STATEMENT OF ROBERT P. CHARROW, ESQ.

BEFORE

THE UNITED STATES SENATE

SPECIAL COMMITTEE ON AGING

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MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

I am deeply honored at being asked to share some of my experiences, perspectives, and thoughts with the Committee. Health care—the way it is provided, the way it is regulated, and the way it is funded—is of critical importance to most Americans. As our population ages, concerns about the quality, availability, and affordability of health care will only grow. These concerns with attendant political and societal pressures will focus primarily on Medicare—a system designed in 1965 and largely modeled after the way medicine was practiced in that era.[1] Our attitudes towards medicine and government, our demographics, and even the way medicine is practiced—both scientifically and structurally, are remarkably different now than they were three decades ago.

Notwithstanding these changes, structurally, Medicare has remained fundamentally unaltered. Indeed, many would argue that while the private sector has achieved greater efficiency, Medicare has gone in precisely the

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[1] The Medicare and Medicaid programs were enacted in 1965 as Titles XVIII and XIX of the Social Security Act, respectively, and began

opposite direction. The dissonance between what we demand from a medical system and the way Medicare operates has given rise to regulatory burdens and inefficiencies that frustrate all—hospital administrators, family physicians, and Medicare beneficiaries alike.

I am here to share my perceptions about Medicare and some of the troubles that it faces and the issues that need to be addressed. I am also here as a penitent, someone who is partly responsible for those troubles. It is a responsibility that I share with many in this room and with many—indeed virtually all—political appointees at HHS of both political persuasions who had responsibility over HCFA or CMS, as it is now known.

I would like to focus on three highly inter-related areas—complexity, enforcement, and accountability. I believe that the system has become too complex, enforcement too arbitrary, and accountability too lacking. As a result, providers, out of fear, are spending significant sums on administrative expenses that are not cost justified and those administrative costs ultimately mean that less money is spent on health care. This is good for lawyers and accountants; it is decidedly not good for those in need of quality health care.

I. Medicare is Too Complex for Mere Mortals to Comprehend

The Medicare statute is more than 400 pages long and is not a model of clarity. In theory, HCFA is supposed to issue regulations to give life to the

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operation on July 1, 1966. *See* Title I, Social Security Act Amendments

statute. The regulatory process, though, takes years, and usually what you end up with is a rule that is comprehensible and accessible only to lawyers. Medicare's regulations take up about 1,300 pages in the Code of Federal Regulations. But that's only the beginning. On top of the statute and regulations—all of which are accessible to the public, but essentially unreadable—are Medicare issuances, publications, program memoranda, manuals, Inspector General Alerts, advisory opinions, local medical review policies, coverage decisions, Departmental Appeals Board rulings, and so on. All told, the 400-page statute has given birth to more than 100,000 pages of secondary Medicare laws, guidelines, issuances, and the like. All of these affect the level of services and how they are delivered. Yet, little of this information is readily available or easily understandable. No beneficiary and no small provider has any hope of understanding most of these materials. Many federal judges have, at one time or another, labeled Medicare as "arcane" and "incomprehensible." The Medicare system is simply collapsing under its own regulatory weight.

Because the system is so difficult to navigate, doctors have to employ a bevy of staff solely to file claims, double check to make sure that they are using just the right code, and then follow-up with the carrier. Any time a physician wants to do anything out of the ordinary, he or she must call an attorney. This costs money; these costs are eventually passed on to Medicare.

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of 1965, Pub. L. No. 89-97, 79 Stat. 286.

How much does the systems' complexity cost? We have no idea and that is a sad irony.

Before the government buys a new $2 billion weapons system, it tests the system for years and requires the contractor to make necessary design and manufacturing changes. Before Congress passes amendments to Medicare, or before HCFA implements a regulatory initiative that could cost significantly more than $1 billion and will affect hundreds of thousands of providers and millions of beneficiaries, does either do any "testing?" The answer is usually "no." In short, we are making changes to a $200 billion system without first testing the impact of those changes.

II. Medicare's Enforcement Scheme Vests Too Much Authority in the Executive Branch

The system is extraordinarily complex. That, in itself, costs money. However, the amount spent by providers on administration may be out of proportion to what is required. Why is that the case? In large measure, I believe that these potentially large administrative costs are amplified—and some would say driven—out of a belief that if a provider errs then he, she, or it will be severely punished.

This fear of punishment—whether realistic or not—has a rational basis. Owing to linguistic lapses on the Congress, far too much authority has been vested in the Executive Branch—on two levels. First, broadly speaking, Congress in the Inspector General Act, authorized the IGs to ferret out

"fraud" and "waste," and by implication, abuse."[2] Second, many of the enforcement statutes, *e.g.*, anti-kickback, are so amorphous that they effectively vest extraordinary authority in OIG and HHS.

Everyone would agree that fraud is evil, is criminal, and should be punished decisively. Moreover, fraud is relatively easy to define. We not only know it when we see it, but we can articulate why some conduct is fraudulent and other conduct is not. For example, the hospital chain that billed Medicare for treating patients who were never hospitalized was committing fraud. Or the physician who bills Medicare for a long office visit, when in fact he saw the patient for less than three minutes is also committing fraud. The federal laws prohibiting fraud apply across the board from defense contractors to universities to hospitals, physicians, clinical laboratories and even beneficiaries. Interestingly enough, although we have been led to believe that healthcare is rife with fraud, in fact the numbers indicate to the contrary. The Inspector General, for instance, reports having recovered less than $500 million on account of all types of improper conduct; when compared to the about $400 billion spent on Medicare and Medicaid, the actual percentage of measurable fraud is relatively small—medicine is about 99 and 44 one-hundredths percent pure; so far, so good.

But what is "waste and abuse." Those are not legal terms. They do not differentiate between what is legal and what is illegal. Rather, they

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[2] *See* section 2 of the Inspector General Act of 1978, Pub. L. No. 95-452,

differentiate between one administration's necessarily fleeting views of what is good and what is not good. This is especially the case in health insurance programs—including Medicare--where one man's "waste and abuse" is another man's "medical necessity." It seems rather ironic that as both Houses prepare to enact some form of a Patients' Bill of Rights which would give doctors and patients greater latitude in deciding what is "medically necessary," the largest insurer—Medicare—is doing just the opposite.

Second, a number of Medicare-specific laws are too broad. In one case, that breadth is due more to a failure of language than anything else. I am talking about Medicare's unique anti-kickback law.

Like fraud, most of us consider that kickbacks should also be outlawed. The physician who accepts a 20% kickback in exchange for ordering a specific battery of tests from a specific clinical lab should be treated no differently than the defense contractor that gets secret kickbacks from its subcontractors. Kickbacks in Medicare are bad—they promote overpayment and over-utilization and inappropriately interject financial considerations into medical decisionmaking. The anti-kickback law that governs federal healthcare programs, though, is far broader and procedurally distinct from the one that applies to the other sectors of the government. In fact, these laws are so expansive that they prohibit conduct that is perfectly legitimate in other settings.

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§ 2, 92 Stat. 110.

Under the anti-kickback statute as written, for example, it is illegal for a physician to sell his practice if the sale includes "goodwill." No arrangement—whether it is a complex merger, acquisition, joint venture, or a simple purchase of hospital or medical office equipment—can be seriously considered without evaluating its anti-kickback implications. Moreover, the healthcare anti-kickback laws vest extraordinary discretion in the Office of Inspector General to modify, to interpret and to apply these already broad laws. The law effectively has transferred significant healthcare policy decisionmaking from the Congress and the political appointees to career OIG attorneys with no formal training in medicine and little in developing or testing cogent policy.

How did all of this happen? Congress first enacted an anti-kickback law for Medicare in 1972;[3] that law, however, was somewhat ambiguous. To eliminate that ambiguity, Congress in 1977 amended the law and broadened its coverage.[4]

The new law went beyond prohibiting kickbacks and other forms of fraud, and sought to use the threat of prosecution as way of regulating

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3 *See* section 242(b), Social Security Amendments of 1972, Pub. L. No. 92-602, 86 Stat. 1419-1420.

4 *See* Medicare-Medicaid Antifraud and Abuse Amendments of 1977, Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1179-1181 (1977). In lieu of the phrase "kickback or bribe," as used in the 1972 law, the amended version banned "any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to induce a referral. 42 U.S.C. § 1396h(b)(1)(1977)(emphasis supplied).

"abuse" and "waste," terms that—as we noted above—have no real legal meaning. Not unexpectedly, the new law proved to be too broad, effectively outlawing all sorts of legitimate business arrangements: a physician could not sell his practice, a physician could not sublease space in his office to another physician if that sublessee referred patients to the owner and so on. To cure this problem, Congress in 1987, enacted legislation that authorized the Secretary of Health and Human Services, with the approval of the Attorney General, to develop so-called "safe harbors."[5] The theory was individuals who a person who conformed their arrangements to the conditions of the safe harbor would not be prosecuted even though the arrangement technically violated the anti-kickback law. In 1991, the Secretary issued the first ten "safe harbors." Today, there are more than twenty "safe harbors," the last group having been issued in November 1999.[6] There are safe harbors for renting office space, for receiving a discount on the purchase of equipment, for obtaining a warranty and for a variety of other normally straightforward business arrangements.

The anti-kickback law has been recodified as section 1128B(b), Social Security Act, 42 U.S.C. § 1320a-7b(b).

5 *See* section 14, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93.

6 *See* 42 CFR § 1001.952; *see* 56 Fed. Reg. 35,799 (July 29, 1991); 57 Fed. Reg. 52,723 (Nov. 5, 1992); 59 Fed. Reg. 37,202 (July 21, 1994); 61 Fed. Reg. 2,122, 2,125 (Jan. 25, 1996); 63 Fed. Reg. 46,676 (Sept. 2, 1998); 64 Fed. Reg. 63,503 (Nov. 19, 1999); and 64 Fed. Reg. 63,517 (Nov. 19, 1999).

The safe harbor system has its problems, however. The Inspector General had been reluctant to issue safe harbors and when she did, they tended to be extraordinary rigid. Moreover, it took years to issue a new safe harbor. Thus, as part of the Health Insurance Portability and Accountability Act of 1995, Congress required the IG to issue advisory opinions—these advisory opinions are essentially single transaction, one time safe harbors. In deciding whether to approve a proposed transaction, the OIG must consider, among other things, whether the proposed arrangement will cause over-utilization or adversely affect patient care. Should these types of policy decisions, requiring expertise in medical economics and medicine itself, be made by lawyers in the Inspector General's Office? I think not. Those whose training is law enforcement tend to see "waste" and "abuse" everywhere. Indeed, the IG has expressly noted that the advisory opinion process "permits this Office to protect specific arrangements that 'contain limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused.'" Advisory Opinion 98-14 (quoting from 62 Fed. Reg. 7350, 7351 (Feb. 19,1997).

Moreover, is it wise to effectively require people to seek governmental approval before entering into a normal business arrangement? The perils associated with violating the anti-kickback law are so great that even those who are providing free goods or services to health charities have sought advisory opinions first. Clearly, this is good for lawyers, since we draft the

advisory opinion requests. But is it good for medicine and health care and does it make sense?

The most interesting aspect of the anti-kickback saga is that a broad anti-kickback law may not make any sense today. Medicare payment has changed since 1977 so that over-utilization is far less of a problem than it was then. For example, in 1977, hospitals were reimbursed for their costs—the more they spent, the greater their reimbursement. If they paid kickbacks to suppliers, those kickbacks were passed through to the government. In such a setting a broad anti-kickback law made commercial sense. In 1983, however, Congress changed the way in which hospitals were paid so that they were no longer reimbursed for their expenses, but instead were paid a fixed fee for treating a given illness. If they paid kickbacks, the hospital, not the government, would eat the cost. Correspondingly, the introduction and quick spread of fee schedules and capitated payment arrangements in the late 1980s and early 1990s also shifted the cost of kickbacks from the government to private parties. In short, there is now a serious question as to whether this complex anti-kickback mechanism is even cost justified. Surprisingly, though, no one at HHS has indicated any interest in studying the problem or attempting to resolve it. The anti-kickback laws provide the government with a way to micromanage medical care and there does not seem to be any desire to give up that authority.

In short, we have an extraordinarily complex system—which is made only worse by the perception that rules are fluid and errors will be severely punished. This creates a climate of fear that leads providers to take costly precautions. Many of these precautions—such as corporate integrity programs and the like—may not make any economic, or indeed practical, sense. We just don't know.

III. Medicare Lacks Accountability

The fear that grips the provider community is further amplified by a vacuum of accountability: CMS and HHS are not subject to the normal rules that constrain and moderate other agencies. What do I mean? The actions of most other agencies are subject to judicial review. If the Environmental Protection Agency issues a rule that makes no scientific sense, folks can challenge that rule in court. If a government contractor feels that it has been underpaid, then there is a mechanism that allows it to challenge the payment decision in court. Access to court is essential if a system is going to be perceived as fair. While most government agencies have become more accountable through judicial review, Medicare has moved in the opposite direction.

Medicare has always attempted to prevent providers and beneficiaries from challenging its rules. At first, it claimed that the Administrative Procedure Act did not apply to it. When Congress threatened to amend the APA to lift any doubt, HHS begrudgingly acquiesced, but when it tried to

back-out of its promise, Congress amended the Medicare law to provide some review.[7] Even so, HCFA consistently has taken the position that a provider or beneficiary's ability to challenge a rule in court is severely constrained. As a result, most litigants spend far more money litigating whether they have the right to litigate than they do over the merits of the case.

While it was always difficult to sue HCFA, two terms ago, the Supreme Court, at HCFA's urging, made it far more difficult to do so. In *Shalala v. Illinois Council on Long Term Care, Inc.*,[8] the Court held that providers cannot attack a regulation until all administrative remedies have been exhausted even if the administrative process would prove futile and the attendant delay would impose undue hardship on the providers. In most cases, this means that the provider or beneficiary must go through a labyrinth-like process that is both costly and time-consuming before one can get into court. Once again, it seems ironic that as Congress is about to require that private insurers become accountable to patients and physicians, the government is moving in the opposite direction with respect to its own health insurance program.

There is a well-developed body of social science research that demonstrates that as people's control over a process decreases, the perceived fairness of the process also decreases. Thus, the Anglo-American adversarial system is perceived as being fairer than the European inquisitorial system.

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7 *See* Section 1871 of the Social Security Act, 42 U.S.C. § 1395hh.

Litigants have far greater control over the course of the litigation under the adversarial system, than they do under the inquisitorial system. These perceptions are not only transnational, but also independent of whether the litigants won or lost. Since perceptions drive fear and fear drives costs, is it not about time that we change people's perceptions by giving them access to the courts?

Obviously, it is much easier to develop policies and to issue rules when you know that those who are being regulated will have little ability to challenge your decisions. However, our government is not designed for the convenience of the bureaucrats or political appointees, but rather for the benefit of the citizenry.

So What Does This All Mean?

Neither complexity nor regulation is free—the more regulation, the less that can be spent on health care. The real question is how much regulation is optimum, and for that we must be willing to conduct experiments or develop models to see how best to curtail regulation. There is certainly evidence, albeit anecdotal, to suggest that over-regulation adversely affects the quality of care by shifting resources from the medical treatment to paper pushing and compliance activities.

You might ask, how can this be? After all, HCFA constantly reminds us that Medicare's transaction costs are 80% less than those of private

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[8] 529 U.S. 1 (2000).

insurers. HCFA has achieved low government transaction costs by shifting those costs from the government to the private sector. For example, private insurers take on the responsibility for conducting compliance programs and auditing functions. Not so with Medicare; HHS expects providers to undertake those functions.

Many now believe that when you add in all the compliance activities and added administrative burdens associated with Medicare, its overall transaction costs far exceed those of the private insurers.
Given that providers—whether hospitals or physicians—are paid fixed fees, those extra transaction costs must be paid from somewhere and, in many cases, they are coming out of the treatment side of the office, rather than the administrative side. Given a choice, do we want our hospitals to hire more coding clerks and compliance officers, or more nurses and physicians? I am not advocating that we abandon regulation; nor am I suggesting that regulation is unnecessary. Rather, I am merely advocating that regulation is not free. We should at least determine empirically which regulations make sense and should be retained, and which are counter-productive and ought to be abandoned.

Correspondingly, the costs of regulation increase as those who are regulated fear prosecution, even if that fear is unfounded. Unfounded fear and perception of unfairness drives up costs. I believe that much of the fear is a function of the fact that HCFA is not immediately accountable.

Revitalized judicial review will go a long way toward improving the entire process and could save significant money in the long run.