

Quality health care in a regulated society

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The decade that began in 1966, when Medicare and Medicaid were introduced, has been termed "The Decade of Regulation." Health care continues to be a target of regulation today. The 2,883 health-related bills introduced into the 95th Congress represent approximately 11 percent of the total. The office of the Federal Register reports that 61,000 pages of regulations were published in 1978, compared to 20,000 in 1970, an increase of more than 300 percent. Federal and state governments enact these numerous regulations each year for social, economic, political, and other reasons, supposedly to benefit society. Although some regulations are needed, others border on the absurd, are difficult if not impossible to administer, and may be conflicting or contradictory. In my role as executive officer of a large medical center, I have realized the complexity of these regulations perhaps to a greater degree than would be apparent to many others. This ex-

perience, plus my involvement with numerous regulations that affect the College compels me to stress this topic to you. It is not my purpose to condemn regulation but to demonstrate some of the overregulation that is present and steadily increasing.

Voluntary regulation

Since its inception, the American College of Surgeons has been in the forefront of voluntary regulation to improve the quality of patient care. The College was established to elevate the standards of surgery and to formulate a plan that would indicate to the public and to the profession that the surgeon possessing its Fellowship was specifically qualified to practice surgery as a specialty. Stated more simply, the College has worked to establish standards of competence and character for practitioners of surgery. Some of Franklin Martin's initial plans were earth-

The new President of the College, Dr. William H. Muller, Jr., was appointed Stephen H. Watts professor and chairman of the department of surgery at the University of Virginia in Charlottesville when he was only 35. This year he observes his 25th anniversary of that appointment.

Dr. Muller is also surgeon-in-chief and vice president for health affairs at the University of Virginia Medical Center. His goals have been to expand the surgical program in cardiovascular



and plastic surgery.

Dr. Muller was the first surgeon to perform a successful operation for partial correction of transposition of the pulmonary veins, and he developed and applied clinically an operation for banding the pulmonary artery.

A Fellow of the College since 1952, he has chaired many of its committees.

He was named to the Board of Regents in 1971 and was elected Board Chairman for the years 1976 to 1978.

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shaking to many of his fellow surgeons and physicians throughout the country. There was a threat to many surgeons in the intent of the new college to "formulate a minimum standard of requirements, which should be possessed by any authorized graduate in medicine allowed to perform surgical operations independently." Even more threatening was Martin's plan to "seek a means of legalizing, under national, colonial, state, or provincial laws, a distinct degree supplementing the medical degree, which would be conferred on physicians possessing the requirements recognized by this law, as necessary to be possessed by operating surgeons."¹

Martin also wished to seek the cooperation of medical schools, and to authorize them to confer this supplemental degree of "surgeon" on those who had fulfilled the requirements. None of this was open to argument as far as he was concerned, but some of it was considered overregulation and was never adopted by the College. Martin emphasized the importance of protecting the unsuspecting patient, who had no way of discriminating between trained and untrained surgeons. The "standardizing of surgery" would also enhance the public's appreciation of the conscientious, trained surgeon.

The condemnation of the common practice of fee-splitting, and the pledge by the Fellow to live in strict accordance with all the principles, declarations, and regulations of the College seem only appropriate today, but, in terms of impact then, could be compared to the Flexner Report on medical schools.

Equally important was the development of minimum standards for hospitals, adopted by the Regents in 1919. Our College's work on the development and elevation of hospital standards has been recognized by all branches of medicine, ultimately resulting in the establishment of the Joint Commission on Accreditation of Hospitals (JCAH) in 1951.

The requirements of the College and the JCAH to upgrade surgery and hospitals are examples of voluntary regulation by the profession itself, through the private sector; this form of regulation constitutes what is usually considered the most desirable type of control. Such voluntary regulation grew through the 1920s and 30s, and the acceptance and success of many medical and surgical specialty boards seemed to preclude the thought of significant federal regulation. The medical profession seemed alert and active in the pursuit of a high standard of care.

Government steps in

However, in the late 1950s, there were rumblings of a physician shortage. Physicians were criticized for not making house calls and not being available to the public. They were also criticized for the rising cost of health care, which exceeded the prevailing, relatively low rate of inflation.

Of course, there were many reasons—other than the physician—for these cost increases. Among the most important were the introduction of expensive technology into practice and the corresponding demand by patients for the more expensive diagnostic and therapeutic methods, the new minimum wage, and the rise of many federally supported programs.

In its attempts to make health care more available, the federal government began to increase medical school enrollment through fiscal incentives. It also assisted in the establishment of new medical schools, subsidized the construction of new health-care facilities, and removed the previous limitation on entrance of foreign medical graduates into the country. Medicare and Medicaid laws provided care for the indigent, elderly, and children with certain categories of disease. As in the case of the British National Health Service, the actual cost since enactment has far exceeded governmental projections.

The Social Security Amendments of 1972 (Public Law 92-603) made important provisions both for the regulation of medical practice and the reimbursement of physicians in a teaching setting. Section 227 of Public Law 92-603 included physicians' services in teaching hospitals under a hospital reimbursement category. The regulations were so impractical that implementation of Section 227 was repeatedly delayed by new legislative enactments and other maneuvers. Many physicians, along with many congressmen, believe that the law is highly biased and could disrupt the quality of patient care as well as the quality of medical education. The uncertainties surrounding this legislation, passed more than six years ago but still not in effect, illustrate its complexities and probable inappropriateness.

Another portion of Public Law 92-603 established Professional Standards Review Organizations to assure that health-care services paid for by the government "are medically necessary, conform to appropriate professional standards, and are delivered in the most effective, efficient, and economical man-

ner possible." This is a cumbersome way to describe practice under review by one's peers. The College has always favored peer review, and, in fact, so stated before a congressional subcommittee. However, the costs of hospital care rise significantly with the need for more personnel to monitor and report on health-care services as well as to comply with other red-tape requirements of the law.

Health planning and the FTC

In 1975 the Congress passed the National Health Planning Act (P.L. 93-641). The influence of this far-reaching regulatory law was only slowly appreciated as its various agencies began to function. These agencies have the authority to approve or disapprove not only inpatient and outpatient additions to hospitals, but also certain renovations and the acquisition of some equipment for hospitals and even for physicians' offices. Some of these agencies have considered undertaking the review and preliminary approval of research grant applications and other similar activities that would seem to lie more appropriately within an institution's purview.

The law also required greater involvement of the lay community on planning committees and greater coordination with other institutions in developing community master plans. It is moving us toward stricter local hospital codes, more complex state and local standards, and the quantification of indications for need. Undoubtedly there will be an increased number of legal challenges to recommendations by these governmentally sponsored agencies. All of this requires greater physician effort, more managerial personnel, and added expense for the medical institutions and the taxpayer.

A particular frustration and concern has been the attempt by the Federal Trade Commission (FTC) to impose rulings on the activities of the health-care professions. This involves FTC advocacy of advertising and solicitation of patients by physicians. Such activities have always been considered violations of long-standing ethical principles. There are various other attempts to apply antitrust laws to limited membership professional societies. Antitrust laws were enacted to assure free enterprise and the unrestrained competition that is considered to be in the best interests of society, and to assure that private efforts to restrain competition do not succeed. That these laws were passed more than 60 years ago, were never applied to profes-

sionals, and have apparently just come to the attention of the enforcing agency is of no apparent concern.

Those who now press these laws imply that professional organizations, some of which were established before the laws were passed, are either doing something inappropriate now that they did not do before, or that current activities that once seemed correct and desirable are no longer acceptable. No consideration is given to the fact that professional organizations encourage competition by requiring the candidate for membership to attain a certain level of education and experience and that, in most instances, the organization is simply following its primary goals to promote education, exchange knowledge, and improve the quality of patient care.

This recent change of attitude by the FTC was the result of the Goldfarb decision of 1975, in which the court held that the nature of an occupation or its public service aspect is insufficient reason to warrant exemption from antitrust laws. This ruling, plus the large portion of the Gross National Product that goes to health-care services and the rise in health-care prices, has emboldened the FTC to concern itself with medical professional associations. Inasmuch as the Goldfarb decision originally concerned the price of lawyers' services, its extension to medicine was naturally in the area of physicians' fees, with special attention to relative value scales or the relation between the cost of one medical professional service and another. It was therefore difficult to defend price-setting legally through this mechanism. However, the issues raised by the FTC related to limited membership societies seem much more defensible.

National Health Insurance

Perhaps the greatest form of regulation will come if a comprehensive national health plan is instituted. The impetus for this legislation comes from an aggressive segment of the public, who believe that health care is a right, that the average individual is unable to assume the cost of prolonged, severe illness, and that every citizen should have access to high quality medical care at reasonable cost. The Congress has received numerous bills over the past 15 years, each with different plans and funding schemes, but all excessively costly. In every presidential campaign during this period, the promise of a national health-care

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plan has been given top priority. Why then do we not have one in effect today?

The chief reason is that the various factions responsible for the introduction and passage of such a bill cannot agree on what is wanted, needed, affordable, or what can be administered. However, a national health plan will probably be instituted in the future, and the major laws enacted during the past decade are viewed by many as a superstructure and major component of such a plan. I favor a private-public system, combining the advantage of a market economy through private insurance with subsidy from the government, to underwrite the needed programs for the indigent, the medically indigent, and catastrophic illness. I also think it is fair to say that most Americans believe that what is done by government is often less well done, more costly, and associated with more red tape than if it were undertaken by individuals alone, or as a private organization.

Bureaucracy

Because of rapid growth and the proliferation of legislation over the past two decades, health care under these laws could hardly function today without appropriate regulation. However, the regulations are excessively time-consuming and costly because of their immensity and complexity, which are compounded by the reporting requirements and by the lack of communication among agencies. It is relatively easy to explain why health regulations grow increasingly numerous and complex. As the voluminous health-care legislation becomes law, it must be interpreted and made viable for application to the public. Laws are therefore assigned to agencies, or new agencies are formed to interpret them and write the regulations. One new major agency and several minor ones have been set up by the federal government each year since 1968.

There are certain incentives for these agencies or bureaus to become larger. As Downs pointed out in his book, *Inside Bureaucracy*,² growth within a bureaucracy improves the chance for promotion. Promotion often increases supervisory duties, thus increasing

salary; therefore, there is a tendency to overstaff the bureau at each level. As each level becomes larger, and as more information passes through it, the lines of authority become hazy, and the information may be distorted, according to the interest of the people who deal with it. Finally, a significant portion of the activity may be unrelated to the original goals, or to the goals of the top hierarchy.

Bureaucracy provides little incentive to improve efficiency, but great pressure for control, monitoring, and accountability. Each hierarchy is held responsible by the one above, until, ultimately, responsibility to the Congress or the public is reached. The pressures for monitoring often necessitate the development of internal and external requirements and reporting at each level, so that these activities of accountability become bureaucracies on their own.

Nor is there an incentive to save money. Indeed, the incentives run in the opposite direction. The less money an agency spends in one year, the less it is likely to have the following year, since future budgets are often awarded incrementally on the basis of the previous year's award. Bureaucracies are self-perpetuating, and as they become larger, they wield significant political influence, both as organizations and through the voting power of their vast work force. Bureaucratic employees have a much greater incentive to vote for new programs than the average voter, and because about one American family in five has at least one member in the government's employ, a strong voting block results.

William Niskanen³ contests the belief that centralization promotes efficiency, and has calculated that creating the Department of Health, Education, and Welfare increased the cost of performing that agency's functions by 25 percent. The creation of other large departments has brought little measure of effectiveness. For instance, despite the establishment of the Department of Housing and Urban Development, decay and collapse have obviously continued in some of our major cities. Following establishment of the Department of Transportation, many railroads be-

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came bankrupt, requiring nationalization. Though there may have been external, contributory forces to cause these declines, there is no evidence that setting up a large agency was of significant benefit.

Controlling costs

Most health-care regulations since the 1940s have been concerned with controlling rising health-care costs, especially since 1965. The mechanism for control has been largely directed toward utilization review and the development of alternative systems for delivery, such as Health Maintenance Organizations (HMOs), and the encouragement of ambulatory care. Studies indicate that hospital costs have risen significantly above the cost-of-living index during the past two decades, and in recent years they have increased by as much as 17 to 18 percent annually. During the past several years, however, there has been a concerted and successful voluntary effort by hospitals to reduce the size of these yearly increases. Physicians' incomes have risen significantly, although not in proportion to the rise in hospital costs. Recent presidential addresses by Drs. Dunlop and Altemeier have stated many of the reasons for these increases.

In his recent Shattuck Lecture, “In the Public Interest,”⁴ Theodore Cooper points out that because it is unpopular to propose rationing of medical care, policy makers attempt to restrain expenditures and lower costs by regulation. Some of the possible approaches which he lists are:

- Limit facilities, particularly hospital beds, and thus defer treatment and waiting lists.
- Use less expensive and less educated “physician expanders” for many activities previously deemed the responsibility of the physician.
- Set physicians' fees and salaries, or even set the total annual compensation.
- Legislate what can be done and thus exclude certain expensive types of therapy.
- Reorient the system to less expensive approaches.
- Insure that hospitals and physicians will perform only those treatments that have scientifically proven beneficial effects.

- Eliminate waste and fraud by improving management.

Whether or not the enactment of these proposals will actually cut costs, it seems that the quality of health care would likely suffer by the institution of most of them.

Cost of regulation

The cost of regulation itself siphons off a large share of the health-care dollar, as revealed by several recent studies. A Washington University study⁵ estimated that federal regulation costs each American citizen \$300 a year, or a total of \$65 billion yearly, and government economists estimate that the inflation rate is increased by three-quarters of one percent per year because of environmental and safety regulations alone. A study of more than 300 hospitals and other health-care facilities by the Hospital Association of New York State⁶ found that in New York State alone, there are 164 federal and state regulatory bodies to oversee hospital-based health-care delivery, and that 25 percent of hospital costs stem from these regulatory requirements. The annual cost to patients and taxpayers is more than \$1.1 billion, and 115 million man-hours are required, the equivalent of 56,000 hospital employees spending all of their time with these matters. The forms and reports required by regulation alone cost more than \$128 million annually. Of special interest is the finding that registered nurses, who have traditionally been thought to spend all of their time with basic health care, actually spend one-quarter of their time dealing with regulations. The incremental cost of new regulations in New York State was estimated to be more than four percent each year.

Nor is the actual cost in dollars the only fiscal impact. As reported in *Hospitals (JAHA)*,⁷ the Hospital Intensity Index, which provides a means of understanding the adverse impact of regulations on hospital productivity, showed that in the year between November 1977 and November 1978, the growth rate of the real service volume had decelerated to 5.1 percent from a historical rate of 6.9 percent. Two departments, Medical Records and Administrative and Fiscal

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Services, which are the most affected by regulation and account for approximately 14 percent of the total hospital operating expenses, were found to account for this change.

The Congress recognizes the need for regulatory reform, and in the immediate past session, more than 30 bills were introduced on the subject. These included "sunset" proposals, changes in rule-making procedures, and the veto of regulations by the Congress.

Persistent inflation and concern over government spending have intensified public pressure for greater accountability within the federal bureaucracy, and the President has set up several high-level task forces to review regulatory activities and coordinate rule-making. However, although former HEW Secretary Califano said that existing regulations had been reduced by one such effort (Operation Common Sense, initiated in 1977) he would not comment on how many new regulations were adopted since then. Commenting on legislation to reform the government's rule-making procedures, American Hospital Association President J. A. McMahon⁸ said, "With increasing public and private concern for ever-increasing health costs, and with the development of ever-widening areas of national legislation, it is essential that the regulatory process facilitate and not burden the nation's health-care resources." Former Attorney General Griffin Bell has made the strongest comments on the growing problem of government regulation and rule by bureaucracy. He has indicated that the viability of the republic is at stake, and that we are on the verge of societal suicide. He even compared our federal government's bureaucracy to an army of occupation, more pervasive and more powerful than all the Union armies of Reconstruction.

Despite attempts at reform, it is improbable that regulation will be significantly reduced. Rather, it is more probable that, during the next decade, legislative control and a more comprehensive national health plan will have a major impact on hospitals and practitioners as regulation continues to proliferate.

The physician's challenge

The hospital, which has traditionally been considered the physician's workshop, is paradoxically being required to apply increasing control over its staff because of regulation governing its own activities. The implementation of controls for utilization and quality, and the acquisition of new equipment and

programs to meet community demands are brought about not only through legislation but also because of litigation and court decisions that now place the responsibility for patient care with the hospital, as well as the physician.

It is therefore important that physicians as individuals and through professional organizations develop a planning strategy to cope with regulation, and to challenge regulations when they seem arbitrary or based on a lack of proper knowledge or information. An awareness of the general intent of health regulation, as well as a knowledge of the major implications of existing regulation and up-to-date information about future regulatory efforts, will allow the physician to respond to various regulatory pressures more quickly and with greater resilience. This will preserve our application of the art and science of our great profession with greater effectiveness and satisfaction. Above all, it is important to maintain the original objectives of the American College of Surgeons, essentially unchanged since they were set forth 66 years ago: to elevate the standards of surgery and to establish a standard for competence for practitioners of surgery, thus continuously maintaining the highest quality of surgical care.

Even with increasing regulation, surgical quality may be maintained through dedication, leadership, integrity, and hard work. It is this challenge, so successfully met by many Fellows who have preceded you, that I pass on to you at this time. It is yours to grasp and conquer. May you do so with all your might, and with the best of fortune.

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