutes a felony of the federal variety. So, while most teaching physicians viscerally disagreed with these new regulations, at least they were clear enough.

The obvious problem with the PATH audit was that not only did it apply these newly "clarified" regulations retrospectively, to events that took place during a time when the existing rules were ambiguous and unclear, but also the new rules require actions that stand in clear and marked distinction to the de facto standards that had been used in the nation's best teaching institutions for decades prior to 1996.

The audit "model" used by the feds in their PATH initiative, therefore, was none other than the Regulatory Speed Trap. The first four steps of the Speed Trap were successfully completed with the publication of the new 1996 regulations, as follows: 1) formulation of ambiguous regulations; 2) over decades, establishment of de facto standards; 3) long-term tacit acceptance of those de facto standards by the feds; and 4) sudden reinterpretation (i.e., "clarification") of the ambiguous regulations.

Up to this point, of course, the motives of the feds might still have been viewed as being essentially benign. It was only the aggressiveness of the retrospective application of the new regulations (the fifth and most telling step of the Regulatory Speed Trap), that revealed the true motivation of the OIG.

That level of aggressiveness became apparent immediately. The first audits occurred at the University of Pennsylvania and Thomas Jefferson University. After conducting these audits, the OIG extracted settlements from these two prestigious institutions of \$30 million and \$12 million, respectively. While these universities paid a lot of money to settle, they did so - as they themselves made clear - only because they faced hundreds of millions of dollars in fines, having submitted millions of claims over the 6 years in question, that were subject to fines of up to \$11,000 per each, plus triple damages. Settling, even at extortionate rates, was their only real option.

The amount of these settlements grabbed the attention of the medical academic community, which then listened in

stunned silence as the OIG explained its plan for the broader PATH audit (both in writing, and in a particularly chilling videotape, dutifully viewed by your humble author, that was distributed to academic medical centers). Those plans were, to say the least, extremely intimidating:

In this menacing video, the OIG intoned the following: All academic centers in the U.S. would be audited during the next year or so under the PATH initiative. Medical centers would have a choice between two methods of conducting the audit, neither of which was attractive. "PATH 1" would involve the office of the OIG itself conducting an on-site audit. The potential danger here, the OIG pointedly warned, was that many times federal auditors will notice things - peripheral issues aside from the main event - that will cause one thing to lead to another. Once a federal auditor arrives at an institution, the OIG implied, no telling what other Medicare violations he/she will find, or when he/she will leave. "PATH 2" would allow the teaching hospital, at its own expense, to engage an external auditing firm that is acceptable to the OIG. However, the hospital electing this method would surrender certain legal and accounting privileges (including the attorney-client privilege), and would be required to see that a representative of the OIG be present at all meetings related to the audit.

Whether a hospital elected to be persecuted under PATH 1 or PATH 2, only approximately 100 patients' charts would actually be audited from each hospital. The "error rates" in billing (based on the new standards retrospectively applied) would be determined from this sample, and extrapolated across all the billing that the hospital had done during the six-year period in question, in order to calculate the total amount "overbilled." (Any underbilling that might be discovered during the audit, of course, would not be taken into account.) The False Claims Act would then be invoked to allow the OIG to recover up to three times the calculated amount the hospital had overbilled during this six-year period. Because the total amount a hospital would likely owe the government, under this process, could easily run to the hundreds of millions of dollars, many institutions, the OIG suggested, may want to consider an early settlement, just as the two index institutions had wisely decided to do. (In the OIG's defense, he did not, for emphasis, crush anybody's skull from behind with a baseball bat during the video.)

Step five of the Regulatory Speed Trap thus was clearly fulfilled.

The Association of American Medical Colleges and other organized groups appealed to reason, and asked the OIG to desist. Two former Secretaries of HHS (Bowen and Sullivan) wrote in a letter to Congressman John Porter (R-IL) about the unfairness of the PATH audit, that, "Really since the inception of the Medicare program HHS has had a difficult time in setting forth a bright line standard that could be used to separate the services provided by an attending physician that are strictly teaching in nature and those that involve care to a specific patient. . . . Given the contorted history of [IL372] through the years, it would appear to be an unlikely candidate for an OIG investigation."

In a 1997 response to the president of the AAMC, even Harriet Rabb herself, General Counsel of HHS, said that "the standards for paying teaching physicians under Part B of Medicare have not been consistently and clearly articulated by HCFA (Health Care Financing Administration) over a period of decades." However, she then went on to defend the PATH audit, which continued unabated.

If anyone working in a teaching institution at the time had any doubt about the Wonkonians' ultimate intentions regarding their pursuit of healthcare fraud, the PATH audit should have clarified those doubts. The feds were not fooling around. They went out and got themselves the weapons, as well as the public support to use those weapons, and then they set about using them, brazenly, arrogantly, and to the fullest extent possible. Their goals seemed to be a) to extract as much money as they could from providers, and b) to coldly intimidate as many doctors and hospitals as possible. The Wonkonians were saying, to great effect, "You think the Gekkonians are running things? Think again."

It was becoming increasingly difficult for physicians to know exactly to whom they were supposed to sell their patients out.

#### Post-PATH

In 1998, largely as a result of the PATH audit, the American Hospital Association (AHA) sent a letter of desperation and surrender to the Secretary of HHS and the OIG, in which, noting that almost 5000 hospitals were already under siege by federal law enforcement and investigative personnel, they pled for a temporary cease-fire on FCA-based whistleblower actions. The climate of accusation and allegation, the AHA said, was out of control. They prayed for a six-month moratorium on further actions under the FCA, and offered to use the time to initiate a joint effort with the government to institute voluntary compliance programs, and to establish clear criteria for distinguishing simple errors from genuine fraud. They, in effect, were asking for relief from entrapment, and wanted to have the new rules clearly explained to them so they could avoid taking any actions that the feds could construe as fraud.

Now, when federal investigators had gone after the defense industry in the 1980s, largely using the same FCA powers, they first conducted a sufficient number of prosecutions to get the industry's attention, then squired the industry through the development of an adequate compliance program, then finally moved on to something else (many of these

investigators moved on to healthcare, as a matter of fact). In 1998, the feds had now reached that same point with the healthcare industry. They had rapidly gotten the attention of the alleged perpetrators of fraud, and these malefactors were now begging for the same variety of relief the defense industry had been given.

If the real motivation of the Wonkonians was to reduce fraud in healthcare, and not to establish a system where they could find as much fraud as they wanted to, they would have again declared victory at this juncture and "helped" the providers learn to become better citizens. In 1998, however, the response of the feds was a flat "no." In fact, the OIG responded by vociferously attacking the AHA's request, indignantly claiming that to accede to their wishes would cripple the government's anti-fraud initiatives.

The AHA didn't give up. They next lobbied Congress for relief, and found sympathetic members of the House of Representatives willing to sponsor a bill that would prevent HHS from abusing the provisions of the FCA. As a result, later that year the OIG suddenly reversed field and issued a set of "best practice guidelines" on implementation of FCA actions.

These guidelines do not have the force of law; they are just guidelines that HHS may or may not choose to follow. But the guidelines achieved their purpose, which was to induce the House to drop their proposed bill that would have limited the power of HHS. Since that time, arguably, large-scale federal initiatives as egregiously abusive as the PATH audit have not occurred. The Wonkonians began laying low, however, too late to keep objective observers like you and me from seeing their real intentions. The underlying infrastructure and the regulations that permitted the PATH audit remain entirely intact, and can be picked up again when the time is right. Criminalizing healthcare - the downside

Nobody can argue that it isn't important to reduce fraud in the healthcare system; and an argument can certainly be made that in order to fight that fraud effectively, the kind of power the government has gathered to itself is reasonable and necessary. Furthermore, there can be little doubt that the Wonkonians' anti-fraud initiative has successfully reduced the amount of actual fraud in healthcare. But unfortunately, it also appears evident that when all that federal power is applied within an environment of covert rationing, the ostensible primary objective - fighting fraud - sometimes is relegated to a secondary status. At least occasionally, the patterns of behavior displayed by the Wonkonians more nearly fit a goal of intimidating and controlling those who work in the healthcare system - and even of hastening the looming bankruptcy of that system.

Many who work in the healthcare industry - like those who worked in the defense industry in the 1980s - have been stunned by what the feds consider as constituting fraud, and by the lengths to which they are willing to go in prosecuting that fraud. In an effort to avoid committing inadvertent fraud, the healthcare industry is now spending billions of dollars on compliance efforts, efforts vastly complicated by regulations that are exquisitely opaque, constantly changing, and retrospectively applied. Virtually all of the money being spent on reducing this compliance risk ultimately comes from health insurance premiums, which means that a good bit of this money is being siphoned away from the care of patients. Whether at the end of the day the anti-fraud initiative is adding to or removing dollars from actual healthcare is at best arguable.

That their anti-fraud efforts may be inducing the waste of even more healthcare dollars ultimately plays right into the hands of the Wonkonians. Forcing doctors, hospitals, Gekkonian health plans and the biomedical industry to spend billions on compliance programs (especially since such expenditures may not substantially eliminate the risk of being hit with a fraud accusation), and making it ever more difficult for doctors to remain participants in Medicare (thus creating growing numbers of angry Medicare patients), will only hasten the day when the whole system is so bankrupt and broken that government-controlled healthcare seems like the only viable remaining option.

The Wonkonians have amply demonstrated their zeal for using the Regulatory Speed Trap to bring physicians under their sway, and to the extent that the public and Congress continue cheering them on, there is little reason for them to stop. While they clearly pushed things a bit too far with the PATH audit (to the extent that they briefly awoke the interest of Congress), they seem to have titrated their activities more effectively since then, and it is unlikely they will allow their pursuit of physician fraud to accelerate to orgiastic proportions, at least for the foreseeable future.

They are being more subtle than that. When a shark is preying on a school of mackerel, it does not allow its feeding to become so frenzied as to disperse the school. It makes quick, terror-inducing strikes, grabs a few fish, then retreats, allowing the mackerel to re-form in a semblance of serene, piscatorial calm. The shark and the Wonkonians are thinking long-term.

I believe physicians are resolving themselves to a mackerel-like mentality. "The shark probably won't get me. But it's always out there, and it's always hungry. It will continue to strike now and then, viciously and at random. I'll try to stay in the middle of this school, away from the edges, and do nothing to draw attention to myself. And I'll always be alert for it, always watching, even as I try to fulfill my own mackerel-needs."

I can almost hear a few of you dear readers saying something like, "Nuts to the doctors. Couldn't happen to a nicer

bunch."

I'll be the first to admit that doctors have - by their historically exuberant embrasure of a runaway Tooth Fairy healthcare system, and more recently, their wholesale abandonment of the doctor-patient relationship - lost much of their moral authority. It is partially the ostentatious and avaricious behavior of many doctors, the outright fraudulent behavior of some others, and the inability or unwillingness of the profession to police itself, that has helped to render the feds' fraud argument so persuasive in the first place. So if doctors have to rely on the sympathy of the public to relieve them of the burden of excessive fraud and abuse charges, they'd better pack enough socks, underwear and toothpaste for 5 to 10 years.

The reason the general public should be concerned is not because of what is happening to the poor doctors. It is because of what is happening to them. For what can more effectively separate the interests of doctors from the interests of their patients than the threat of a career-ending federal conviction, loss of all personal assets, and hard time in a federal prison? When patients are discussing their chest pain with their doctors, or asking advice about mammograms, avoiding fraud is not what they want the doc to be thinking about. Consider - what is a physician to do when faced with a decision on whether to offer a medical service he believes is needed, but for which he suspects the insurer won't want to pay? In the old days a disagreement with the payer over such a service might result in, at worst, a few unpleasant telephone exchanges and having to return a contested payment. Now it might result in federal charges. Reasonable discretion, therefore, dictates that the doctor simply withhold that medical service.

The physician's wariness of the feds is not merely an occasional thing, either. It is rapidly becoming an ever-present and pervasive concern; as important to every healthcare decision as avoiding the scrutiny of the IRS is to every financial decision. The major impact of the E&M regulations, in fact, is to guarantee that the physician will spend time thinking about how to avoid a fraud rap during each and every encounter with a patient. It's the law.

Once again we see the futility of trying to avoid the rationing of healthcare by eliminating waste and fraud. Whether these efforts are made through market forces or through federal regulations, the result is simply to increase (not decrease) rationing. Just as the HMO coerces physicians to withhold services by threatening the loss of income or the loss of jobs, the anti-fraud initiatives coerce physicians to withhold services by threatening crippling fines or jail terms. Either way, the physician is coerced and intimidated into relegating the needs of the patient to a secondary position, in order to mollify a master who has amply demonstrated both the ability and the willingness to ruin them if they behave otherwise.

What we have to do, we patients and doctors, is to figure out how to rededicate ourselves to our commitment to each other. Until we do, the wedge wielded by the anti-fraud and abuse crowd will continue driving us apart, leaving each of us to flounder on our own in a healthcare system that has marginalized us, commoditized us, and criminalized us.

Next: Covert rationing and end-of-life healthcare