Writing the Regulations for Health

DREW ALTMAN and HARVEY M. SAPOLSKY

Department of Political Science, M.I.T.

ABSTRACT

The development of regulations in health is much more than a purely technical procedure. Rather, it involves decisionmaking and bargaining processes that engage a wide range of individuals and organizations with diverse interests and varied resources. Attempts at statutory precision and goal clarification may improve, but will not fundamentally alter the regulation writing experience. The dynamics of regulations development are revealed in three cases. The primary case, The Health Maintenance Organization Act of 1973, suggests that despite the efforts of the regulations writers themselves, there are limits to the extent to which basic interest conflicts and questions of health policy can be resolved in the process. Other cases examined are the Professional Standards Review Organization Act of 1972 and the National Health Planning and Resources Development Act of 1974.

The most basic issue in health policy, the question of whether or not external controls should be imposed upon the organization and practice of medicine, is beginning to be addressed. For years the issue was obscured by the debate over the establishment of a federal role in the financing of medical services. The first steps in establishing such a role, the passage of the Medicare and Medicaid programs which provide health insurance coverage for the aged and the poor, however, came about only when there was an explicit pledge by proponents of these measures that federal intervention in the financing of medical services would not be accompanied by attempts to alter the structure of medicine. Now, well before the extension of national health insurance to the entire population and less than a decade after the enactment of Medicare and Medicaid, the structural issue is the prime focus of conflict in health politics.

Rapidly increasing health costs, often attributed to the Medicare and Medicaid programs, have brought attention to the structural issue. Many now are convinced that without major changes in the organization and practice of medicine, the fiscal burden of health expenditures will become unbearable both for government and for individual consumers. In addition, there is a growing concern over the distribution and quality of medical services. Some areas of the nation are unable to attract physicians. Several medical specializations are said to be oversubscribed. And there is belief that many needless or harmful surgical procedures are being performed. Again the remedies for these problems are thought to be structural.
Three pieces of legislation define the range of structural intervention that is currently being considered. At one end of the spectrum is the Professional Standards Review Organization (PSRO) program established by the 1972 amendments to the Social Security Act. Emphasizing self regulation, PSRO programs involve a minimum of structural change. Instead, reform to achieve a reduction in costs and improvements in quality is to come about largely through action within the profession. At the other end of the spectrum is the National Health Planning and Resources Development Act of 1974. This law provides strong federal direction and support for state and local planning and regulatory activities to be conducted by a set of newly created organizations. It replaces a number of ineffective health planning activities embodied in the Hill–Burton Hospital Construction Act, the Regional Medical Program, and an earlier comprehensive health planning law. Many observers believe the new planning law will also prove to be ineffective leading soon to much more stringent and direct federal regulation of the health sector. Somewhere in the middle is the Health Maintenance Organization (HMO) Act of 1973 which offers a market solution to the nation’s health problems. At the core of the HMO Act lies the belief that the creation of health care delivery organizations instilled with market incentives and a competitive orientation is a much more efficacious structural reform than is either self regulation or federal regulation.

Despite differences in the substance and the constituencies of the laws, there are undoubtedly elements common to the three of them. The HMO law, while based on a faith in the market mechanism, actually provides for considerable regulation not only of the organizations themselves, but of their marketplace as well. In so doing, it allies itself with the spirit of the planning law. The planning law establishes some of the organizational apparatus necessary for national health insurance; the HMO law attempts to specify services that may appear as a “base” in a national health insurance program. Both the PSRO Law and the Planning Law champion a “planning ethos” as a remedy for spiralling health costs. The PSRO's are intended to regulate their own industry; HMO's are intended to determine their own rates of expansion. In both the HMO Law and the Planning Law, consumer participation is encouraged as a value and a mechanism for control. The rhetoric of scientific planning and political accountability appear in varying degrees in all three acts.

The battle among the alternatives does not take place solely within the legislative arena. A large and complex network of federal agencies has been established to design, delineate, and administer health programs. What is decided in Congress must be interpreted and redecided within these agencies in order for a law to be implemented.

What we seek here is an understanding of the process by which health laws are implemented. We do so by examining the writing of regulations for the health legislation noted above. It is too soon, of course, to know how the structural issue will be settled; as we shall see significant obstacles block the path of each of the alternatives. Yet an examination of the regulation writing process tells us much about the agencies and officials who will help decide the issue and the likely outcome. Because its regulations are the most fully developed of the three, our attention will focus on the Health Maintenance Organization Act of 1973.