# Effective Regulation of Private Sector Health Service Providers

Lilani Kumaranayake,
Health Policy Unit,
Department of Public Health and Policy,
London School of Hygiene and Tropical Medicine,
London, UK

Draft: June 1998

Paper prepared for the World Bank Mediterranean Development Forum II, Morocco, September 1998. Lilani Kumaranayake is a member of the DFID-financed Health Economics and Financing Program.

# Table of Contents

**I. Introduction**

**II. The Public and the Private in the Health Sector**
- A. The Process of Privatization
- B. The Rationale for Regulation

**III. Regulation: Concepts and Definitions**
- A. Concepts
- B. Regulation Within the Health Sector

**IV. Regulation: What have we learned?**
- A. Effectiveness
- B. High Administrative and Transaction Costs
- C. Implementing and Monitoring Is Resource-Intensive
- D. Regulation is a Political Process
- E. The Role of the Consumer is Critical
- F. Rent-Seeking Behavior
- G. Lack of or Biased Information in Monitoring Legislation
- H. Incentives
- I. Informal Coping Mechanisms
- J. Regulatory Change is an Incremental Process

**V. Operational Principles**

## I. Introduction

> " Physicians [and other health sector providers] have many different roles and operate in different environments. From the point of view of regulation, the doctor is far more than a physician: he or she is both an economic actor with skills to sell and commonly a member of a pressure group with interests to defend." (Moran and Wood, 1993).

The increasing privatization of health systems around the world has also led to wide-spread interest in the role regulation has to play in achieving and structuring positive benefits from this private sector activity. The purpose of this paper is two-fold. First, it reviews the available literature and experience of regulation within the health sector and second it proposes some operational principles for designing and implementing effective regulation of private sector health service delivery. The context for the review is global and the derivation of operational principles is of particular relevance to the Middle East and North Africa (MENA)[1].

The MENA region contains countries with differing ethnic compositions, political structures and stages of economic development. The region is generally characterized by high fertility rates. There is a wide range of income levels within the region: from a high of over $17,000 GNP per capita in the United Arab Emirates to the poorest countries such as Yemen and Egypt ($260 and $790 GNP per capita) in 1995 (World Bank, 1997). The countries also differ in prevailing health problems, being at different stages of the epidemiological and demographic transition. There is increasing discrepancies between the rich and poor as well as the urban and rural health care, as greater resources flow into more costly and technology-intensive non-communicable disease treatment which favor the better-off. Given the heterogeneity of countries found in the region, the operating principles are quite general in nature.

The paper begins by considering the nature of the privatization process within the health sector and the rationale for regulation. It then discusses concepts and definitions of regulation. Section IV discusses what we have learned about the use of regulation within the health sector. The last section proposes some operational principles for the development of effective regulation.

---

[1] In this paper, MENA refers to the following countries: Algeria, Bahrain, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Palestinian Administration, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates, and Yemen.

# II. The Public and the Private in the Health Sector

## *A. The Process of Privatization*

Privatization has been described as the process in which "non-government actors become increasingly involved in the financing and provision of health care services." This can result in changes in roles, responsibilities and ownership within the health sector (Muschell, 1995). Thus privatization encompasses both for-profit (FP) and non-profit (NP) entities. Unless mentioned explicitly, the paper will use the term private sector to mean the FP sector.

In many countries, there is now substantial private sector activity in health care provision. For example, in Indonesia more than 60% of health expenditure was spent in the private sector. In India, more than half of the hospitals and 49% of the dispensaries are privately owned (Aljunid, 1995). Countries such as Pakistan, Kenya and India respectively have 50%, 70% and 47% of all physicians working in full-time private practice. In Thailand, although only 10% of physicians are in full-time private practice, 90% of those who work in the public sector also work in private practice (Roemer, 1993).

There is not a lot of information about the nature of the private sector in MENA countries. In 1994, it was estimated that half of the expenditures are done in the private sector, with more than 60% of health expenditures being spent privately in Lebanon, but private expenditures constituted less than 30% of spending in countries such as Algeria and the United Arab Emirates (Maede and Preker, 1995). In recent years, most countries have seen a rapid growth in the size of the private sector. For example in Jordan, between 1988-94, the number of private hospital beds increased by 28% (Taylor Associates International, 1997).

In general, there are three main reasons for this global increase in private sector activity within the health sector:

### 1. Deliberate Policy Choice (e.g. Health Sector Reform)

Encouraging the development of the private sector as an alternative means of health care provision has been an explicit part of health sector reform packages. This has been spurred on by increasing resource constraints and the poor performance of the public sector. These scarce resources were often allocated inefficiently (e.g. towards curative rather than preventative care). Services were often of "poor" quality with long waiting times and inadequate drugs/supplies (Cassels, 1995). The poor performance of the public sector, increasing economic difficulties and changes in prevailing ideologies led to calls for a reduction in the role of the state and an increased role for the private sector (Zwi and Mills, 1995). Through increasingly competitive markets for health care, privatization has been seen as a way to improve resource allocation, efficiency and quality, as well as broaden consumer choice.

**2. A Response to Weak Provision of Public Health Services and Rapid Increase in Informal Sector Activity**

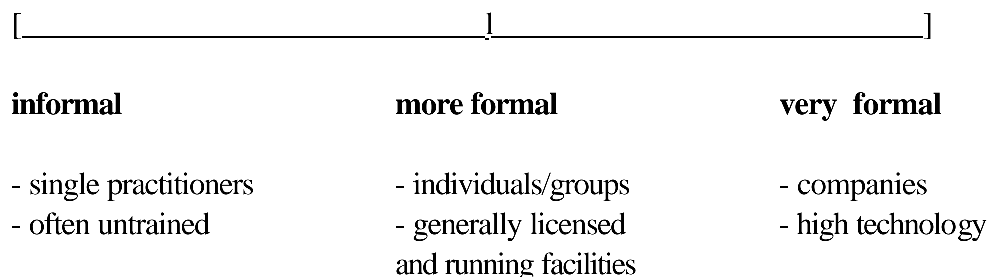
The development of private sector activity also emerged spontaneously, independently of actual policies. Again in response to poor and inadequate public services, there has been a rapid development of informal private sector provision of health care. This can be characterized by individuals operating for profit. These providers are often untrained or unlicensed, but are seen as a source of inexpensive care by patients. These providers can range from health care professionals operating at home or other premises to the drug-seller on the street corner.

**3. As a Response to Increased Consumer Affluence (e.g. increasing middle-class) and preference for greater quality Services**

Particularly, in fast-growing economies of South-East Asia and Latin America, as well as urban areas in many low and middle income countries (LMICs), the demand for private sector care has been driven by its being seen as a higher-quality service. In this context, we no longer see just individual providers working alone, but now have the emergence of clinics/hospitals as well as private companies organizing private health care (some of these companies are even listed on national stock exchanges). In areas where patients/consumers have increased demand for private care, we often see
the use of high technology equipment.

The private sector is not an homogenous entity. Rather, the extent and type of private sector activity can vary by country and within the country. It is always important to keep in mind the level or nature of private sector development for the context in which discussions about regulation are taking place.

Visually we can characterize private sector development in a simple continuum:




In addition, to the level and nature of private sector development, another complexity in characterizing private sector activity is the relationship between the public and private sectors. Traditionally services have been characterized in a four-fold classification: public/private and provision/financing. However, in practice this classification is not so distinct. Burchardt (1997) adds an additional level of classification which she calls

"decision-making" For decisions to be made privately, "there must be a range of services available to the consumer which are close in terms of price and quality, and the choice of services must be made directly by the consumer. For public decisions, agents acting on behalf of consumers or decisions on level of service and identity or provider are made by a public body rather than individual consumers."
Thus a third component is now added to the taxonomy:

| **Type of Relationships/ Markets** | **Provision** | **Financing** | **Decision-Making** |
|---|---|---|---|
| **Purely Public** | public | public | public |
| **Purely private** | private | private | private |
| **User Charges** | public | private/public | public |
| **Contracted Services paid by consumer** | private | private | public |
| **Contracted Services paid by State** | private | public | public |
| **Private services bought by vouchers, tax-relief and grants** | private | public | private |
| **Public services bought by vouchers** | public | public | private |
| **Public services bought by individuals** | public | private | private |

Almost all these forms of relationships are observed in LMIC . One key feature of private sector activity within the health sector is the co-existence of actors with highly complex internal organization alongside individual providers. Thus we have both a varied range of markets and market mechanisms as well as extremes in terms of private sector development within these markets (Kumaranayake, 1998b).

Within MENA countries, private providers, are for the most part, characterized by individual practitioners, and the emergence of private clinics and hospitals in urban areas. These private facilities depend on the existence of public hospitals for referrals and specialized care. The importation and distribution of drugs is another prominent area with

significant private sector development. Most financing of private care, including on drugs, is made by out-of-pocket payments rather than health insurance. Private health insurance is now expanding across countries.

### *B. The Rationale for Regulation*

Regardless of the precise reason for private sector activity in the health sector, "regulation" is often discussed in the context of privatization. Regulation is often seen as a potential response to address the many problems which arise in the private production, financing and delivery of health services. It is seen as having a crucial and balancing role in the push towards privatization.

Problems associated with private sector activity in the health sector include: poor physical infrastructure and a shortage of qualified staff; low standards of care; poor equipment or inappropriate technology; misuse of public resources within the private sector (e.g. public supplies and time of professional staff diverted to the private sector); and medical malpractice and negligence (Bennett, 1991).[2] Yesudian (1994) describes examples of the misuse of privileges, medical malpractice and medical negligence among licensed private doctors in Bombay.

Increasing inequities in the provision of health care have also been associated with increased private sector activity. For example in the Chilean promotion of ISAPREs, which included the transfer of government revenue to these private companies, about 2/3 of the population were excluded from the private insurance schemes (Hsiao, 1995). This is a classic example of adverse selection in insurance markets where the schemes select the better-off, leaving the elderly, disabled, unemployed and poor to rely on the public provision of services.

Private sector provision can also be inefficient and lead to cost-escalation. This may be due to things such as overcharging and the use of unnecessary high technology equipment and over-reliance on laboratory tests. The discussion above has focused to a large extent on traditional models of price competition, which assumes variations in quality away. These models suggest that as competition becomes more intense prices will drop. However, quality is a crucial factor in health care, particularly for patients who seek private health care (Aljunid, 1995). Quality competition is often (but not always) associated with higher investment in high technology equipment and the hotel aspects of care. It is less commonly suggested that quality competition actually leads to improvements in process quality. Patients may judge hospitals by rather crude indicators such as availability of certain equipment or the style of the building. Thus providers may invest in these aspects in order to 'signal' to the patient the quality of the service. Thus quality competition is often associated

[2] These problems can also be found in the public sector. For example, in pre-reform Tanzania, many public health workers were charging patients fees in order to supplement their income, although private practice was not allowed at the time (Mogedal et al, 1995). However, given the profit-oriented motives that are dominant in private sector activity the scale and frequency of these problems has been systematically associated with private sector provision in many LMIC.

with excessive high technology equipment being accumulated. For example, Zwi and Mills (1995) cite studies which find that South Korea has three times the number of CAT scanners per population than Canada. The city of Bangkok has a CAT scanner per population ratio that is higher than most industrialized countries, with the exception of Japan and the United States. Both South Korea and Bangkok have a substantial degree of private sector activity. The sheer rapidity of growth in private sector activity may also mean that it is hard to maintain quality.

A shift towards privatization may also lead to an inappropriate mix of health care services. For patients with imperfect knowledge, items such as pharmaceuticals and injections are visible indicators of the quality of service. Thus, one would anticipate that private practitioners may try and signal quality through these mechanisms and this leads to irrational prescribing practices. Mnyika and Killewo (1992) found that over 60% of health workers prescribed drugs requested by patients, and workers admitted that they occasionally gave drugs not indicated for the disease in order to satisfy them psychologically.

The response to many of these problems is a call for the imposition of regulation. The World Bank's 1993 World Development Report on health, which promotes private delivery of specific services to improve quality and decrease costs, posits a significant role for regulation in achieving these positive benefits from privatization:

"Strong government regulation is also crucial, including regulation of privately delivered health insurance to encourage universal access to coverage and to discourage [perverse] practices that lead to overuse of services and escalation of costs..... As less developed countries take steps to encourage a diversified system of health service delivery, they need to strengthen government's capacity to regulate the private sector. Regulations are required to ensure that quality standards are met, that financial fraud and other abuses do not take place, that those entitled to care are not denied services, and the confidentiality of medical information is respected" (World Bank, 1993).

The traditional economic rationale for the introduction of regulation is based on the existence of market failures (e.g. monopoly) which lead to inefficient resource allocation. However, the characteristics of health and health care also mean that there is a strong case for government involvement The key characteristics are the:

- presence of externalities (here differences between private and social benefits arise when there are **externalities** so that the total benefits of a transaction to society are not taken into account by the parties involved in the transaction, thus leading to an underinvestment in a good, if left to the market to allocate resources.)

- existence of public goods where the total costs of production do not increase as the number of consumers increase. The two key characteristics of public goods are that they are **non-rival** (the amount that one person consumers should not affect the amount

that other people consume, e.g. a street light) and **non-excludable** (once this good is produced there is no way to stop anyone else from consuming it e.g. the creation of an army for national defence will protect everyone). In the case of a pure public good, these characteristics will mean that people will not be will to pay for something which they could get if someone else bought the good. Thus there would be no private market for a pure public good. In practice, the degree of non-rivalness and non-excludability will vary, and since it is difficult to charge users to cover the costs of production, the private market will produce an output lower than the socially efficient level of output.

- existence of asymmetric information. When information is not freely available to all, two important sources of failure when privately held information is bought or sold are due to **moral hazard** and **adverse selection** So that when insurance leads people to engage in more risky behaviour, social costs are unnecessarily high and when buyers and sellers have unequal knowledge about their transaction, the outcome will be less efficient than if there were full information. This arises in the principal-agent relationship.

- uncertainty. Given the nature of health and health care, there are inherent uncertainties in terms of both the probabilities of having health problems and the resulting effect that care might have.

Markets may also be inefficient because they fail to achieve other social goals such as:

- improving equity - and important characteristic of the market economy is the distribution of income that it determines. People whose services are in heavy demand relative to supply earn large incomes relative to others. Thus redistribution of income may be thought to be an important goal of the society in terms of improving equity and distributive justice.

- protecting individuals from others - maximising behaviour may lead to exploitation of individuals in ways that society finds offensive (e.g. child labour or hazardous working conditions).

- merit goods - they may be goods that society deems to be especially important (e.g. such as education and health care) and those in power feel individuals should be required/encouraged to consume.

Thus even if the price system allocated goods and services with complete efficiency, members of society may not want to rely solely on the market since they have other goals that they want to achieve. It is clear that markets within the health sector are largely imperfect. These markets have many characteristics (such as asymmetric information, moral hazard and uncertainty) which lead to market failure. Thus a priori, there is a strong public interest rationale for government involvement in the health sector. The more difficult question is just what form this intervention should take.

The almost symbiotic relationship between private sector activity and regulation is clearly illustrated in the American health care system, which is among the most market-oriented in the world and yet this sector remains one of the most intensely regulated sectors in the American economy. (Phelps, 1992). Thus the problems associated with privatization may not result in a diminished role for government but rather one which is involves the regulation and monitoring of health service provision (Muschell, 1995).

# III. Regulation: Concepts and Definitions

## *A. Concepts*

Generally, **regulation** can be thought of as occurring when a government/state exerts control over the activities of individuals and firms (Roemer, 1993). More specifically, regulation has been defined as government " action to manipulate prices, quantities [and distribution], and quality of products" (Maynard, 1982). There are several actors involved in the regulatory process: health care professionals, managers, the ministry of health, commercial interests, non-governmental organizations, community and consumer groups.

The exact "action" is often described as the **regulatory intervention or regulatory mechanism**. These interventions which are used to affect variables such as price and quality can be categorized as:

1) **legal restrictions or controls** where participants must conform to legislated requirements. If participants do not abide by these laws then they will face punishment. In addition to these formal rules, more informal codes of conduct, guidelines or recommendations may exist. These informal rules are not binding on the regulatees (Moran and Wood, 1993). These type of legal restrictions are only successful in the context of a well-resourced regulatory framework (e.g. both for implementation and monitoring) as well as the existence of a well-functioning judicial system (for enforcement and sanctioning). Information is crucial in determining whether a particular regulation is being followed.

2) **incentives**, in response to which participants change their behavior and which lead to changes in the target variable (e.g. price, quality being affected). These incentives could be in both monetary and non-monetary forms. The underlying notion of incentives to accomplish regulatory goals is that:

> " regulation configures the economic system so that individual
> actors making decisions in their own best interest achieve allocative efficiency
> for society." (Jackson and Price, 1993)

Interest in using incentives to accomplish regulatory goals was first seen in utility regulation. It was recognized that with the institutional, informational and capacity constraints that are apparent, the implementation and impact of these legislated mechanisms is limited. Even in countries with a great deal of resources, legal controls to affect price, etc. may have serious drawbacks in practice. For example legislation aimed at lowering profits of monopolies, such as rate-of- return regulation, was heavily dependent on being able to gain detailed knowledge of the cost and revenue structures of the regulated firm .

3) **incentive regulation** -A further extension of the use of incentives is the use of incentive regulation which can be thought of as "rules" which regulate the relationship of verifiable outcomes such as price (Laffont and Tirole, 1993). To understand the rationale for

incentive regulation, it is important to go back the economic theory of incentives. Originally developed in the context of a firm and employee, the theory uses the context of agency relationships as its basis. Essentially because of information problems, the behavior of the agent (or manager or regulatee) can, through some hidden action, lead to a sub-optimal allocation (e.g. lower profits).
The solution to the problem (e.g. how to affect the behavior of the manager so that profits are maximized) results in different contracts where the different wages are paid for different observable outcomes.

In the case where effort is unobserved, then the solution to the problem depends on whether the parties are willing to bear risk. Within this context, the incentives must be structured so as to allow for managers or individuals to be willing to participate in the firm (the participation constraint). Second, the incentives are structured in such a way as to allow for a greater return if there is higher effort than the return to the manager for a lower effort (the incentive-compatibility constraint). Thus the result mechanisms is a rule which relates returns or wages to different observed outcomes.

Incentive regulation can be market-based. Rather than attempting to micro-manage an individual participant's behavior, these schemes can adopt market-based criteria. For example, in the regulation of telecommunications in the UK, a price-cap incentive scheme has been put into placing, replacing the rate-type regulation. In this case, the rule is written as P=RPI -X%, where P is price and RPI is the rate of inflation. Price-cap regulation attempts to address the same problems as rate-regulation but breaks the link between revenue and costs. Thus the firm/market prices is based on last year's price, corrected for inflation and then decreased by some percentage X. This X factor means that the real price will fall over the period of the price cap. Thus, the price-cap reduces the disadvantage of new firms trying to enter. There is some incentive to lower quality and so this must be monitored by the regulator. Other incentive regulation schemes are based on the government and contractor/regulated sharing costs or profits. Alternatively if X is constant, then firms are allowed to keep cost improvements which are greater than X% (Propper, 1995a). The advantage of such schemes is that if the variables are well-specified and easily observable, then the monitoring and implementing costs of such regulation is relatively low.

Both incentives and incentive regulation can be implemented through contractual obligations, rather than legislated requirements.

Another distinction which is made is between **formal and informal** regulations. The types of interventions described above can be considered as formal, whereby there is mixture of formal rule setting and explicit contractual agreements. Informal regulation is described as a system which uses cooperation between parties (e.g. health professionals, the ministry of health, and other interested parties) to achieve outcomes (MacIntosh, 1997). Interventions in this case may be the development of good practice norms and the regulation largely works due to the social norms where people behave in accordance with social rewards such as approval or disapproval of others (Lindbeck 1997). These interventions may be structured so that benefits are shared for the different possible outcomes of intervention.

These types of informal approaches have also been described as "institution-light options" rather than "institution-intensive options" for regulation (World Bank, 1997). These approaches can also include bottom-up regulatory approaches such as public information, local initiatives to strengthen citizens' voices and initiatives by local authorities. Institution-light options may also involve more formal approaches such as the use of incentives and incentive-regulation which are based on simple rules.

In general the use of formal regulatory mechanisms requires that there be precise rules or incentives which are established and are monitored by a regulatory body. Within the health sector, we find that there is quite substantial **self-regulation,** particularly among health care professionals. Instead of an independent regulatory body, professionals are often regulated by a group of peers (e.g. Medical Councils) who have the authority under existing legislation to license and sanction them. Again, the advantage of such a process is the relatively small resource requirements required to administer such self-regulation. However, there are very real questions of effectiveness and transparency in the case of self-regulation. Even without self-regulation, a close relationship between the regulatory body the regulatee may jeopardise the implementation of regulation, as the regulatory may be sympathetic towards or easily manipulated by the regulatees. This phenomena has been described as **regulatory capture**.

### *B. Regulation within the Health Sector*

The key roles that regulation can play within the health sector include:[3]

- control of market entry and exit
- control of competitive practices
- control of market organization
- control of remuneration
- control of standards/quality
- ensuring safety

In all LMIC there exist some basic legislation with respect to licensing (e.g. market entry) for medical professionals such as physicians, nurses and pharmacists. Many of the licensing regimes create medical councils of professionals who then self-regulate their profession. Many countries also have requirements regarding the registration of private and public facilities (e.g. hospitals, clinics and nursing homes). However many do not. There also exist widespread pharmaceutical legislation controlling the entry of drugs. Quality of provision is essentially done through the self-regulating function of medical professionals. Although some middle-income countries are now starting to use accreditation of hospital facilities as a means to improve quality and standards of facilities (e.g. Taiwan and Brazil). Incentive schemes could include such things as the introduction of quality assurance mechanisms such as accreditation on a voluntary basis. The advantages of such schemes are that

---

[3] Taken from Allsop and Mulcahy (1996).

participation is voluntary, with participants willingly providing a great deal of information, and the bureaucratic support that is needed is quite small. Taiwan has successfully implemented a system of accreditation over the past 15 years, and now eligibility for payment by National Insurance is linked to accreditation (Huang, 1995). Thus the state in it role as procurer of services can link tendering and public funding of contracts with these quality criteria.

Measures to organize and control competition (e.g. mergers) are almost non-existent in LMIC. Apart from accreditation, most of these regulations are in the form of legal controls or legislation, which carry some punitive action if the controls are not followed. Within the MENA region, there are generally very few regulations aimed at the private sector. The private insurance market remains small, although growing, and unregulated (Maede and Preker, 1995). There are some incentives available to the private sector which can be used by private health care providers. For example in Egypt, 5 and 10 year tax holidays are available for new construction - physicians and facilities are taking advantage of this to expand in size (Taylor Associates International, 1997).

## IV. Regulation: What have we Learned?

> "Once the legislation is passed, we'll have a greater ability to enforce it as there will be sanctions, but we haven't yet worked out what these will be."[4]

This section looks at the lessons learned from regulatory experience around the world, focusing mainly on legislated controls.

### *A. Effectiveness*

Despite the existence of basic legislation, the degree to which regulations are enforced and effective is low (WHO 1991; Asiimwe and Lule, 1993; Mujinja, Urassa and Mnyika, 1993, Yesudian, 1994, Kumaranayake, 1997). For example, Bennett and Ngalande-Banda (1994) found that the enforcement of regulatory controls is often weak or lacking in Sub-Saharan Africa. Many regulations affecting the health sector are old, inherited from pre-independence days, cumbersome and irrelevant to the concerns of today's health sector.

The use of licensing is designed to restrict entry (e.g. to qualified professionals, appropriate drugs) and to thus guarantee quality. In addition to the lack of enforcement, the failure to guarantee quality is attributed to limited funding available to the professional bodies which are responsible for regulating the profession. Second, even if professional bodies are adequately resourced, they can be reluctant to operate against their own membership and self-interest. Bennett and Ngalande-Banda (1994) present the case of the Zimbabwean Medical Council which has not publicized any cases of malpractice for fear of damaging the reputation of the profession.

Other examples of regulatory capture , where regulatory bodies are hampered by close relationships to industry are also apparent. For instance, The Public Citizen's Health Research Group (HRG), in the US, found one-third to half of 1700 hospitals examined by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) lacked adequate procedures for grading and reviewing physician hospital privileges, failed to ensure a safe physical environment, lacked adequate infection-control programs, and had poor monitoring and evaluation of surgical and anesthesia procedures. However, the JCAHO accredited 99% of these facilities. The JCAHO was founded 45 years ago by industry groups including the American Hospital Association and the American Medical Association. HRG concluded that the JCAHO customers were the hospitals rather than the public (Firshein, 1996).

Evidence from LMIC on the impact of drug regulations is quite disheartening. Widespread problems with pharmaceutical prescription and distribution require particular attention in LMIC. For example, Bhutta and Balchin (1996) did a survey to examine the effectiveness

---

[4] Dr. Lev quoted in Siegel-Itzkovitch J (1995).

of deregistration of 6 paediatric drugs. They found that while the deregistered products had been successfully withdrawn from the majority of outlets, black-marketing of the products was still taking place. The lack of inspectors and monitoring meant that the extent and pace of withdrawal of these drugs was determined by the pharmaceutical companies themselves. They found that many practitioners were unaware of some of the problems associated with the drugs and while they did not prescribe them, they substituted other irrational practices. Thus regulatory intervention was not enough, it needed to be accompanied by efforts to change patient attitudes and physician prescribing habits.

Irrational prescribing practices are rampant, there is extensive selling of prescription drugs from drug sellers, there is wide-spread counterfeit or fake drugs being sold and there is also an extensive black market for drugs (Roemer, 1991). Again there are too few resources expended on monitoring these regulations.

The experience of LMIC with respect to regulation is in marked contrast to that of Canada and Europe, which have significant private sector activity within their health systems. In these countries, a strong regulatory framework is reinforced by public responsibility and resources (Muschell, 1995).

### *B. High Administrative and Transaction Costs*

A traditional analysis of regulation assumes that there are no transaction or other operating costs for implementing, monitoring and enforcing the regulatory intervention. In practice, the regulatory process can become both cumbersome and bureaucratic. In the extreme, an almost parallel state machinery can be created with large staff as well as the development of lobbyists to interact with the regulators on behalf of various interest groups. For example, in New Jersey, USA it was estimated that the Hospital Rate Setting Commission and the regulatory process surrounding it cost about $10-15 million dollars, which represented a third of the total cost savings envisaged by the intervention (Liss, 1995).

Several countries have found that the design of appropriate regulatory mechanisms is difficult and the actual enforcement of these mechanisms imposes high administrative costs on both the regulator (state) and the regulatee. For example, the weak regulatory capacity in Chile allowed private insurers to deny coverage to high-risk individuals (World Bank, 1993). There has been very little work done on transaction costs for other types of regulatory mechanisms. Liss (1995) estimated that the operating costs for implementing, monitoring and enforcing the Hospital Rate Setting Commission in New Jersey was about a third of the total cost savings envisaged by the intervention (about $US 10-15 million).

The experience of regulating private health insurance to avoid problems such as adverse selection requires quite complicated regulatory mechanisms. These are very difficult to implement and require personnel with specialized skills. Estimated transaction costs are also high for the implementation of such legislation. In Chile, it has been estimated that transaction costs represent about 30% of premium revenue in the regulated insurance

market. Transaction costs have been estimated to be about 25% of premium revenue in the United States (Hsiao, 1995).

### *C. Implementing and Monitoring is resource-intensive*

Ngalande-Banda and Walt (1995) examine the experience of Malawi after allowing physicians, paramedical and allied health professionals to enter private practice. The 1989 Statute which allowed private practice also laid down basic standards for premises and the drugs which private practitioners were able to sell. Since 1989, the Medical Council has made initial inspections of premises for anyone applying to open a private practice (although there are few licenses refused) as well as performing periodic spot checks. However, in a survey of private practitioners, Ngalande-Banda and Walt find that 73% of practitioners have no fridge and that they dispensed a wide variety of drugs (even some not on the approved list).

The Malawian example shows a relatively stringent monitoring of regulatory controls compared to other countries. (For example, in most countries, private practitioners merely register with the Ministry of Health and there is no systematic inspection of premises). Two points to note: first, even with this relative stringency, regulators were not able to maintain standards regarding drug quality. This was largely due to resource constraints. Second, the number of private providers was initially small (starting with 24 physicians in 1989). However, the number of medical practitioners has grown substantially over 5 years: the number of physicians has almost doubled and the number of paramedicals has increased 11-fold (Ngalande-Banda and Walt, 1995). Given available resources, the level of monitoring cannot continue to be so stringent.

The potentially large resource requirements for implementing regulations can also be seen if we look at the example of Brazil. Its National Health Surveillance Secretariat handles applications for registrations of drugs, food, cosmetics and other products. The agency receives more registration requests than it can process. For example in one month, it received 5511 requests, 2122 related to drugs. The applications to register new drugs are often disguised as requests for minor changes to an existing product, such as changing the labeling or packing. Of the 2122 applications made, 61% related to product modification. Given this volume, it is very difficult to handle quality control - last year a technical commission found more than 800 irregularities (Csillag 1995). The resource requirements for such a job, particularly for LMIC, look overwhelming if we consider that the US Food and Drug Administration center for drug evaluation and research employs 1400 people full-time, including over 130 doctors (Guest 1995).

### *D. Regulation is a political process*

Regulation is also an inherently political process involving individuals and groups with vested self-interests attempting to influence the relative success or failure of a regulatory intervention. For example in Malawi, one of the driving forces behind the liberalization of

private practice was the interest/lobbying of physicians to allow private practitioners (Ngalande-Banda and Walt, 1995).

A second example occurred when Pakistan attempted to increase universal access to essential drugs. The proposed policy required pharmaceutical companies to produce a small fixed percentage of their output in the form of essential drugs to overcome the chronic non-availability and short supply of many important essential drugs. However, Ministry efforts were disrupted when the Pharmaceutical Bureau, an organization representing transnational pharmaceutical companies (and accounting for about 80% of market) showed their strong opposition. The proposed policy was subsequently dropped by the Ministry (Mirza, 1996)

### *E. The role of the consumer is critical*

Consumers are important in bringing to light information on the functioning of the health care system and the impacts of regulatory interventions. The key channels are the complaints procedures and legal action. Traditionally, the participation of consumers have been neglected in much of the regulation literature, apart from references to the possible benefits which they may enjoy.

Educating consumers is thus a powerful way to mobilize and make people aware of their rights and what constitutes good medical practice . For example, in Zimbabwe campaigns against excessive injections and prescriptions and many drugs have thought to be successful (WHO, 1991).

The role of consumer groups was vital in overcoming the lack of action by the Indian Medical Council on malpractice and negligence complaints by patients. Consumer groups took the case to Court and argued that paying for medical services was like paying for any other good, so patients should receive the same consumer protection as for other goods, as set out by the Consumer Protection Act of 1986. The Indian Supreme Court ruled in their favor, despite the strong campaign mounted by the Indian Medical Association against the inclusion of medical services. There are currently an estimated 8000 cases against doctors are pending in consumer courts with charges such as unnecessary surgical operations or inappropriate treatment to medical negligence leading to disabilities or deaths of patients (Mudur, 1995). The procedural ease of consumer protection courts, absence of hefty court fees or lawyer's charges and relatively speedy action have all facilitated the use of consumer courts.

### *F. Rent-seeking Behavior*

In theory it is suggested that once a regulation is implemented (regardless of the cost), then desired outcome is achieved. However, this does not take into account the response of those being regulated. In situations, where large rents (profits) are being made, providers

will attempt to protect these rents and this rent-seeking behavior may lead to adverse consequences. For example, studies have found that hospitals respond to the threat of regulation (designed to reduce costs) in ways which lead to a decline in the quality of services and increase in mortality rates. They may respond by reducing staff, eliminating selective services, consolidation of services and postponement of capital improvements (Marquez, 1990).

### *G. Lack of/ or Biased Information in Monitoring Legislation*

The regulator will to a large extent be dependent on the regulatee to provide information about the firm. The firm is in a position to delay or mislead the regulator by delaying the transmittal of data or by presenting inaccurate information.

### *H. Incentives*

In the review of regulatory mechanisms, we have seen that there has been little work done in LMIC on the effects of regulatory interventions. However, it is recognized that with the institutional, informational and capacity constraints that are apparent, the implementation and impact of these legislated mechanisms is limited. Even in countries with a great deal of resources, legal controls to affect price, etc. may have serious drawbacks in practice. For example, rate regulation depends to a great extent on the detailed knowledge of the cost and revenue structures of the regulated. This type of intervention is designed to micro-manage the participant's behavior. Clearly, obtaining this kind of information is time-consuming, costly and there is no incentive for the regulated to reveal the true state.

Given these informational, transaction, administrative and political constraints interest has now turned to examining whether incentive schemes may accomplish the same end. Incentive schemes are already apparent in LMIC (for example in Malaysia, there are allowances paid to encourage physicians to remain in the private sector).

Incentive schemes rely on two methods. First, the government has the ability to subsidize or tax regulated firms., Transfers can take several forms: direct subsidies, government loans, at low interest, government guarantees for borrowing on the private markets, transfers of public inputs, etc. (Laffont and Tirole, 1993). Second, the government can make transfers to participants through its purchasing function.

There has been little study of the role of incentives within the health sector. Hughes (1993) examines the target payments to physicians in the NHS. He finds that the introduction of target payments (lump sum payments for achieving target levels of immunization coverage and cervical smears) lead to a short-term increase in the number of smears being performed. However, in the long-term physicians had the incentive to reorganize existing services, rather than provide extra services and still receive the target payment. This was due to the fact that payments were not linked to outcomes, but rather to information about the patients.

In a social experiment on incentive regulation of nursing homes, Norton (1992) looked at whether monetary incentives can improve the access and health of Medicaid residents in nursing homes while saving money. Nursing homes were given three kinds of financial incentives:

- tied to admission (daily reimbursement rate was changed to depend on case-mix in order to increase the admission of sick patients)
- tied to case outcomes ( a lump sum bonus was awarded when a resident improved her health)
- tied to discharges (a lump sum bonus was awarded when a resident was promptly discharged to home or to an intermediate care facility to encourage nursing homes to fill their beds with people who could most benefit from their care).

Norton found that the incentive regulation was found to have had beneficial effects on access, quality and costs of care. The admission incentives induced the nursing home to take in people with severe disabilities. The cautionary note about this experiment was the need to have independent confirmation of discharges.

Whynes and Baines (1998) suggest that for incentives to fulfill their role, the regulatees must have some discretion over their behavior. They suggest that the income-based economic incentives for UK GPs have had limited impact because a high-proportion of their income continues to be determined by patient characteristics and thus the scope for a discretionary response to income incentives is correspondingly small

Thus the incentive type mechanisms seem to have much lower transactions costs associated with them. However, monitoring is still important, particularly to see if the incentive is having the desired effect on behavior.

### *I. Informal Coping Mechanisms*

Despite the many problems encountered in the review, there have also been examples of the development of coping strategies in the presence of these failures. For example, in Zimbabwe it was found that informal arrangements were made between the centralized regulatory body (Health Professions Council) and local municipalities, whereby the local municipalities would inspect and carry out other monitoring functions, which the centralized body was unable to do so (Hongoro et al, 1998).

### *J. Regulatory Change is an Incremental Process*

The recent example of Lebanon (van Lerberghe et al, 1997) highlights the fact that real change is generally accomplished by an incremental process of both experimentation and alliance building (in this case between the Ministry of Health and International Donors), rather than a rapid overhaul of the system. The Lebanese example also points to the importance of recognizing the political process in which the regulatory intervention is planned.

## V. Operational Principles

Given the earlier review of evidence, the following operational principles are suggested when attempting to introduce (or remove) regulations concerning the private sector:

1. For all countries, there is need for basic legislation governing the entry (e.g. licensing and registration) of health professionals and facilities. Despite the evidence that these regulations may be ineffective, without being backed by adequate resources, experience suggests that as the private sector develops or as resources become available, it is much harder to implement legislation. Although, these type of regulations will not affect the informal sector (which by definition is outside the government's ambit), this basic legislation can be thought of as establishing minimum standards which to strive for. Second, the existence of basic legislation also means that as the judicial system is strengthened, or consumers become more aware of their rights, then there is legal recourse through which to pursue the implementation of regulations.

2. The timing of regulation is crucial. As the private sector develops and becomes more formalized coalitions of interest emerge, it is very difficult to put into place basic regulatory legislation which works against private sector interests. In the MENA region, many countries are just embarking on a process of health sector reform and privatization. This is then the ideal opportunity to consider the regulatory framework that should be in place. Even though the extent of private health insurance is small at the moment, experience from countries such as Thailand suggest that it is virtually impossible to implement legislation for private health insurance, once the industry is well-established.

3. Understanding the political process is crucial, and the development of alliances essential for successful implementation of health provider regulation. Thus, a mapping of interested parties and their likely interests and natural allies should be created, in order to increase understanding of the latent political processes. Creating strategic links and partnerships between the private sector (e.g. with key leaders) and the public sector (e.g. the Minister) can assist in the improved application of interventions.

4. The role of consumers and patients should be strengthened in order to have a widespread understanding of appropriate preventative and therapeutic regimes. The recent case in India illustrated how consumer groups can take effective action to ensure the provision of minimum standards through the judicial process. Key to this was consumer awareness of their "rights", good medical practice, and established legal standards.

Continuing education for health workers, particularly with respect to pharmaceutical prescribing practices is also important. This allows health workers, including physicians and paramedicals to stay abreast of changing practices and drug regimes. Methods for influencing education include influencing training and medical school curricula, as well as refresher and continuing education courses

5. Judicious use of incentives, particularly in middle-income countries can work. While little use has been made of incentive mechanisms, it is clear that participants do respond to

financial incentives (although not always in the manner predicted). The example of Taiwan, suggests that linking the government's purchasing power
to accreditation and improved quality can be successful. The key is to recognize when opportunities for incentive-based intervention exist.

Second, in terms of types of markets where incentives may be used, this review suggests that there needs to be some pre-existing relationship between regulator and regulatee. This is because the implementation of regulatory incentives will usually rely on the use/redesign of existing systems of government transfers and procurement. Thus in terms of the various market structures which were reviewed in section II, market structures where governments still retain roles in provision or financing (e.g. public, contracting out of services and public provision) are more suitable for incentives (and possibly incentive regulation).

6. Incentive regulation may have limited uses in the health sector. Incentive regulation in the public utilities field include profit/cost and risk sharing based on verifiable performance measures and this may be amenable to use in the health sector (Laffont and Tirole, 1993). As in the case of public utilities, it is clear that regulation based on detailed knowledge of the provider's organizations and practices is not successful, and points to the need to move from this level of micro-management to favoring market-based incentive schemes (Abbott and Crew, 1995). Within the health sector, characterized by uncertainty and multi-dimensional aspects of care, it is difficult to get simple indicators of outcome.

The quality dimension is particularly problematic. Improving quality using incentive regulation seems to be quite difficult given the multidimensional characteristics of quality and the difficulty in measuring it. The need for clear formulae and narrow outcomes suggest that incentives with respect to quantity or output and price (or remuneration), which is more easily quantified may be more feasible (Kumaranayake, 1998b).

7. The regulatory process must be seen as a process of incremental change, although this is not inconsistent with having a strategic or overall idea of where the regulatory framework is heading towards. However, changes should be planned through a phased-in process, recognizing the political context that surrounds the changes.

8. When considering the process of reform regulation needs to be thought of concomitantly to privatization strategies. If potential gains from privatization are to be realized, then this may require a regulatory framework in place. Privatization and regulation should be planned for jointly.

10. Regulation is limited in what it can accomplish. While there is a tendency to view regulation as the solution to the various problems associated with the private sector, the ability of regulation to address these problems must be recognized. Some problems may require much broader-scale changes such as overall organization or administrative processes being changed.

11. Emphasis on improving government's capability, in order to improve effectiveness. There is no automatic formulae to ensure successful implementation of regulation. Rather, the actual design of any intervention will vary from system to system, and its institutional and regulatory capacity. Regardless of what type of intervention is desired, there is always a need for strong monitoring capacity within the government

# REFERENCES

Abbott III TA. (1995). Health Care Policy and Regulation. Boston: Kluwer Academic Publishers.

Abbott TA and Crew MA (1995) "Lessons from Public Utility Regulation for the Economic Regulation of Health Care Markets: An Overview." in Abbott (1995).

Allsop J and Mulcahy L . (1996). Regulating Medical Work: formal and informal Controls. Open University Press: Buckingham.

Asiimwe D and JC Lule. (1993). "The Public/Private Mix in Financing and Provision of Health Services in Uganda." in Bennett S and Mills A (eds). Proceedings from the Workshop on the Public/Private Mix for Health Care in Developing Countries. Health Policy Unit Report. London: London School of Hygiene and Tropical Medicine.

Aljunid S. (1995). "The Role of Private Medical Practitioners and their Interactions with Public Health Services in Asian Countries." Health Policy and Planning. 10(4), p.333-349

Bennett S. (1991). The Mystique of Markets: Public and Private Health Care in Developing Countries. PHP Departmental Publication No. 4. London: London School of Hygiene and Tropical Medicine.

Bennett S. and Ngalande-Banda E (1994). Public and Private Roles in Health: A Review and Analysis of Experience in Sub-Saharan Africa. Geneva: WHO.

Burchardt T (1997). "Boundaries Between Public and Private Welfare: A Typology and Map of Services." Center for Analysis of Social Exclusion Paper, LSE.

Cassels A (1995). "Health Sector Reform: Key Issues in Less Developed Countries." Journal of International Development 7(3):329.

Csillag C. (1995). " Brazil Tries to Control Drug Registration." Lancet 346:1480.

Firshein J (1996). "Report criticizes US hospital inspection and accrediting." Lancet 348:189.

Hsiao WC. (1995). "Abnormal Economics in the Health Sector." in Health Sector Reform in Developing Countries: Making Health Development Sustainable. ed. P. Berman. Boston: Harvard University Press.

Huang P. (1995). "An Overview of Hospital Accreditation in Taiwan, Republic of China." The International Journal of Health Planning and Management. 10(3), p.183-192,

Jackson PM and Price CM (1994) Privatization and Regulation: A Review of the Issues. Harlow: Longman Group.

Guest R (1995) "Japan Criticized for Unsafe Drug Licenses." British Medical Journal 311:1521

Hongoro C, Kumaranayake L, Chirove J, Musonza T. (1998) "Regulation of the Private Health Sector in Zimbabwe." PHP Department Paper, LSHTM.

Hughes, D. (1993). "General Practitioners and the New Contract: Promoting Better Health Through Financial Incentives." Health Policy 25:39.

Kumaranayake L. (1997). "The Role of Regulation: Influencing Private Sector Activity Within Health Sector Reform." Journal of International Development, 9(4):.641.

Kumaranayake L. (1998a). "Economic Aspects of Health Sector Regulation: Strategic Choices for Low and Middle Income Countries." PHP Department Paper, London School of Hygiene and Tropical Medicine.

Kumaranayake L. (1998b). "Quasi-Markets, Markets and Incentive Regulation in the Health Sector: Perspectives from low and middle-income countries." Paper presented at Quasi-Markets Research Seminar, April 1998. London, UK.

Laffont, J-J and J. Tirole. (1993). A Theory of Incentives in Procurement and Regulation. Cambridge: MIT Press.

Lindbeck A (1997) "Incentives and Social Norms in Household Behavior." American Economic Review 87(2):370

Liss G. (1995). " Comment" in Abbott (1995)..

MacKintosh M (1997). "Informal Regulation: A Conceptual Framework and Application to Decentralized Mixed Finance in Health Care." Paper presented at conference on Public Sector Management for the Next Century

Maeda A and Preker A (1995). "Private-Public Roles in Health in the Middle East and North Africa (Maghreb) Region, (MNA)." Human Development Department, The World Bank.

Marquez P. (1990). "Containing Health Care Costs in the Americas." Health Policy and Planning. 5(4), p.299-315.

Maynard A. (1982). "The Regulation of Public and Private Health Care Markets." in McLachlan, G. and Maynard , A. (eds). A Public/Private Mix for Health: the Relevance and Effects of Change. London: Nuffield Provincial Hospitals Trust.

Maynard A and Bloor K. (1995). "Health Care Reform: Informing Difficult Choices." International Journal of Health Planning and Management 10:247

.

Mirza Z (1996) "Non-emergence of Pakistan's National Drug Policy." Lancet 348:119.

Mogedal S., Steen SH and Mpelumbe G. (1995). "Health Sector Reform and Organizational Issues at the Local Level: Lessons from Selected African Countries." Journal of International Development. 7(3), p.349-368 .

Moran M and Wood B. (1993). States, Regulation and the Medical Profession. Buckingham: Open University Press.

Mynika, KS and JZJ Killewo. (1992) "Irrational Drug Use in Tanzania." Health Policy and Planning. p. 180-184.

Mujinja, PGM., Urassa D; and Mnyika KS. (1993). "The Tanzanian Public/Private Mix in National Health Care." in Bennett S and Mills A (eds). Proceedings from the Workshop on the Public/Private Mix for Health Care in Developing Countries. Health Policy Unit Report. London: London School of Hygiene and Tropical Medicine.

Mudur G. (1995). "Indian Doctors May Be Tried in Consumer Courts." British Medical Journal 311:1385-6.

Muschell J. (1995). "Privatization in Health." WHO Task Force on Health Economics. Geneva: WHO.

Ngalande-Banda E and Walt G. (1995). " The Private Health Sector in Malawi: Opening Pandora's Box?" Journal of International Development. 7(3), p.403-422.

Norton EC (1992) "Incentive Regulation of Nursing Homes." Journal of Health Economics. 11:105

Phelps, CE (1992). Health Economics. New York: Harper Collins

Propper C (1995). "Agency and Incentives in the NHS Internal Market." Social Science and Medicine. 40(1): 1683-1690

Roemer MI. (1991). National Health Systems of the World. Vol I. Oxford: Oxford University Press.

Roemer MI. (1993). National Health Systems of the World. Vol. II. Oxford: Oxford University Press.

Siegel-Itzkovitch J (1995). "Israeli Doctors Allowed to Advertise." British Medical Journal 311:1526

Taylor Associates International (1997) "Private Hospital Investment Opportunities." Prepared for the International Finance Corporation.

Torres G and Mathur S (1996). "The Third Wave of Privatization: Privatization of Social Sectors in Developing Countries." Private Sector Development Department, The World Bank.

van Lerberghe W, Ammar W, El Rashidi R, Awar M, Sales A and Mechbal A. (1997). "Reform follows failure: II Pressure for change in the Lebanese health sector." Health Policy and Planning 12(4):312-319.

World Bank. (1993). World Development Report 1993: Investing in Health. Washington, D.C.: World Bank.

World Bank. (1997). World Development Report 1997: The State in a Changing World. Washington, D.C.: World Bank.

World Health Organization. (1991). The Public/Private Mix in National Health Systems and the Role of Ministries of Health Geneva: WHO

Yesudian CAK. (1993). "Behavior of the Private Health Sector in the Health Market of Bombay. Health Policy and Planning. 9(1), p.72-80.

Whynes DK and Baines DL (1998). "Income-Based Incentives in UK General Practice." Health Policy 43:15.

Zwi A and Mills A. (1995) "Health Policy in Less Developed Countries: Past Trends and Future Directions." Journal of International Development 7(3):299.