



THE FIRST HEALTH LAW FIRM

**TESTIMONY OF DAN MULHOLLAND¹
BEFORE THE JOINT ECONOMIC COMMITTEE
MAY 13, 2004**

Health care can mean the difference between life and death. Doctors, hospitals, nurses and other health care providers do their best day in and day out to save lives, help the sick and injured, and comfort the dying. There is no way their contributions to society can be measured, in dollars or otherwise. But the cost of governmental regulation of the health care field can be quantified – objectively and subjectively. Either way, it's far too high. It is especially ironic that the Federal government – which is the largest single payer for health care – is also its biggest cost-driver by virtue of the volumes of confusing and often self-contradictory rules that have been imposed on health care providers over the years.

The health care regulatory system has reached the point where no one – no doctor, no hospital, no lawyer, no government agency – can even begin to fully understand it, let alone comply with it. This hampers the ability of caregivers to provide vitally needed services in an environment where virtually everything they do can be second-guessed by lawyers, whistleblowers or government agents. The costs imposed by such unnecessary and burdensome rules are ultimately borne by consumers and taxpayers. Even more troubling is the fact that the regulatory system has sewn the seeds of distrust among health care providers, who must work as a team to furnish quality health care services. Unless meaningful regulatory reform is pursued, our health care system will continue to deteriorate.

The statutes and regulations that apply to health care providers are too numerous to mention. However, certain federal laws bear particular attention, because they have had the opposite effect of what they were intended to accomplish. Rather than improve the quality of health care services or enhance access to care, these laws have driven a wedge between health care providers, fostered disruptive conflicts, and actually reduced the availability of needed health care services, while driving up costs. Examples of such well-meaning but counter-productive regulatory schemes that will be highlighted in this testimony include the Emergency Medical Treatment and Active Labor Act ("EMTALA"),² the Privacy Regulations adopted under Health Insurance Portability and Protection Act ("HIPAA"),³ Medicare prohibitions on "physician self-referral" (the so-called "Stark Law"),⁴ and the National Practitioner Data Bank.⁵

1. EMTALA

The EMTALA statute was passed in 1985 in response to concerns that patients were being denied needed emergency medical treatment because they could not afford to pay. The law requires all hospitals to provide a medical screening examination as well as stabilizing treatment to any patient presenting to the hospital's emergency department prior to admitting, discharging or transferring the patient. This seems fairly straightforward and, on its face, unobjectionable. However, like so many other laws, the devil is in the details. One of the provisions of EMTALA⁶ requires hospitals to maintain a roster of physicians who are "on call" to provide specialized treatment. If a patient needs the services of a specialist, that physician must respond to the call from the emergency room or face sanctions along with the hospital for violations of EMTALA.

Prior to EMTALA, hospitals had informal relationships with on-call physicians. With the exception of a handful of highly publicized cases where patients were turned away from emergency rooms, this system worked well. However, once EMTALA was enacted, and on-call procedures became more rigid and formalized, the fear of sanctions for failing to properly respond to a call from the emergency department has caused doctors to be less willing to voluntarily provide emergency room call coverage. The EMTALA on-call requirement coupled with the potential for greater exposure to malpractice liability resulting from treating patients in an emergency room setting, has led many doctors to demand payment for providing call coverage. This has created a serious strain on fragile hospital finances and driven up the cost of care.

In some markets, physicians have refused to provide call altogether or retired from active practice because of the demands placed on them by the formalized EMTALA on-call rules. In one community, Lake Charles, Louisiana, there used to be five neurosurgeons who were available to provide call coverage at the two tertiary hospitals in that city. Now there are only two. According to health care executives in that community, this was a direct result of the increased burden placed on the neurosurgeons as a result of EMTALA call coverage requirements.

As a result, emergency room call coverage for neurosurgery can only be provided in that community two out of every three weeks. During the week when there is no neurosurgery coverage, patients with serious head or spinal trauma must be transferred to other communities, which can seriously jeopardize their health or even their lives. A similar situation occurred in Las Vegas, Nevada last year, which received national attention. Trauma centers had to close

because of the lack of neurosurgery coverage. Similar problems have been reported across the country, in communities large and small. Access to vital emergency services is threatened as a result of a law originally designed to enhance access to those services.

2. HIPAA Privacy Regulations

The HIPAA privacy regulations are another example of good intentions having less than favorable results. No one can argue that patients have a reasonable expectation that their medical information will be maintained in a confidential manner. This was a universally accepted principle observed by health care providers for years. However, the regulations issued by HHS to implement the privacy provisions of the HIPAA statute attempt to micro-manage virtually every conceivable communication involving health information and have snarled health care providers in red tape. Hospitals, physician offices and other health care providers have spent substantial amounts trying to comply with these rules. With the advent of the HIPAA security regulations scheduled to go into effect next year, even more costs will be imposed. These costs and the disruptions associated with changing basic practices to comply with these complex rules not only demoralize health care providers. They also breed distrust between patients and providers when informal confidentiality rules that have been respected for centuries are now replaced by diktat which simply serve as a trap for the unwary.

3. The Stark Regulations

The regulations issued on March 26, 2004⁷ interpreting the prohibitions against physician referral of "designated health services" to hospitals and other entities under Section 1877 of the Social Security Act (commonly called the "Stark Law" after its sponsor Rep. Pete Stark, the ranking minority member of this Committee) are even more mind-numbingly complex. The law that

these regulations implement started from the reasonable premise that physicians who owned clinical laboratories would have an economic incentive to order more tests, some of which may not be medically necessary. However, now that that statute has been amended to cover a wide variety of "designated health services" (including all inpatient and outpatient hospital services), any financial relationship between a hospital and a physician, no matter how small or inconsequential, is presumptively illegal. The regulations implementing this law define the concept of "financial relationships" so broadly that even seemingly innocuous things such as free meals at the hospital's cafeteria, quality-enhancing continuing medical education, or time-honored customs such as professional courtesy can be challenged if they do not fit within the narrow confines of the rules. Hospitals are now saddled with onerous record-keeping requirements having to account for every benefit (both monetary and non-monetary) realized by physicians who practice at the hospital. This will lead to substantial additional compliance costs and legal fees. It will also further erode the relationship between hospitals and physicians, who may fear that any kind of economic relationship could be suspect.

The concern about these regulations is heightened by the fact that anyone can, pursuant to the whistleblower provisions under the False Claims Act,⁸ secretly charge a hospital or physician with violations of the Stark law and stand to recover a huge windfall completely disproportionate to any impact that the hospital-physician relationship might have on the Medicare program. For example, under the new regulations, if a hospital provided a dinner for members of its medical staff which cost more than \$25 per doctor, the dinner would constitute an "incidental benefit" that would technically exceed the regulatory threshold and taint the entire relationship between the hospital and each physician. As a result, every referral by those doctors to the hospital could be found to violate the Stark law and give rise to False Claims Act penalties of \$11,000 per

referral plus three times the amount paid to the hospital by Medicare. The whistleblower could receive up to 30% of this penalty. It is hard to believe that this was ever contemplated when this law was enacted.

These rules are creating a state of paranoia among providers. They will likely create an atmosphere where providers will avoid otherwise beneficial relationships for fear that violating these rigid rules will result in ruinous liability. Once again, patients will ultimately suffer if the professionals and institutions who serve them forgo the benefits of closer integration due to fear of government sanctions.

4. National Practitioner Data Bank

Finally, the National Practitioner Data Bank has created an extremely adversarial relationship between doctors and hospitals. To some extent, it actually threatens the future of voluntary medical peer review. The Data Bank was enacted as part of the Health Care Quality Improvement Act of 1986⁹ as a mechanism of enabling health care entities and licensure boards to find out if doctors had been subject to licensure sanctions, professional review actions or malpractice payments. Among other things, any final professional review action by a hospital, as well as any resignation by a doctor while under investigation or in return for not conducting one, needs to be reported to the Data Bank. This has led to a situation where even minor hospital peer review inquiries are fought tooth and nail by physicians who fear that they may ultimately lead to a Data Bank report. Hospitals have also been sued by physicians alleging that reports to that Data Bank were defamatory, sometimes because the hospital simply used reporting codes mandated by the Health Resources Services Administration.¹⁰

As a result, every peer review action is now likely to be contested because it could lead to what is perceived to be a career damaging report to the Data Bank. Doctors on peer review committees are therefore less likely to aggressively pursue bad medicine for fear of being embroiled in nasty litigation. Thus, the peer review system, which is the only meaningful mechanism to assure the ongoing quality of medical services, has been threatened by a well-intentioned attempt to track physicians who have had competence or behavioral problems.

These are just a few examples of the many rules and regulations that impact the relationships of health care providers. These regulations impede rather than facilitate the delivery of quality and affordable care. This situation is compounded by the byzantine Medicare reimbursement rules, the failure to enact meaningful tort reform, and often conflicting federal and state regulatory schemes which impose additional burdens. Health care providers should be free to care for patients, not saddled with rules that impede their ability to do so. We would therefore respectfully suggest that this Committee, as well as all policymakers in both the Legislative and Executive branches of government, carefully assess the regulatory burden on the health care system and take into account the costs and practical effects of any future regulatory initiatives.

ENDNOTES

1. Mr. Mulholland is a senior partner in the health care law firm of Horty, Springer & Mattern, P.C. in Pittsburgh, Pennsylvania. The firm represents and advises hospitals and health systems throughout the country. In providing testimony to the Committee, Mr. Mulholland is not acting on behalf of any client.
2. 42 U.S.C. §1395dd
3. 45 C.F.R. Parts 160 and 164
4. 42 U.S.C. §1395mn
5. 42 U.S.C. §11131 et seq.
6. 42 U.S.C. §1395CC(a)(1)(I)
7. 69 Fed. Reg. 16054
8. 31 U.S.C. §3729
9. 42 U.S.C. §11101 et. seq.
10. E.g., Wheeler v. Methodist Hospital, 95 S.W.3d 628 (Tex. App. 2002), Stephan v. Baylor Med. Ctr., 20 S.W. 3d 880 (Tex. App. 2000); Simpkins v. Shalala, 999 F. Supp 106 (D.D.C. 1998).