Healthcare regulation: Past, present, and future

BARBARA ROSS-LEE, DO
MICHAEL A. WEISER, BFA

Excessive regulation has created a formidable barrier for physicians to surmount when treating patients. This article examines the increasing intrusion by regulatory agencies—government and private—into the patient-physician relationship. The authors examine the history of healthcare policy leading to today's highly regulated approach to cost-containment. They trace the development of the emphasis on regulatory controls from 1900 to the present. Further, they examine in detail the specific impact of diagnosis-related groups, utilization review firms, and the Clinical Laboratory Improvement Amendments of 1988 on the patient-physician relationship. Diagnosis-related groups set the hospital administration as monitor of the patient-physician relationship. Utilization review firms insert themselves as another gatekeeper in decisions of appropriateness of care. The Clinical Laboratory Improvement Amendments causes laboratories to close, thereby restricting access to care. The reform movement would respect the patient-physician relationship and remove excessive regulation from this confidential interaction.

The past decade has seen everincreasing intrusion into the patient-physician relationship by both government and private sector agencies intent on controlling rising healthcare costs. This intrusion attempts to correct perceived deficiencies in the overall system of healthcare policy, but often results in weakening the other supporting policies within the system. At this juncture in the United States' ailing healthcare system, we must ask, What will the health reform proposals do to relieve this atmosphere of added interference? Throughout this next year, and most probably the years to come, various aspects of the proposed reforms will be hotly debated and will undergo slight to drastic revisions. However, many areas of the plans now address the taxing regulations that exist between the physician and the treatment of patients.

The Clinton Administration's health reform proposal, the American Health Security Act of 1993, promises to establish a healthcare system to achieve the six guiding principles of security, simplicity, savings, choice, quality, and responsibility. Around this system of care, the Act would create a reimbursement system based on managed competition. Beyond the basic guarantee of health coverage for all Americans regardless of employment or health status, the Act will organize a system by which all health plans must meet national standards on benefits, quality, and access to care while leaving the states free to tailor their individual systems to meet their unique needs. Perhaps most important to healthcare professionals, the plan provides for less regulation and bureaucracy, which have overwhelmed both consumers and health providers.

Much regulation in the recent past, while attempting to address a specific problem concerning a specific policy objective, has confounded...
other healthcare policy objectives and intruded into the patient-physician relationship. The reform proposals are an attempt to address access, quality, and cost-effectiveness in one stroke, rather than having to patch holes left in healthcare policy following uneven growth or singularly based agendas of the past. In effect, the proposals are directed toward establishing an integrated system of healthcare delivery within which a more appropriate, less procedurally based system of reimbursement will be integrated. Crucial to the new integrated system will be an emphasis on cognitive skills, health promotion, and disease prevention.

Regulatory history in healthcare policy

Major advances in American healthcare policy have been found to follow an approximate 30-year cycle. In the early 1900s, the training of physicians changed radically when Flexner surveyed the nation’s diversity of medical schools for the Carnegie Foundation.1 The 1930s saw the passage of the Social Security Act of 1935, the most sweeping social reform package of its time. Medicare and Medicaid were born in 1965, another 30-year leap. Finally, we find ourselves in the early 1990s poised on the brink of the next major step.

Current healthcare reform policy emphases revolve around three basic objectives:

- improved access to care,
- improved quality of care, and
- control of the costs inherent in administering care.

The objective of access aims at assuring the inclusion of populations presently excluded from adequate healthcare coverage and basic healthcare service. The objective of quality aims at assuring that needed care is administered following state-of-the art outcomes of care and not directed toward the process of delivering care. The objective of cost control aims at assuring that necessary, medically appropriate care is administered in the least costly manner.2

Current policy has evolved, since the advent of Medicare and Medicaid, as a process of expansion, limitation, and redefinition of existing policy strategies. Attempts to achieve the objectives of cost, access, and quality have involved either regulatory, market-based, or public health interventions. While the limitation of physician autonomy was not the intent, the current 30-year cycle has created a conglomeration of regulations that have effectively limited that autonomy.

The current system of healthcare began as the result of numerous amendments to and government acts affecting the Social Security Act of 1935, particularly the Medicare and Medicaid amendments of 1965. The period immediately following passage of the 1935 Act saw an era of expansion. During this period, government placed itself in the role of benefactor of the American people and set out on a course to establish the best system of care for its people. Between the 1940s and through the 1960s, access and quality objectives dominated the healthcare agenda. The focus of this era was growth, with acts like the Hospital Survey and Construction Act of 1946, known as the Hill-Burton Act, which subsidized the development of healthcare resources to facilitate access to care. This era also witnessed mammoth growth in the budgets to the National Institutes of Health to increase monies for research and technology, and the Department of Health, Education and Welfare to increase the supply of physicians to promote access to quality healthcare. Tax policies of this period, also aimed at improving access, encouraged growth of private health insurance coverage for healthcare.2

The most important of all access-enhancing policies came in the mid-1960s. In 1965, Congress passed Title XVIII of the Social Security Act—the Health Insurance for the Aged Act—better known as Medicare. This act provided for the reimbursement of medical care costs to persons 65 years of age or older and to those disabled persons deemed eligible by the Social Security Administration. In 1965, Congress also passed Title XIX of the Social Security Act creating Medicaid. The goal of this amendment was to provide access to needed medical care for the indigent (families with dependent children and the aged), the blind, and the disabled.

By the end of the 1960s, the federal government was subsidizing the construction of hospital beds, the development and dissemination of medical technology, and the expansion of medical schools and training programs for physicians and other healthcare professionals.2

During the next decade, healthcare policy shifted toward a concentration in the objective of cost-effectiveness. The 1970s saw cost-containment policies focused on utilization review, rate control, and capital-expenditure control. In a 1972 amendment to the Social Security Act, Congress established professional standards review organizations (PSROs). These organizations attempt to contain costs by reducing unnecessary utilization of health services. Rate control of hospital reim-
bursancement was another program designed to contain costs. Developed at the state level, hospital rates were controlled for a short time nationally between 1971 and 1974 through the Nixon Administration's Economic Stabilization Program. The National Health Planning and Resources Development Act of 1974 attacked multiple problems with the intent of fulfilling all policy objectives in one broad stroke. The Act was an attempt to fill the gaps left by the great variety of single policy actions of the earlier expansionist era. Unfortunately, the Act was doomed from the start by conflicting objectives. One group of objectives focused on continued enlargement of access to quality healthcare, while another group of objectives strove for efficiency and economy within the healthcare professions. In addition to the conflicting objectives, the Act joined two diametrically opposed processes in the same program: planning and regulation.

Planning is a process looking to the optimal solution to a problem in an idealistic universe. Regulation is a process grounded in rules and decision-making, following rigid guidelines and real-world constraints of economies and budgets. This program resulted in a healthcare system consisting of a patchwork of separate responses to a variety of problems. The Act was repealed in 1986 by President Reagan, reflecting a shift away from a purely regulatory stance to policy concerns toward a more procompetitive atmosphere.

The 1980s, into the 1990s, fostered growth in competitive medical plans and health maintenance organizations (HMOs) aimed at bringing market forces to bear in the pursuit of policy objectives. The federal government began to recognize the limited ability of regulation to achieve policy objectives, and more important, to limit its own expenditures in the healthcare arena. The passage of the Social Security Act of 1983 established a system of prospective payment based on diagnosis-related groups (DRGs) for hospital care provided to Medicare recipients. Intended as a tool for measuring the efficient use of hospital resources, DRG research was supported by the federal government, which used its potential as a prospective payment system (PPS). The Act shifted focus to the prices that the government paid for services rendered to Medicare recipients. This action clearly aimed at reducing federal support for Medicare and at controlling healthcare costs at the federal level. Cost controls were primarily aimed at hospitalization, the costliest area of federal healthcare support. This aim has resulted in a rapidly increasing cost-share shift to the outpatient setting.

Through the past decade, while reducing its regulatory involvement at the health systems level, the government has continued regulatory expansion into the patient-physician relationship. Three examples follow.

**Government intrusion: Case 1**

**Diagnosis-related groups**

Diagnosis-related groups have long been associated with Medicare's PPS, but they were originally meant as an instrument of hospital management. Robert B. Fetter, DBA, and John D. Thompson, professor emeritus of public health and nursing administration, developed DRGs in response to the problem of utilization review, which arose in conjunction with the advent of the Medicare program. All hospitals were required to provide a system of utilization review and quality assurance in order to receive Medicare funds. In 1967, a group of physicians approached Fetter and Thompson and questioned the applicability of industrial standards of cost and quality control to the hospital industry.

The process, which continues to evolve today, centers on the measurement and evaluation of activities within an institution as a means of evaluating performance. Fetter and Thompson's work focused on developing a procedure for measuring hospital performance leading to the development of a system that would be able to predict and thus control costs. At the initial stages of their work, and as they view the results of their work today, Fetter and Thompson saw DRGs not only as a tool for containing costs, but also as a tool for bettering the quality of care.

The DRGs are based on the similarities that exist between the procedures used to treat patients with a common illness or medical condition. However, as work began on tackling patient classification in 1969, Fetter and Thompson found that they lacked both a system of measurement and a system for interpreting clinical data. In the early 1970s, they had developed a system for analyzing hundreds of thousands of patient records statistically and clinically in search of those characteristics revealing relatively homogeneous processes of treatment. They were looking for the underlying structure that would allow them to measure and evaluate the activities taking place in a hospital in order to arrive at an efficient measure of production relative to cost and quality. Their objective was to develop a system that was able to discern
that point at which the quality of care is at its greatest and the cost of that care is at its least, resulting in a profile of optimal quality and value.

Fetter and Thompson also sought to develop a responsive system based on the concept of social utility. The social utility model would be concerned with the changing and unique needs of populations served and promote more active participation in the management of the system by healthcare providers.5

Although DRGs were intended as a management tool for hospital administrators, they have largely been used by the federal government as a means of identifying and evaluating treatment, and then attaching a price tag to that treatment to cover hospital reimbursement. This practice has resulted in a system that views each person with a particular ailment exactly like the person in the next hospital bed with the same ailment, given that they fall within the same DRG. However, not all ailments end in the same manner.

In a recent study of DRGs on the cost of hospitalization for patients with end-stage renal disease (ESRD), the authors found that for a variety of acute illnesses, the occurrence of ESRD resulted in costs for dialysis that were not covered by Medicare funds.6 This situation produces a strain on the hospital, which must incur and absorb this additional cost. A set limit on what will be paid for a particular treatment forces physicians to effectively utilize healthcare resources, but it also places the economics of the situation before the care of the patient. Physicians are pressured to work within the window of payment and the allowance of time for each illness rather than by the uniqueness of each individual case and patient. Medicare reimburses hospitals at a rate set by each DRG regardless of how long a patient is actually required to stay in the hospital. This system produces a barrier to access and quality of care provided to hospital patients.

Diagnosis-related groups also have the effect of altering a hospital's case-mix and utilization of medical technology. Hospitals have begun to use DRGs to analyze cost-per-case patterns and the usage of hospital resources when making resource allocation decisions. As one hospital buys new technology and leads the market in treating a particular illness, other hospitals may elect to change their case-mix away from that illness and toward another advance in medical research. Full-service hospitals will then become specialized in more narrowly focused offerings, which may have the effect of increasing the quality of a given treatment but also prove to narrow access for some patients.

Physicians' decisions about length of stay and intensity of treatment for their hospitalized patients are preset, independent of the physician's evaluation of the individual patient. When the physician encounters a complication, a formal appeal to extend the length of stay must be filed with the hospital administration, who may then request additional reimbursement if the documentation meets the required standards. In effect, DRGs have made the hospital administration the monitor of the patient-physician relationship.

Private sector intrusion: Case 2

Utilization review firms

Government regulation is not the only form of intrusion into the patient-physician relationship. Private industry also has impacted the dialogue between physician and patient. Utilization review firms (URFs) have added another layer of gatekeeping to the discussion of medical problems and the ultimate treatment of those problems. These organizations are layered between patient care and payment for coverage of treatment by private insurance (third-party payer).

The utilization review function is either to allow or to disallow payment for treatment. If treatment is disallowed, there are generally provisions for reconsideration; however, the credibility of the physician with the patient is brought into question. The problem for the patient remains: Whose assessment of the condition is correct? Whom should he or she trust and, if he or she opts for treatment as recommended by the physician, what will be the cost and how will he or she pay?

A system of peer review has existed as a means of control on the quality and appropriateness of prescribed care for many decades. Utilization review, in its current form, arrived in the healthcare system as a cost-containment function within HMOs. But, allowing this function to exist outside the professional community, often as the creation of or an offshoot to the insurance industry, reduces its focus to cost-saving for the industry that it serves and not toward the betterment of care.

When questioned about their contribution to the quality of care or benefit to the healthcare profession, URF workers think that they are adding to the administration of care because they safeguard the patient against unnecessary procedures. Also, they believe that they aid healthcare providers by educating physicians to alternatives in health-

Healthcare policy • Ross-Lee and Weiser

JAOA • Vol 94 • No 1 • January 1994 • 77

Downloaded From: http://jaoa.org/pdfaccess.ashx?url=/data/journals/jaoa/932625/ on 11/09/2018
care or by affirming the prescribed care and serving as a documented second assessment of the condition.

There are more than 300 URFs exercising decision-making power in the patient-physician relationship across the country, and each varies in its approach to healthcare utilization and criteria used to arrive at a verdict. Some URFs are staffed primarily by nurses armed with computer terminals loaded with medical protocols, statistical information and models based on the previous history of illnesses, the duration of the illnesses, and prescribed treatment modalities. This statistical-model style of utilization review delivers judgments based on the information stored in the computers, with conflicts being addressed by physician-advisers.

The clinical model, on the higher end of the spectrum, provides for direct physician-to-physician consultation. Nurses take down each case’s pertinent information, which is then routed through full-time physicians and specialists. These physicians then review each case, either approving the attending physician’s diagnosis or discussing the case and options to the initial diagnosis directly with the attending physician. The continuum on which these two styles of utilization review exist is wide and, regardless of whether one is better than the other, they both constitute another hurdle for patients to cross when seeking care.

Many physicians and administrators in the medical community view utilization review more skeptically, seeing the necessity for a review of every professional judgment as a questioning of their ability to properly treat patients. Physicians serving with URFs would counter that physicians, in general, are not instructed as to how to administer cost-efficient care through their education. This being the case, these URF professionals promote their position in the field as a way to ensure that cost-effectiveness is achieved. However, maintaining an industry-wide level of gatekeeping establishes another level of bureaucracy and serves to regulate all physicians rather than focusing on the offenders who either misdiagnose or overdiagnose a patient’s condition. Although physicians chafe at the bureaucracy of utilization review, they have successfully avoided the discussion of accountability for cost-effective care in their own ranks.

Since utilization review became a common function within the reimbursement scheme in the late 1970s, the list of programs available to client firms have steadily grown through the years. What began for one URF as a system of hospital-stay review and retrospective review pushed out into the areas of surgical review, short-term patient home healthcare management, outpatient surgical review, hospital bill audit, maternity management, disability assessment, and psychiatric/substance abuse management. Finally, coming into the 1990s, URFs have entered the area of point-of-service fee negotiation. As each decision concerning healthcare and healthcare coverage is discussed, URFs seem to be there to confront both the physician and the patient as an overinterested fourth party.

Once again, we arrive at a conflict in achieving healthcare policy objectives. The aim of utilization review would seem to point toward assuring that appropriate quality care is administered in the least costly manner. However, if a patient must wait to receive care because his or her physician-of-choice has had a diagnosis questioned, access has been denied to the patient. Also, it stands to reason that adding another layer to the decision-making process adds costs to that process. The crucial question then seems to be, Do savings of health resources, patient and physician time and monies spent on care outweigh the expenditures of utilization review? Additionally, how can persons not intimately involved in the patient examination know fully the uniqueness of the illness affecting that patient? These questions reflect the continuing conflicts and concerns relating to utilization review.

The Clinton Administration’s plan does not appear to address this issue directly. Instead, the plan proposes to treat the clinical judgments of professionals with respect and protect the integrity of the patient-physician relationship. It also seems apparent that the Clinton plan will maintain utilization review as a force in the healthcare discussion. Thus, a system of utilization review is implied in the Clinton Administration’s health reform plan to ensure appropriateness of care.

The plan would, however, ease the regulatory atmosphere considerably. The focus of regulation would be directed at addressing those instances of abuse to the system or circumstances of proven poor performance. This system would allow physicians to practice medicine without the need of jumping through the numerous hoops currently existing between the examination of the patient and the actual administering of care. This is not to say that all bureaucracy would be removed by the plan, but regulations such as those previously discussed herein would be streamlined to address infractions and not overburden the entire system. The plan recognizes the integrity and experience

(continued on page 82)
of the physician relying on the intimacy of the patient-physician relationship to ensure the quality of care, rather than questioning that relationship at each turn.

As the procompetitive atmosphere gains momentum and market forces truly come to bear on the utilization review industry, perhaps those companies practicing a system of review closer to actual peer review will come to be the industry standard and may finally build accountability. Alan Greenfield, MD, MBA, an attending physician with a URF, expressed the vision that in a future of cost-contained, cost-efficient healthcare, utilization review would more resemble retrospective profiling rather than point-of-service review. In a fully capitated industry, physicians would have to become more accountable for practicing by research rather than practicing experientially, without regard for the advances in the field.

Evolving government intrusion: Case 3
The Clinical Laboratory Improvement Amendments of 1988

The Clinical Laboratory Improvement Act was actually passed in 1967. This law was enacted on the premise that laboratories that accepted tissue and body fluid specimens across state lines were engaged in interstate commerce and thus subject to federal regulation. This law followed the 1965 creation of Medicare and Medicaid, which defined laboratories as either hospital-based or independent, and provided that each must meet certain conditions for participation in those programs. With the 1967 law, interstate laboratories had to be licensed by the federal government. The Centers for Disease Control was responsible for writing, implementing, and enforcing regulations at the federal level.

The law also provided for equivalency through exemption from licensure through accreditation, or licensing through the private sector or state programs. Only two programs were established for this purpose: the College of American Pathologists Laboratory Accreditation Program and the New York State Licensure Program. The law exempted any laboratory receiving fewer than 100 specimens per year in interstate commerce, yet any laboratory receiving interstate specimens had to register and then apply for exemption. And hence, each interstate laboratory bore the brunt of added costs. Federal government laboratories, state government laboratories, and physician office laboratories were exempt from all regulation unless they received interstate specimens.

A 1988 article in the Wall Street Journal prompted the concern that resulted in the amendment to the Clinical Laboratory Improvement Act of 1967: The Clinical Laboratory Improvement Amendment of 1988 (CLIA 1988). The article sensationa­ly depicted the state of clinical laboratory testing in the United States. It focused on the poor quality of gynecologic cytology examinations (Papanicolaou testing) that had resulted in two women's results being misread as negative when malignant cells were indeed present. The CLIA 1988 was enacted as a comprehensive law to ensure consistent laboratory testing procedures and thus to safeguard the public. Neither the congressional hearings and testimony nor the Wall Street Journal article revealed that cytology examinations were already covered under the Clinical Laboratory Improvement Act of 1967, and that all cited instances of unacceptable laboratory performance had been subject to enforcement under the existing regulations.

The CLIA 1988 statute has been far-reaching in its application and effect on laboratory testing in the United States. The all-encompassing definition of laboratories affected by this new amendment extended federal regulation from the approximately 12,000 hospital-based and independent laboratories engaged in interstate commerce or service to Medicare patients to nearly 140,000 facilities, most of which had never been subject to federal regulation. Included under the new regulation are all clinical laboratories; all physician office laboratories; all federal and state government laboratories; and all research facilities testing specimens for patient care. The effect of this law is to regulate all laboratories regardless of the individual quality records through registration fees, inspection fees, proficiency testing, and the myriad rules and guidelines to be followed when performing specimen testing.

Often, the burden of the regulations, referred to by physicians as the "hassle factor," has led many physicians to limit their practices, and, in this case, to discontinue laboratory services to patients. Early estimates by the Health Care Financing Administration (HCFA) officials estimated that 180,000 to 220,000 laboratories would be registered by this time. As of September 1993, only about 150,000 laboratories had registered. For a program envisioned as self-sustaining through compliance fees, registration fees, and inspection fees, the enrollment of one-fourth to one-third fewer laboratories than anticipated has been financially troubling to say the least.
Physicians continuing to provide laboratory services must incur the requisite fees and then must pass on the added costs in the fees they charge to patients. And, in communities without laboratory facilities, small communities, and rural communities, patients must incur the costs of traveling to areas with the needed laboratory services and pay an inflated rate because of the aforementioned added costs to physicians. A program that had set quality in laboratory testing as its objective has instead decreased access to care for some and produced increased costs for consumers and healthcare providers alike. This law, in short, has compromised access and sacrificed cost-effectiveness in the pursuit of quality.

Looking specifically at CLIA 1988, regulation will continue for laboratories that perform a comprehensive menu of tests; perform a large volume of tests (50,000 or more per year); engage in critical testing; interpret Papanicolaou smears and cytology samples; or conduct testing to monitor care as it is being delivered. The Clinton plan would ease the regulatory burden on laboratories that perform simple tests and would add more simple tests to the list of waived tests. When the Final Rules for CLIA 1988 were written, the list of waived tests included dip-stick urinalysis, visual end-point pregnancy and ovulation tests, erythrocyte sedimentation rate, stool guaiac test for occult blood, hemoglobin by copper sulfate, spun hematocrit, and certain capillary blood glucose monitoring devices approved by the Food and Drug Administration (FDA) for home use. All laboratories performing waived tests and microscopy would be exempt from all requirements under CLIA, including registration and payment fees to the Department of Health and Human Services (DHHS). It is estimated that 79,000 of the 150,000 presently registered laboratories would be exempted under the Clinton plan (working draft, the American Health Security Act of 1993, Clinton Administration).

The Clinton plan also provides for the easing of the regulatory burden on laboratories conducting moderately complex testing. The plan would also create a new category of moderately complex tests that would be performed using FDA-approved, highly reliable equipment that would be subject to less-stringent inspection requirements. The outline of changes affecting CLIA calls for a report to be issued by January 1, 1996, in which the Secretary of the DHHS would review the extent to which laboratories conducting moderately complex testing should continue being regulated. Another change to the CLIA statute would streamline inspections, focusing on high-volume, high-risk laboratories.

Finally, the Clinton plan would revise some of the personnel requirements for certain laboratory positions under CLIA to provide needed relief in urban and rural areas (working draft, the American Health Security Act of 1993, Clinton Administration). The American Health Security Act would change the focus of regulation away from broad, industrywide actions to measures pointed at correcting instances of poor performance.

Comment
As we osteopathic physicians approach the 30-year mark initiating the next phase of healthcare policy in America, we find ourselves inundated with regulations from government and private-sector agencies which impact our ability to provide direct patient care. For osteopathic physicians, this atmosphere is doubly full of problems because nearly 50% of all osteopathic physicians practice solo while another 40% are in partnerships or small groups. For the physician operating a small practice, these regulations are not merely hurdles to cross, but rather they pose major questions concerning the comprehensiveness of care that a physician can reasonably provide within a 24-hour day.

The small-group physicians and solo practitioners must decide whether to provide laboratory services to patients by weighing the costs of compliance, registration inspections, and proficiency testing against the value of that service and the revenues that will be generated to cover the costs of providing that service. Unfortunately, the current regulatory atmosphere surrounding the medical professions has diverted the time and resources of physicians away from patient care to the flood of red tape and excessive regulations flowing between the physicians and the care of their patients.

Some of the healthcare reform proposals introduced at the federal level have addressed this issue of overregulating the patient-physician relationship. The Clinton Health Care Reform Package has set the reduction of bureaucracy as one of its primary objectives. The plan states that the American Health Security Act will reduce the burden of paperwork and administration; that regulatory, billing, and reporting requirements will decline; and that consumers will experience a streamlined and simpler system. In regard to streamlining regulatory activities, uniform stan-
Standards for the licensing of healthcare institutions will focus on essential performance requirements related to patient care. As these standards are developed, they will replace current regulations, and agencies charged with certifying health institutions will turn their focus toward those institutions that have exhibited unacceptable performance and problematic records.

References