



# Policy Brief

## Why regulation?

There has been a dramatic upsurge of entrepreneurialism in health care systems in Europe, spurred by interests in better efficiency and quality. The characteristics of entrepreneurial behaviour include seeking opportunity, promoting innovation, and genuine accountability. However, experience so far indicates that entrepreneurial behaviour does not make for an effective health care system in an unregulated “free-for-all”. Supporting regulation is needed to avoid some of the dangers inherent in entrepreneurialism which could sacrifice the core policy objectives of a socially responsible health care system. Bringing a carefully calibrated degree of market-style mechanisms into the health care sector – or entrepreneurialism tempered by regulation – can achieve the best of both worlds: more patient responsiveness and efficiency, combined with publicly accountable providers and values. This does not normally mean more privatization. The key is “a carefully calibrated degree of market-style mechanisms” or, in other words, regulatory strategies that seek to capture the benefits of entrepreneurial innovation without jeopardizing the core policy objectives of a socially responsible health care system. These objectives – widely-held common concerns such as equity and justice, social cohesion, economic efficiency, informed citizens, health and safety and individual choice – underlie the practical operation of regulation in any health

care system, and if they are ignored, may threaten to destroy the public’s faith in their health system and in their government itself. Thus, regulation is required to ensure that decision-making is consistent with broader social objectives.

### In brief:

Well-designed regulatory mechanisms can stimulate needed entrepreneurialism while simultaneously safeguarding social objectives.

## What form can regulation take?

In industry, the aim of innovation is to increase profits; in government, it is to increase efficiency and quality. Increasingly, the state is “rowing less but steering more”; in other words, it is not doing all the work itself but it sets the route and ensures that its objectives are reached. Traditional approaches known as “command and control” are being replaced by more subtle “steer and channel” regulation. The increasingly common model of a regulatory state is one which enables but not necessarily provides services, and establishes carefully constrained markets in some formerly state-run sectors.

Regulation can be defined in different ways, such as:



- a set of rules operated by a state agency;
- state policy steering the economy;
- all mechanisms of social control affecting a society;
- a continuum of government restraint on otherwise unrestrained market activity;
- any sustained control by a public agency over socially valued activity, known as the stewardship approach.

When planned market mechanisms are introduced into the health sector, and some managerial autonomy exists for providers, “command and control” has to give way to “steer-and-channel” regulation. Five general types of “steer-and-channel” options have been identified, which policy-makers can use individually or combined:

- Decentralization: when the power to make regulatory acts is passed on to others, whether it be to independent government agencies (“deconcentration”), to regional/local authorities (“devolution”), or to social insurers (“delegation”). This can also cover privatization, such as that adopted for primary care provision in countries in central and eastern Europe (CEE).
- Enforced self-regulation: when professionals or enterprises set standards for the behaviour of their membership, This is the case in Germany and in most countries with systems based on social health insurance. This has some advantages, but tends to be weak if not backed up by state-enforced compliance.
- Accreditation and licensing: usually only used as part of a range of regulatory tools.
- Independent regulatory agencies: not widely used, but some exist, such as the

National Agency for Accreditation and Evaluation in Health (ANAES) in France. In the Netherlands, an independent agency supervises self regulators.

- Intersectoral cooperation: when external strategies are used to pursue objectives, such as taxing tobacco to deter smoking.

## Who regulates?

Regulation is normally introduced by local, national or international government, or by independent agencies. It is typically carried out by laws, decrees, guidelines, etc., which can be challenged in court. These tools are then used in a variety of strategies by governmental bodies, to persuade or to deter. Recently, market-style incentives have been widely used. Beyond tools and strategies, there is implementation of these mechanisms, which requires management capacity and trained people.

When deciding who should do what, it is useful to bear in mind which actors are good at which functions, and plan accordingly.

There are many potential regulatory actors. When deciding who should do what, it is useful to bear in mind which actors are good at which functions, and plan accordingly. Main strengths and weaknesses can be briefly summarized as follows:

- Local authorities are good at accountability, but not strong on coordination;
- Parliaments are strong on democratic authority, not good at sustained scrutiny;
- Self-regulators are good at specialist knowledge, not accountability;



- Courts are strong on fairness, not planning;
- Central departments are strong on coordination with government, but not neutrality;
- Agencies are strong on expertise, but not neutrality;
- Directors-general are good at specialization, not at spreading discretionary powers.

It is also important to consider whether the same actor both sets the rules and supervises them.

## What is regulation aiming at and how?

Governments may choose to implement a mixture of measures to get the right balance.

First, policy-makers often want to stimulate entrepreneurial opportunities in the health sector by encouraging more competitive behaviour. Routes to this may include, for example:

- Having volume or performance-based payments instead of fixed budgets;
- Permitting hospitals to retain operating surpluses;
- Providing subsidies or exemptions for certain services;
- Allowing institutions to set their own fees, allowing patients to choose their hospital, etc.

Second, if policy-makers want to sustain competitive markets, but also put in place some protection to offset their more negative aspects on structure and behaviour, they might consider:

- Setting minimum standards through licensing, etc.;
- Restricting mergers;
- Introducing measures to reduce adverse selection by health care payers and providers;
- Requiring that health insurance funds accept all applicants.

Third, some regulation focuses on entrepreneurial decisions to safeguard social objectives rather than facilitating competitive markets, such as:

- Minimum service hours for hospitals and outpatient care;
- Maximum waiting time guarantees;
- Funding through income-related contributions, not risk-related premiums;
- Regulations that affect all subsectors, such as setting uniform prices, or profit margins, minimum and maximum reserve levels for insurers, etc.;
- Health care quality assessment;
- Guidelines and protocols for treatment;
- Regular quality assurance for providers, etc.

This kind of regulation may also address public safety concerns by providing more customer information in the pharmaceutical sector, or restricting drug advertisements.

Governments may choose to implement a mixture of measures to get the right balance.



## What can be learned by the health sector from other sectors?

Finding the balance between regulation and entrepreneurial behaviour is complicated, and pro-competitive regulation must reflect the unique characteristics of the sector for which it is designed. This will depend on the type of competition to be generated, the contractual issues involved, and costs of regulating. While other sectors can teach the health sector about how to encourage entrepreneurialism, the content may be too different to be useful. Despite this, encouraging competitive behaviour in health care is often treated in the same way as any other economic sector. For example, within the European Union there is tension between the single market and the subsidiarity principle under which national governments run their own health services. This tension was in the spotlight during debates about the legal status of sickness funds in the Netherlands. Within the European Union there is a question as to whether member states may have to abandon competitive initiatives entirely in order to retain publicly funded and delivered health care arrangements.

## What has been the experience with entrepreneurialism to date?

Over the 1990s, some patterns have emerged across Europe. The strongest levels of entrepreneurialism are in dental care and pharmaceuticals, with some experiments in social and home care services. Entrepreneurialism

has also made some inroads in the most important and expensive areas, such as hospitals, primary care and funding structures. This is the case in most of western Europe, both for tax-funded or social health insurance funded systems. (See the box on initiatives).

It is difficult to evaluate what difference the increase in entrepreneurialism has made to the patient, and even to determine the assessment criteria to use. Typically, such evaluation takes time, and Culyer's famous evaluation mantra applies: "too early, too early...oops, too late".

Despite this, based on current evidence, there is some agreement on the impact of entrepreneurialism.

- Increased entrepreneurialism has brought more economic efficiency to hospitals, and to a lesser degree, to social and home care and primary care.
- The introduction of entrepreneurial incentives within tax-funded health systems has worked best where it has been combined with enhanced patient choice.
- In funding health care, only weak entrepreneurial initiatives are tolerated. This is because in the area of funding, entrepreneurialism directly confronts core social and policy objectives and beliefs. Overall, policy-makers in western Europe approach change with caution and considerable trepidation.

These reforms introduce the idea that public-sector care can operate at the same high standards typically associated with the private sector. However, increased entrepreneurial activity is not all positive. In the Russian Federation and in central and eastern Europe, it was unleashed too rapidly and with inadequate regulation. This has increased corruption and widespread informal payments



## Entrepreneurial initiatives by sub-sector

### Hospitals

In Europe as a whole, changes now being made gradually are among the most notable and important. Much hospital governance in northern Europe has gone from command-and-control to steer-and-channel. Similar efforts to loosen the decision-making reins on hospitals are occurring in southern Europe. In the CEE countries, the introduction of social health insurance (SHI) systems also separated hospitals from the (newly established) payers, but autonomy has been slow to follow. The least amount of change has occurred in western European SHI systems with traditional hospital-payer splits and a public-private mix of hospitals. It should be kept in mind that what is often viewed as “deregulation” (i.e. giving more independence to hospitals) actually increases both the scope of regulation and the demands on regulators. An important conclusion is that increased regulation does not automatically mean fewer entrepreneurial opportunities for hospitals.

### Primary care

The past decade has also seen increased entrepreneurialism in primary care. In Spain, Portugal, the United Kingdom and the Nordic countries, primary care physicians have a growing degree of autonomy, while remaining within the public system. In some central and eastern European countries, much primary care is now private. Privatization has important implications that must be considered *ex ante*. For example, when talking about general practice, a stepwise approach to changes in transitional countries is preferable to rapid, large-scale changes. Sudden privatization of primary care introduces competition among general practitioners where professional values have not developed to serve as a countervailing power to personal interests. In trying to keep a balance between private and social interests, state regulation could seek to increase responsibility at lower levels, and create small

groups of better qualified general practitioners while maintaining their salaried status. Professional values should be developed by means of retraining and vocational training programmes, through the introduction of peer review and the development of professional standards and protocols. When a professional infrastructure has developed and professional values influence behaviour, the next step to self-employed status can be taken.

### Pharmaceuticals

Entrepreneurial behaviour can help increase efficiency in the pharmaceutical market, but it also signals the need for regulation to prevent opportunities for maximizing profits at the expense of important values. Regulatory mechanisms such as patents and the Pharmaceutical Price Regulation Scheme in the United Kingdom have attempted to promote entrepreneurial behaviour, while others have sought to reduce the negative effects of this behaviour, like consumer protection regulation and the monitoring of prescribing and dispensing. As in many markets, there are important trade-offs which need to be considered in the decision-making process and perhaps here, more than in other markets, these issues are of tremendous importance due to the vexing expenditure issues that pharmaceuticals present to governments. To deal with this some countries have put into practice such mechanisms as cost-effectiveness pricing. For example, the Netherlands, Portugal and the United Kingdom have introduced guidelines for pharmacoeconomic studies that enable the government to demand economic evidence for reimbursement decisions.

### Social and home care

There are many entrepreneurial experiments with social and home care, for example in Denmark, Germany, the Netherlands and the United Kingdom. They involve the state or the insurer making payments to the individual, who can then spend the funds on various public, private, for-profit or not-for-profit services.

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Experience to date has uncovered several implications for the structure and regulation of social services. Putting aside funding issues, the regulation of social care needs to attend to information issues and the alignment of incentives between purchaser and provider. More flexible and innovative forms of contracting may provide the answer.

#### Dental care

As dental care has traditionally been largely run in an entrepreneurial manner, perhaps it has experienced fewer changes than other sub-sectors, but lessons learned from this sub-sector are important. Recent developments in dentistry are interesting, such as the existence of private corporate organizations, like the Dental Bodies Corporate in the United Kingdom, to run dental practices. Positive aspects from these corporate bodies include the fact that there are economic and managerial benefits from joining practices to corporations and chains, patients expect some accreditation or approval that they are attending a licensed practice, and not all dentists enjoy the daily management of a dental practice. On the other hand, these organizations could develop negative opportunistic behaviour as they are

driven mainly by the expectations of their investors, not the needs of the patients and practitioners and, thus, there is a clear role for health authorities to monitor and consider appropriate regulation of this new service sector.

#### Third party payers

The focus of entrepreneurial mechanisms in funding and in a competitive structure of health purchasing depends strongly on the prevailing values in society and also on the starting point of new developments. For example, in western Europe, cost containment is an overriding public goal, although there is still broad consensus that risk-pooling and solidarity be maintained. In CEE and FSU countries, on the other hand, where cost containment is less relevant due to chronic underfunding of health systems, a competitive health purchasing model may be seen as a strategy for patient protection. In these countries, concerns about equity are not as strong because, in the process of transition, freedom of choice and of entrepreneurship have become prevailing issues. These countries could benefit from studying approaches to combine these issues with solidarity (e.g. Germany and the Netherlands).

and there are real concerns about unbridled entrepreneurial freedom. (See the box on corruption.)

## What overall lessons can be learned?

Steer-and-channel regulation is likely to play an increasingly important role in the short and medium term. Those who want to guide competitive behaviour in directions consistent with core social objectives may benefit from the “Rules of the Regulatory Road”:

- Regulate strategically – think it through:
  - It is part of strategic planning;
  - It is a means rather than an end;
  - It should further core social and economic policy objectives;
  - It is long term not short term;
- Regulate complexly:
  - It can involve multiple issues simultaneously;
  - It can combine mechanisms from competing disciplines;
  - It requires an integrated approach that coordinates multiple mechanisms;



- It should fit contingencies within each health system;
- It requires flexible public management;
- No de-regulation without re-regulation:
  - Deregulation requires a new set of regulatory rules;
  - Re-regulate before you deregulate (to avoid disaster);
- Trust but verify (regulation without systematic monitoring engenders disrespect):
  - Regulation requires systematic monitoring and enforcement (or it engenders disrespect and loss of state authority). Thus, only regulate when you can monitor it properly;
- Self-regulation requires systematic external monitoring and enforcement.

In central and eastern European countries, administrative capacity-building is needed to ensure that regulations are respected and enforced, thus also addressing corruption. This experience suggests three lessons for central and eastern Europe:

- It is important to move from large-scale contracts to more nuanced institutional approaches;
- It is also essential to move incrementally;
- It is important to tailor new regulations carefully to the emerging entrepreneurial environment.

### The example of the hospital sector

Different models of public hospital are currently emerging. Hospitals that were previously public are now being separated from purchasers, with increased managerial autonomy for managers. A recent World Bank study classifies public hospitals into:

- **Budgetary:** where the hospital is an integral part of the public health service, and its revenues are determined through a line-item budget. Its managers are administrators and the hierarchy of the health service makes all decisions, including those regarding technology, services and salaries.
- **Autonomized:** day-to-day decision-making shifts to management. Objectives are more clearly specified. Sometimes this has involved a new government agency, with performance requirements, financial autonomy with a global

budget where savings on one service can be shifted to another. Hospitals may also be allowed to generate revenue from private patients, etc. and retain some of their budgetary surplus from year to year.

- **Corporatized:** managers have virtually complete control. The hospital is independent, has budget constraints, and is fully accountable to the governmental owner for its financial performance. Thus, it not only keeps excess revenues but is also responsible for losses. Each of these different models of hospitals will create different challenges for policy-makers with regard to devising appropriate regulation.

### Supporting entrepreneurial activity in the hospital

Social entrepreneurs work for the public good in fields previously dominated by bureaucratic or professional medical principles. To do this properly involves:

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- **Trust:** Organizations are more innovative and effective on the basis of trust rather than suspicion. This calls for latitude in legislation, and abandonment of a system of prior consent for decisions made by the individual hospital, in favour of a clear division of tasks between the government and the hospital.

- **Transparency and public accountability:** Hospitals need to operate on an open and accountable basis and actively provide information to stakeholders, especially government and third-party payers.

- **Supervision:** Regulations are required to establish the rules of the game in advance, and to provide audits in retrospect. The conduct of social entrepreneurs has to measure up to generally accepted values and norms in the health care system.

- **Entrepreneurial skills training:** Social entrepreneurs need “political” skills and professional management skills, so this calls for investment in training.

#### **Where regulation is useful in hospitals**

What is often viewed as “deregulation” actually increases the scope of regulation and the demands on regulators; and giving hospitals more autonomy requires more regulation than before. Increased regulation does not automatically mean less entrepreneurial opportunities for hospitals, it can be enabling. Important concerns for regulators are:

#### **Setting up hospitals**

For countries that rely on a mix of providers, ensuring access to hospital care means that during the planning process, account should be taken of private and not-for-profit hospitals as well as public hospitals. This can involve either regulating future hospital capacity, and/or regulating existing capacity by incorporating it into a plan. In Switzerland, health insurance law requires that private hospitals are taken into account, and they then qualify for reimbursement of services under the compulsory health insurance. In the Netherlands, hospitals may

not be constructed or renovated without a license, and acquiring this includes proving the need, getting the building plan approved, etc.

#### **Access to hospital**

Regulatory standards are typically imposed by governments to tackle three central issues of access: whether a hospital is required to have an emergency department; to have physicians available at all times; and to treat any patient regardless of insurance status or potential profitability. Some countries have taken steps to enhance patient choice and create incentives for public hospitals to improve their services. In Sweden, Denmark and Norway, some money “followed the patient”; they also had waiting time guarantees. In Sweden, this led to improved service quality but also an increase in utilization and, therefore, total expenditure. This also happened in Italy. It is worth bearing in mind when planning that when service is improved, more people use it and costs can rise.

#### **Reimbursement**

Financing hospitals through line-item budgets does not stimulate entrepreneurial behaviour but all other forms of financing does, though leading to different outcomes. There appears to be no compelling evidence for demanding a uniform payment system for all hospitals, because local circumstances determine whether particular payment systems induce the desired entrepreneurial behaviour.

#### **Protecting hospital employees**

Regulations that protect hospital employees are usually directed towards employers in general, and, in some cases, hospitals have argued for exemption, e.g., over working hours.

#### **Steering business behaviour**

Once hospitals are established as independent public enterprises, regulators have to determine the appropriate financial restrictions and obligations to place on them, such as whether they can roll over operating surpluses, borrow money from banks, take over other hospitals, etc.



### Corruption as challenge to effective regulation

Much corruption takes place at the nexus of state, private and quasi-private activity. It can take the form of bribery, theft, bureaucratic corruption and misinformation:

- **Bribes** are made to secure a service, or preferential access to contracts. Some patients want fast access to medical care, or to medicine that the facility cannot afford. Payments may arise because of a gap between the state commitment to medical care and their inability to deliver what is promised. They may pay the staff's wages. But in some cases, treatment is effectively withheld until payments are made, and payments known as "gratitude payments" or "under-the-table payments" are routinely requested. Bribes also arise when an official has some power over who should supply services, or when doctors accept kick-back payments for buying or using certain drugs, or for referring patients to a particular specialist facility.

- **Theft** may be staff pilfering, or charging for services which are publicly provided. There is also large-scale theft of public money by managers, typically those suddenly given control of large budgets. Several examples of insurance fund fraud have come to light in Estonia, the Russian Federation and countries in central Asia.

- **Bureaucratic corruption;** when state officials and politicians make policy decisions for financial gain or to further their own careers. This may entail steering patients into inappropriate but more lucrative treatments, working with patients in a dishonest arrangement involving services, prescription fraud or false insurance claims. All these activities damage the ability of the health care system to provide good and effective care. It is important to determine if this is happening because wages are low or because of inadequate regulation. Simply determining the

size of the problem is difficult. High numbers may reflect the relative openness of reporting or the level of public antipathy towards the practice. A study in Poland showed that 46% of patients pay for services that are officially free. In Kazakhstan, patients contribute up to 35% of state spending in unofficial payments, and in Bulgaria, 43% of patients reported having paid cash for officially free health services. In Turkmenistan, unofficial payments constitute over 13% of money spent on health care, and in Albania, research suggests that payments are paid routinely at every level, from porters and cleaners to doctors.

Regulating corrupt activity is difficult. Few people are prosecuted for receiving informal payments. Moreover, endemic corruption is a symptom of deeper problems, particularly in countries that do not have a clear system of property rights, an independent legal system or an accountable public sector. Endemic cross-sector problems are hard to tackle only through the health care system. It is important to determine if corruption reflects low wages or inadequate regulation, and thus whether unofficial payments are ensuring the survival of the system or destroying it. Imposing harsh regulation in a system which only survives through informal payments may force doctors and other staff to leave the state sector entirely. The wage gap between the state sector and private sector has to be addressed, either by reducing the service or increasing the funding.

#### Creating accountable systems

Simple and transparent procedures are necessary for good regulation. In Moscow, for example, the immense workload involved in processing prescription exemption claims has led to substantial fraud. Many countries in eastern Europe are dismantling their centralized systems for reimbursing providers in favour of local control or cost-per-activity systems, but while these may increase services, the services themselves may be inappropriate.

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### Keeping the sector functions clear

One way of improving transparency is to encourage organizational separation between the body that provides the money, the body that allocates it and the body that decides how it is used to provide the service. The insurance fund/provider split developing in much of eastern Europe is one example of such a separation, with the aim of making evaluation easier by separating the financial allocation from the outcome of the funding. In eastern Europe, however, a key problem has been ensuring that agencies such as insurance funds and health administrations are really independent, and are accountable to a regulatory agency. Even independence does not mean they are free of corruption.

### Developing strategies to combat corruption

For regulation to be effective:

- Patients' rights must be clear;
- Channels for complaints must be simple and well defined;
- Regulatory agencies must be strong and trusted.

- Ways of combating corruption must be public and transparent.

The rights of patients have to be clear, realistic and enforceable. Straightforward complaints procedures through an independent ombudsman are preferable to going through the courts. In some cases, however, through constitutions in former communist countries, patient expectations are artificially high and are not compatible with the levels of funding. Nevertheless, accountability is key. It may be necessary to pass legislation that makes the head of an organization legally responsible for the body's actions. This would combat a common problem, such as in the Russian Federation, where frequently no one is properly held accountable. Developing a truly effective system of auditing and accountability that not only reveals corruption but also acts on it remains one of the challenges and greatest stumbling blocks to reform in European transitional economies.

## Conclusions

Regulation – if applied within a well-designed framework – can make a major difference.

It is likely that there will be an increase in entrepreneurialism in health care systems, and the test of wills between entrepreneurs and regulators will intensify. Regulation will face challenges from fast developing areas such as the internet, which will make it easier to purchase services from all over the world, but

which also provides information to the patient and raises expectations. The notion of independent regulatory agencies is just one of the issues yet to be fully explored, as new tools and methodologies will be developed and tested. Overall, regulation will remain important, because it is an essential component of a middle way between purely bureaucratic public and purely for-profit private. For policy-makers who want to provide the most efficient, effective and responsive service at the best cost, regulation – if applied within a well-designed framework – is a tool that can help improve the outcome.

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