

NHS
market
futures

REGULATING HEALTH CARE

The way forward

Jennifer Dixon

This paper is one in a series of papers examining the emerging NHS market. Other papers in the series address critical issues such as primary care and commissioning and how to deal with hospital failure. The series will make an important contribution to the debate about the direction in which the NHS is now moving.

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Summary

The NHS is undergoing far-reaching and radical reform. New incentives are being introduced to improve performance, in particular through supply side reforms – greater consumer choice, competition between providers, greater use of non-NHS providers – all underpinned by a new system of paying hospitals, Payment by Results (PbR). These reforms will change the role of the state in the provision of health care. For example, the behaviour of NHS foundation trusts will be shaped by new forms of regulation rather than by direct performance management. The emphasis of regulatory activity will move towards economic regulation, and more attention needs to be paid to how professional self-regulation should be strengthened. All regulators (including the government) will need constantly to monitor the development of the market in health care and to adapt appropriately to the changing environment. This will be no mean challenge, as the health care environment in the short to medium term is likely to be very fluid.

Definitions of regulation are very broad and include the notion of one organisation shaping the behaviour of, and overseeing, another. However, the definitions do not distinguish between the activities of a body which owns another, for example strategic direction, setting objectives and performance management (termed in the paper as internal regulation), and the activities of an independent body which does not own but oversees another (termed in the paper as external regulation). The implication of the direction of the reform in the NHS is that government intervention in the activities of state-owned institutions (particularly providers) will reduce as market incentives bite and as NHS providers compete more effectively with non-NHS providers. But the burden that the state imposes on state-run institutions – internal regulation – is not currently assessed. Although it is appropriate for

the government to decide the volume and type of internal regulation, it should also be aware of the costs and effects of the volume it imposes. This might be done by expanding the concept of the regulatory impact assessment to cover internal regulation and by considering how the recommendations of the Better Regulation Task Force Report (2005) *Regulation – Less is More* might be applied in health care.

Regulation is needed because organisations by themselves may not deliver the objectives required by commissioners or consumers. But in the NHS the boundary between what is internal and external regulation is blurred, especially with respect to improving performance of institutions and achieving desired social objectives such as equity of access. The boundary will have to be scrutinised and the respective roles of government and external regulators clarified. The government's role is to set overall strategic objectives for health care, set targets and to produce a policy framework that clarifies a) the priority of the objectives and how conflicts between them (in particular between economic and social objectives) should be resolved and (b) how the government's role differs from that of other regulators.

As market incentives in health care develop, the government will need to define the tasks to be undertaken in developing economic or market regulation and the part it will play in their execution. In particular, there is a pressing need to develop the process to manage financial instability, distress and failure in NHS trusts to ensure that patient care is protected. The actions of government, through the Department of Health (DH), heavily influence the development of the market. This, plus the fact of significant financial instability in the NHS in the short term, means that the DH is likely to have an extensive and legitimate role in economic regulation in the short to medium term.

The basic features of economic regulation for NHS providers and providers offering care to NHS-funded patients should be similar to those that apply to non-NHS providers through the 1998 Competition

Act as applied by the Office of Fair Trading. Given the distinctive and complex nature of health care, it is likely that a separate independent economic regulator in health care will be needed at least in the medium term rather than a reliance on the Office of Fair Trading.

Given the dynamic nature of reform, economic regulation may soon need to be considered for commissioning, if non-NHS bodies take on this role. In the short term, a better system needs to be developed to assess the performance of NHS commissioners. Although this is a role for government (as part of internal regulation), an external regulator such as the Healthcare Commission may be better placed to carry out such an analytic function.

Economic and quality regulation are inextricably linked. To avoid duplication, it is logical for both functions to be carried out in one independent regulatory body. However, given the intention to merge the Healthcare Commission with the Commission for Social Care Inspection by 2008, it may be more pragmatic to develop economic regulation (the tasks not carried out by government) in a separate but closely linked body in the short term. This would require much closer working between regulatory bodies than has been apparent.

A large challenge for the Healthcare Commission, prompted by the direction of NHS reform, has been how to harmonise regulation between NHS and non-NHS providers and the private sector. This will need significant scrutiny of both the core and developmental standards applying to the NHS and the National Minimum Standards applying to non-NHS bodies. One key question is, what is it legitimate to ask non-NHS providers of NHS-funded care to do? Harmonisation is likely to lead to non-NHS bodies being required to produce more data. The effect of this may be to confine quality regulation to a role of public assurance of safety rather than improvement, but this will depend on how the market develops. The quality regulator may have to expand into promoting improvement and value for money in certain areas of

health care (perhaps where markets are not working well and where government 'internal regulation' no longer applies).

In truth, no one knows how far market forces will penetrate into different areas of health care, or what their effects will be. To formulate an appropriate regulatory response will require significant monitoring and sharing of intelligence in the next few years. This will require unprecedented co-ordination between regulatory bodies.

Introduction

The improvement of performance in both the public and the private sector is a central preoccupation of any government. In recent years there has been a sustained focus on how best regulation might be carried out to this end, for example through the work of the Better Regulation Task Force (an independent body set up by government to advise on regulatory issues), the Office of Public Services Reform (OPSR), the Cabinet Office's Regulatory Impact Unit and the subsequent Better Regulation Executive, the Treasury, and numerous governmental committees. The main objectives have included ensuring that regulation is (a) demonstrably cost-effective and (b) as inexpensive as possible to the bodies concerned. As a result, many recommendations have been accepted and implemented by the government and other relevant bodies, and significant progress made. For example, all government departments now have a duty to review and report the regulatory burden imposed by arm's-length bodies such as the Healthcare Commission and the Audit Commission and the steps taken to reduce it. Departments must also carry out and publish regulatory impact assessments (RIAs), which estimate the costs and benefits of key proposed reforms.

Most of the discussion and analysis has concerned the regulation of business and the privatised utilities (Hampton 2005; Better Regulation Task Force 2001, 2005) rather than of the public sector, but this is changing for two reasons. First, the burden of inspection (activity by independent arm's-length regulators) in the public sector has grown from an estimated £250m in 1997 to £550m in 2002/3 (OPSR 2003a) and its impact has not been clearly identified. Second, the increasing use of market-style incentives to improve performance in this sector, in particular the greater use of private providers, has raised fundamental questions as to the extent and type of regulation now needed.

The government recently announced that the burden of inspection in the public sector will be reduced by 50 per cent by 2008, and the number of arm's-length regulators will be reduced from 11 to 4:

- a single inspectorate for criminal justice by 2007
- inspection of children's services to move to OFSTED from the Commission for Social Care Inspection (CSCI) and the Adult Learning Inspectorate
- in health and social care to merge the Healthcare Commission and CSCI
- a local government inspectorate to be formed by merging the Benefit Fraud Inspectorate with the Audit Commission.

There has not yet been a full analysis of the implications for regulation on the increasing use of market-style incentives in the public sector, in particular in health care. However, the Chancellor, in his 2005 Budget Report, announced a wider review of regulation in health and social care, to report by December 2005. The Department of Health (DH) is now undertaking this review and the terms of reference are shown in Appendix 1. The findings of the review are intended to inform the regulatory framework from 2008.

This report seeks to contribute to this wider review and specifically examines the implications for the regulatory framework of introducing market-style incentives into the NHS. It starts with a brief description of the current and possible future direction of reform, then reflects on the implications for regulation in four areas: the total burden of regulation; the role of the government and the independent regulators; economic regulation; and regulating for quality.

Whereas the regulation of social care is no less important than that of health care and clearly linked to it, the focus of this report is solely on health care, mainly the NHS. The subject is England, because the introduction of market-style incentives is a not central feature of NHS reform elsewhere in the UK.

Current reform of the NHS

The NHS remains a largely state-funded and -run enterprise. In 2005/6, 8.3 per cent of gross domestic product (GDP) will be spent on health care in the UK; 7.1% of GDP on the NHS is funded largely through general taxation. The state not only funds most health care, but also owns all of the commissioners of state-funded care (for example, all strategic health authorities and primary care trusts), many of the providers (for example, all NHS trusts and community health services), and contracts almost exclusively with independent providers of primary care (GPs) and semi-autonomous NHS bodies – NHS foundation trusts. The NHS has some unusual features compared with other enterprises: for example, its budget is cash limited and NHS organisations must either break even each year, or not breach their annual funding limit; it provides comprehensive services that are (largely) free at the point of use; individuals cannot buy NHS care directly but have care bought on their behalf by commissioners (for example, primary care trusts); there are enormous information discrepancies between individuals and service providers, which means that individuals rely heavily on informed agents (for example, GPs) to help direct them to the most appropriate care; and service providers are formally accountable directly to the Secretary of State rather than to the patients treated or populations served (with the exception of foundation trusts).

History

Historically, the government largely left it to the professionals to provide a good-quality service. As Rudolf Klein has noted, there was an implicit pact between the government and the professions whereby the former set the overall budget for the NHS and the latter largely spent it, provided each did not challenge the other (Klein 2000). By the 1980s this had changed, and the government, through the Department of Health (DH) and local NHS bodies, took an increasingly direct role to

improve the performance of NHS institutions, particularly providers of care. This was done through primary and secondary legislation, directives from the centre, and performance management locally, regionally, or sometimes nationally. Where the government has not been able to act directly through operational directives and performance management, in particular with respect to GPs as independent contractors, it has attempted to shape the activities of GPs through legislation and the financial incentives of the national GP contract. The bulk of these efforts has been largely to improve the performance of institutions with respect to politically determined priorities, rather than the quality of care provided by professionals, which has more often been the preserve of the professional regulatory bodies such as the General Medical Council and the Royal Colleges.

Current reforms

The prevailing environment in the NHS is one in which the centre has a very strong role in improving performance. Three broad phases to NHS reform since 1997 have been described (Stevens 2004): phase 1, central direction (national standards and directives); phase 2, financial investment and support (for example the work of the Modernisation Agency); phase 3, ‘constructive discomfort’ or ‘edgy instability’ – the introduction, since 2000, of market-style incentives to improve the quality and efficiency of care. This has been underpinned by policies such as patient choice (Department of Health 2005c); encouraging private providers (secondary, community and primary) to compete for NHS business through the letting of contracts (nationally by government as well as locally by commissioners) to non-NHS providers; introducing a new system of prospective payment to hospitals, PbR (Department of Health 2002); and allowing NHS trusts to achieve foundation status with much greater freedom to operate independently of the state (for example, NHS foundation trusts are not subject to direct performance management). It is intended that all NHS trusts should achieve foundation status by 2008. These reforms are in the early stages of implementation and the market for provision, such as it is, is

immature. There is no prospect of wholesale and overnight privatisation as was the case with the denationalised utilities, rather a gradual development of market-style incentives, plurality of providers, and a payment system for providers to support choice and competition.

Commissioning

In July 2005 *Commissioning a Patient-led NHS* (Department of Health 2005b) announced a significant structural reform of primary care trusts and an intention to involve all general practices in commissioning by 2006, although the precise roles of the trusts and GPs in this respect are not clear. As yet there is no move towards encouraging competition between NHS commissioning bodies, or allowing non-NHS bodies to commission care using NHS funds. However, this may change for two reasons: first, as new non-NHS primary care providers seek to commission secondary care for their populations akin to general practices (not ruled out by *Commissioning a Patient-led NHS*); and second, as NHS trusts, through foundation status, move beyond the reach of state-directed performance management, this activity will focus much more on NHS commissioners. Increased scrutiny of the performance of NHS commissioners will follow, and there may be an increasing logic to subjecting poor performers to a failure regime that includes takeover by other organisations, including non-NHS bodies.

What level of market-style incentives is right?

Health care is an enterprise like no other. It is distinctively complex. In truth, no one knows what the optimum level of market incentives will be in the NHS, nor the extent to which they should penetrate different health care sectors – not just providers, commissioners or specific geographical areas, but also within specific services. For example, market incentives may work more effectively in the provision of elective surgical care (relatively simple uncomplicated services) than for the care of patients with complex, long-standing medical conditions, or for complicated emergency or catastrophic care, where more central control and planning may be appropriate (Dixon *et al* 2003).

Competition between commissioners may or may not cause more problems than it solves. It is possible to learn from health systems abroad, but the optimal blend of market incentives elsewhere is likely to be highly nation specific and depend on prevailing attitudes to the notion of social justice, history and politics, as well as the design, implementation and regulation of such incentives. We will have to learn by experience and monitoring.

The current direction of NHS reform seems clear, although not uncontentious: introduce a plurality of providers, subject all to competition and choice, ensure that all NHS trusts are placed beyond the scope of direct state interference through performance management (by requiring all to achieve foundation status), and allow market mechanisms to improve performance. The underlying assumption is that the state will exert less control as the new incentives bite, but that other methods of shaping the behaviour of providers (and ultimately possibly commissioners) may be needed, for example, better regulation to protect against the known drawbacks of markets in health care; or strengthening the professional ethos and values that underpin the behaviour of key actors, for example clinicians, through better professional regulation.

Implications for regulation in health care

All bodies involved in regulatory activity, including government, will need to adapt to the developing environment in the NHS. A challenge for all regulators will be how to monitor, co-ordinate and adapt to the fluid environment in the short to medium term.

This will be no mean feat and will require much more co-ordination among regulators than is apparent today, and much greater monitoring as to the impact of reforms. There is a need for a change in emphasis of regulatory activity if the market incentives introduced are to operate optimally. This will mean better facilitation of market incentives, appropriate withdrawal of the state from direct control, more developed

economic regulation, a slightly different approach to the regulation of quality, and increased professional self-regulation. The latter is not discussed further as it is the subject of two current reviews, the work of which should clearly be linked to that of the wider review of regulation by the DH.

It is important that the overall burden of regulation (including from government, as discussed above, or from arm's-length regulatory bodies) should not increase unduly. In particular, the burden of regulation – 'economic' or 'quality' – should be similar (but not necessarily the same) for all providers operating in the new market environment, if they are to compete fairly. This is discussed in the next section.

The overall burden of regulation

This section briefly addresses three questions: What is regulation? How might the burden of regulation be better assessed? and Why regulate?

What is regulation?

It is important to clarify what is meant by regulation. There are numerous definitions, including:

The sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes which may involve mechanisms of standard setting, information gathering and behaviour modification.

(Black 2002)

One office or organisation seeking to shape the behaviour of another. Formally there is an arm's-length relationship between the overseeing organisation and that being overseen. The overseer has some sort of official mandate or authority for its oversight.

(Hood and Scott 2000)

Any government measure or intervention that seeks to change the behaviour of individuals or groups.

(Better Regulation Task Force 2003b)

These definitions are very broad but include two linked concepts: 'behaviour shaping' and 'overseeing'.

Regulation, as defined above, and applied to health care, would include the activities of a number of bodies, including government, seeking to shape the behaviour of institutions or individuals: national government (for example through primary and secondary legislation, national

directives, guidance and performance management); local government (through overview and scrutiny committees); and the European Union through legislation. There are also a large number of independent ‘arm’s-length’ national regulatory bodies, such as the Healthcare Commission; Monitor; the Audit Commission; and the National Institute for Health and Clinical Excellence (NIHCE). There is also a large number of essentially private bodies focused on the regulation of individual professionals, such as the General Medical Council and the Royal Colleges. For private sector insurers and providers, regulatory bodies include the Office of Fair Trading (OFT), the Competition Commission and the Financial Services Authority.

These definitions do not specify the types of ‘behaviour-shaping’ activity that regulators might employ. The Better Regulation Task Force, in its 2003 report *Imaginative Thinking for Better Regulation* (Better Regulation Task Force 2003a), focused on the regulation of businesses but suggested that the tools included:

- ‘classic’ or ‘prescriptive state’ regulation (primary or secondary legislation)
- incentives (economic instruments and targets)
- self-regulation (for example, voluntary codes of practice) and co-regulation (voluntary codes of practice with significant government involvement)
- information and education
- doing nothing (the intervention can do more harm than good).

The definitions above may not be helpful, however, because critically they do not distinguish between two types of behaviour shaping and oversight activities in particular. One type includes a range of activities that the ‘owner’ of an organisation might carry out, such as setting strategic direction, objectives, standards and targets or other operational directives, and performance management against these. A clear definition of performance management is not easy to find, but in the NHS it includes ongoing scrutiny of the performance of and with a regulated body, often against a centrally determined target; the use or

threat of sanctions for poor performance; a requirement for a ‘recovery plan’ to be developed to correct suboptimal performance; development or training to help improve performance; and a requirement to make that performance public in an annual report. For brevity this range of activities will be called ‘internal regulation’. Examples in the NHS include activities to reduce waiting lists and implement payment by results, introduce foundation trust status, or implement the *Agenda for Change* (Department of Health 2005a). Clearly, private sector providers of health care will also be subject to performance management against objectives by a parent company, for example.

The other type of behaviour shaping includes a range of activities that an independent third party (independent regulator) might carry out, and the legislation legitimising those activities when the third party does not own the organisation whose behaviour is to be shaped. Such activities include the assessment of performance (which includes inspection); activities to prevent serious failures, or investigations of failure and subsequent action; stimulation of improvement through public comparison of performance; public reporting of failure or activities to prevent failure; setting the criteria for the opening or closure of facilities, or similar. For brevity this is known as ‘external regulation’.

This distinction is important to make when considering the NHS, because it is an organisation whose performance is currently heavily shaped by internal rather than external regulation. Indeed, the former is probably the most potent force currently affecting the overall performance of institutions: witness the impact on waiting times of targets, performance management and sanctions. The implication of the current direction of government policy for the NHS is that, as market forces bite (with respect to performance) then the burden of internal regulation imposed by the state will reduce. Clearly, it is a matter for the state to decide how much internal regulation it wants to impose to achieve desired outcomes for taxpayers’ money, but the point is that

the state could reach a more informed decision as to the burden it imposes than is currently the case – the burden might be decided more by evidence than relative to politics. This will be needed if state-run institutions (for example, NHS trusts or, in future, NHS commissioners) are to compete with non-NHS bodies in an emerging market. If such competition is to be successful it is important that the overall cost of internal and external regulation on NHS providers be no greater than that on private providers (although it may be different).

How might the burden of internal and external regulation be better assessed?

Progress has been made: the government has accepted the principle that the regulatory burden ought to be assessed. For example, the government has asked that no proposal for regulation should be considered by ministers without a regulatory impact assessment (RIA) being carried out by the relevant department. Box 1 overleaf shows the main features of a regulatory impact assessment.

Furthermore, in 2000 the Cabinet Office Regulatory Impact Unit (now part of the Better Regulation Executive) issued guidance to departments on assessing the impact of their regulatory proposals (*Good Policy-Making: A guide to regulatory impact assessment*) which required them to identify and carry out an initial assessment of ‘non-regulatory’ options before deciding to regulate, including:

- relying on consumer choice competition and innovation
- improving advice or information
- using a code of practice
- economic instruments, for example, user charges, taxes or tax concessions
- asking the industry to regulate itself
- doing nothing
- simplifying or better targeting existing regulations through a deregulation order.

BOX 1 REGULATORY IMPACT ASSESSMENTS

A regulatory impact assessment (RIA) is a framework for analysis of the likely impacts of a policy change and the range of options for implementing it. It is a comprehensive and flexible tool which considers:

- any form of regulation – formal legislation, codes of practice, information campaigns etc.
- the full range of potential impacts – economic, social and environmental
- where the impact may fall – business, *the public sector*, the voluntary sector or other groups (my emphasis).

This supports the government's aim of only regulating when necessary and, when it is, to do so in a manner proportionate to the risk being addressed, and to deregulate and simplify wherever possible. All government policy proposals should meet the five principles of good regulation, devised by the Better Regulation Task Force (an independent body set up by government to advise on regulatory issues). These are:

- **proportionate** – to the risk
- **accountable** – to ministers and Parliament, to users and the public
- **consistent** – predictable, so that people know where they stand
- **transparent** – open, simple and user-friendly
- **targeted** – focused on the problem, with minimal side effects.

Now all departments must provide a quarterly return to the Cabinet Office's Better Regulation Executive showing every RIA they have carried out, estimating the likely costs and benefit to businesses, charities, voluntary bodies and the public sector. How this is done in the public sector is briefly described in Box 2 opposite. The full RIAs are published on each department's website and the list for 2005 to date is shown in Box 3 opposite.

BOX 2 PUBLIC SECTOR RIA

For policies affecting specifically the public sector, an initial public sector RIA is carried out at the early stages of policy development. Its purpose is to improve public service delivery by thinking through at an early stage the possible effects on service delivery and the staff supporting it.

The initial public sector RIA is intended to inform submissions to ministers seeking agreement to a proposal. It must be expanded to a full RIA on the basis of two criteria:

1. If the total monetary cost of the proposal is greater than £5m.
2. If the proposal is likely to attract high levels of political or media interest, even if the total cost is below £5m.

BOX 3 THE INITIATIVES SUBJECT TO RIAs IN 2005, PUBLISHED BY DH**August 2005**

- General dental services contracts regulations and personal dental services agreements regulations 2006 (draft partial RIA)

June 2005

- The Medicines (Advisory Bodies) Regulations 2005
- The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 The Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations 2005
- The Medicines (Provision of False or Misleading Information and Miscellaneous) Regulations 2005

BOX 3 *continued*

April 2005

- Amendments to The Medicines (Advisory Bodies) Regulations 2005
- The Medicines for Human Use (Fee Amendments) Regulation 2005

March 2005

- CHAI Fees and Frequency Inspection Am. Reg 2005
- Ext Formulary Nurse Prescribing
- Extension of Supplementary Prescribing to Chiropodists, Physiotherapists and Radiographer
- General Ophthalmic Services Supp List Reg 2004
- NHS Pharmaceutical Services Regulations 2005
- The Medicines for Human Use Prescribing 2005
- Commission for Social Care Inspection regulatory fees 2005/06
- National Service Framework for Long Term Conditions

February 2005

- Water Fluoridation (Consultation) Regulations 2005, Water Supply (Fluoridation Indemnities) Regulations 2005
- Opticians Act (Amendment) Order 2005

January 2005

- European Blood Safety
- National Service Framework for Renal Services, Part Two: chronic kidney disease, acute renal failure and end of life care

Source: DH (http://www.dh.gov.uk/PublicationsAndStatistics/Legislation/RegulatoryImpactAssessment/RegulatoryImpactAssessmentArticle/fs/en?CONTENT_ID=4104022&chk=1YPUXW)

One observation about this list is that the regulations assessed are very narrowly defined – they do not appear to include the range of activities described above as ‘internal regulation’. For example, one of the most significant initiatives affecting NHS organisations in 2005 was *Commissioning a Patient-led NHS* (Department of Health 2005b) – an operational directive that requires the wholesale restructuring of primary care trusts and a full roll-out of practice-based commissioning, all to a tight timescale – and this is not included. Since 2001 no RIAs have been listed on other significant policies, such as payment by results, pay reforms such as *Agenda for Change* (Department of Health 2005a), or the introduction of foundation trusts. However, there is an argument for widening the scope of RIAs (a) if the total burden of regulation is to be reduced, and (b) if NHS providers are to compete effectively with the private sector.

The second observation is that, although RIAs are a start, the total burden of regulation, both internal and external, on the public sector is not measured. There is an argument for going a step further to adopt and adapt the key recommendations made in the report *Regulation – Less is More* by the Better Regulation Task Force (2005), all of which the government accepted. Although the report focused specifically on how better to regulate businesses, the recommendations included:

- measuring the total regulatory burden on regulated bodies using a standardised approach
- committing to a net target for reducing administrative burdens over a period (that is, taking into account any new regulations brought in from government or the EU)
- setting up the necessary organisational structure to do this (including an independent body that advises government).

Why regulate?

Most organisations cannot be left to themselves to deliver an excellent service. Both organisations and the individuals who work in them are subject to a range of influences that may act against the objectives

desired by a commissioner or a user. For example, a common complaint is that NHS services are insufficiently responsive to patients, or that productivity could be higher. Markets in health care have well known inbuilt drawbacks: for example, a primary focus may be on making a profit at the expense of quality of care, which could result in skimping of care, selection bias (where healthier and hence ‘cheaper’ patients are accepted for treatment in preference to others), and lack of access to services in some geographical areas, or across certain patient or population groups (Arrow 1963). As noted earlier, these problems are accentuated because of the distinctive nature of health care, in particular the huge information imbalance between patients and providers and the fact that health care is a public good with ramifications beyond the individual. As the health care market emerges, market (or economic) regulation will need to be further developed (see pp 27–33).

In market-based industries, regulation largely takes the form of protecting the consumer from abuse – public assurance or protection, rather than improving performance and value for money. In the public sector there is some blurring of the boundary between internal and external regulation: the state is largely responsible for improving performance and value for money (through internal regulation), but external regulation (via independent regulators) is concerned with some activities that could be thought of as internal regulation – for example, the Healthcare Commission is required by statute also to improve the performance and value for money of health services. Furthermore, independent regulators may also be required by statute to meet social objectives, for example, to work to reduce health inequalities, as again in the case of the Healthcare Commission. In theory at least, as the NHS changes, this boundary between internal and external regulation will need to be scrutinised carefully and regularly to avoid duplication and excessive growth of external regulation. In practice, with respect to the NHS, independent regulators have significant space to define their activities, including those that may stray into internal regulation,

specifically performance improvement. The Healthcare Commission, for example, seeks to stimulate improvement in various defined ways, such as by publishing comparisons of performance against set standards (the annual health check), by ‘improvement reviews’ of specific service areas or population groups, or by investigation of failures and complaints. This is not intended to stray into performance management of NHS trusts (currently the role of the strategic health authorities (SHAs), and primary care trusts (PCTs) via contracts), but ultimately what is defined as internal or external regulation is set by government, and in health care this is heavily contingent on the role government sets itself. This is discussed in the next section.

The role of government and other bodies in regulating health care

The role of government

If regulation, as broadly defined above, includes the activity of government, the first question to ask is, What role does government wish to have in regulating health care, in particular the NHS? In other words, what does it see as the boundary between internal and external regulation, and what should be the limits to both?

As Dieter Helm (2004) has noted, 'the role of government is to define objectives, and to sort out how the trade-offs between them should be made'.

The broad aims for the NHS in England are that it should provide a comprehensive service on the basis of need, and be free at the point of use. The underlying objectives include that the service should be efficient (offering value for money), of good quality (responsive to patients, good-quality and accessible clinical service) and fair (offering equal access for all). There is probably a wide political consensus about the objectives, less so about the relative weight of each (in particular equity) and the trade-offs that are acceptable. A policy framework must set this out explicitly, including a broad strategy showing how these objectives can be met, and, as Helm goes on to note, 'objectives then require the specification of more detailed targets, and it is the government's role to set these'.

There are many further activities a government may choose to take on to encourage achievement of the targets set, as outlined earlier. Quite how active a government is, the extent to which arm's-length independent regulators are set up, and how active they are, are entirely political

decisions. But for effective regulation to take place it is important that the respective roles of internal and external regulation are very clearly defined.

Some contemporary challenges to the government's role in regulation

As noted earlier, the logic of the current NHS reforms raises some immediate challenges to the government's role with respect to regulation. First, the assumption is that direct control of providers will be less necessary or desirable, as market incentives, if properly developed, will reduce that need. The aim of current policy is that all NHS trusts should achieve foundation status by 2008, and thus be legally beyond the reach of direct performance management. The direct efforts of the state to achieve overall objectives and targets in hospitals will then focus on commissioners of NHS care – currently primary care trusts (PCTs). At present it is appropriate that NHS commissioners are directly subject to performance management, but in *Commissioning a Patient-led NHS* (Department of Health 2005b) it was unclear what the role of PCTs would be in the medium term. As commissioning is devolved to groups of independent general practices – or possibly other private bodies – the mechanisms by which the state can influence these bodies will need to change. They must include greater scrutiny of performance, and possibly putting the functions of failing commissioners out to competitive tender. They may also include strengthening accountability to the populations served, either by encouraging greater public involvement or by allowing consumer choice of commissioner.

Second, if there is to be greater reliance on market mechanisms to improve performance, economic regulation will need to be developed. At present different aspects of economic regulation are carried out by government and a number of other bodies. It will be important to review these functions, assess whether more are needed, and assess

what is properly the role of the state (with regard to internal regulation) or external independent regulators, and the merits of having both in one organisation or many (*see below*).

Third, because markets are not designed primarily to produce socially desirable results, there is still an obvious role for government or others to ensure that key objectives in health care are achieved. It may be that market incentives improve efficiency, but the cost might be greater inequity of access to and quality of care, for example. As Helm (2004) notes, key objectives must be spelled out by government in a policy framework, and if equity of access is a key objective the question is, who should ensure that this objective trumps those of a developing a market, and how? There may be lessons here from the privatised utilities, as noted by the Better Regulation Task Force (2001). The Utilities Act 2000 blurred the boundaries between the role of government and the regulators (in this case Office of Gas and Electricity Markets (Ofgem) by requiring the regulator to ‘protect the interest of consumers wherever appropriate by promoting competition, and in doing so *have due regard to the interests of individuals who are disabled, chronically sick, of pensionable age, with low incomes or residing in rural areas*’ (Better Regulation Task Force 2001) (my italics). As the Better Regulation Task Force noted, this blurred the line between the objectives of competition (the role of an economic regulator) and those of redistribution (the usual role of government). The challenge to government is, as economic regulation in health care is developed, how are social objectives to be ensured? If this task is assumed by a ‘quality’ regulator (such as the Healthcare Commission, as is currently the case), how will conflicts between this body and the ‘economic regulator’ be settled? Similarly, how will conflicts be settled by a combined (quality and economic) regulator?

Finally, it will be important to clarify the boundary between government and the regulators with respect to the achievement of social objectives.

The role of external regulators

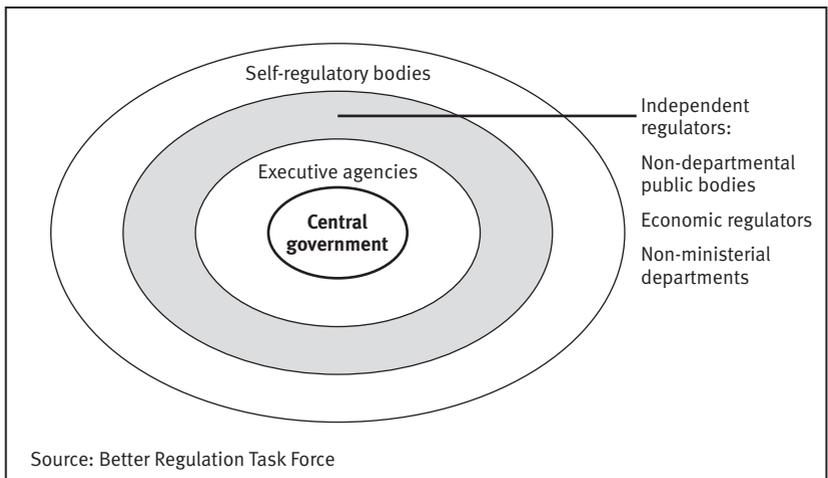
There are many bodies involved in regulating health care. For the rest of this report the focus is on independent or arm's-length regulators, as defined below:

A body which has been established by Act of Parliament, but which operates at arm's length from government and which has one or more of the following powers: inspection; referral; advice to a third party; licensing; accreditation; or enforcement.

(Better Regulation Task Force 2003b)

In health care these bodies include the Healthcare Commission, Audit Commission and Monitor. They are independent, have a sponsoring minister, and must account to Parliament for their activities (Figure 1).

FIG 1 WHERE THE INDEPENDENT REGULATORS SIT IN RELATION TO CENTRAL GOVERNMENT



Clearly they carry out a number of functions, including:

- standard setting
- monitoring (oversight)
- reporting (including to the official body to which they are accountable and to the public)
- improving performance – a range of activities, from improvement across a comprehensive range of areas (largely set by government) such as the ‘annual health check’ by the Healthcare Commission, to improvement against specific target areas set by government (such as waiting times or achieving financial balance), to reducing the risk of specific anticipated problems, such as infections from multi-resistant staphylococcus aureus (MRSA).

With a change in the role of government, it is difficult to be precise about the role and functions of other regulators beyond a broad direction linked to the current of reform. However, the immediate challenges are how economic regulation and ‘quality’ regulation should be developed. This is the subject of the next two sections.

Economic regulation in health care

As noted earlier, given the emerging market in the NHS it is a pressing task for the government to decide what elements of economic regulation should be developed and what the objectives should be. These could include the facilitation of market incentives, the assessment of areas in which market incentives are not operating, and reducing the undesired effects of the market. Exactly what ‘undesired effects’ are depends on social objectives, which should be made explicit in a policy framework set out by government.

The extent to which these activities should be performed by government (or its agents, such as strategic health authorities or NHS commissioners) or an external independent regulator also urgently needs to be clarified, and depends largely on what the government sees as its role with respect to the internal regulation of state-run institutions. To some, the role of external economic regulation is clear: to prevent the abuse of consumers by the market; but even this objective could spawn a wide range of activities, which in the NHS could legitimately include performance management by government.

To help clarify what might be the respective role of government or an independent regulator, it is important to spell out what might be the broad elements of economic regulation. These are shown in Table 1 overleaf, compiled by the Independent Regulator for Foundation Trusts (Monitor) and slightly modified.

TABLE 1 TASKS INVOLVED IN ECONOMIC REGULATION IN HEALTH CARE

	Commissioning	Payments	Providers
Participants/ components	PCTs	PbR Non-PbR Private contract	PCTs (for primary care) NHS trusts NHS foundation trusts Private providers
Economic regulation/ market management	Financial monitoring Failure management Enforcement of 'rules of the game' If this becomes contestable then regulation needs to cover entry/exit and competition	Accurate tariffs Transparent and independent tariff setting process System affordability Claims validation	Regulation of market entry and exit Financial monitoring Facilitating competition Addressing failure Enforcement of 'rules of the game'
Consumer protection	Facilitation of access and choice Contracting for quality	Incentives for quality and innovation in patient care	Quality of care Access to care Patient safety standards and performance data

Source: Monitor 2005

The question of how to identify the most appropriate elements of economic regulation for the new environment in health care in England, and how they should be developed, should be thoroughly debated, but this is not the place. Instead, the focus here is on:

- Which of the functions noted above is it appropriate for the state rather than another body to carry out, and why?
- To what extent should various functions be carried out by one organisation or by many?

- To what extent should economic regulation of NHS providers, or NHS foundation trusts, be harmonised with that applying to private providers?
- Should economic regulation be merged with ‘quality’ regulation in one organisation?

Which functions should be carried out by the state?

If a market is to develop, it will be important for it to be seen to be as free as possible from unnecessary and direct government interference, to command public confidence, and for the decisions of the regulator to be as objective, transparent and predictable as possible, given with adequate notice to allow the market to respond appropriately. Clearly, then, there is a role for an independent regulator.

However, the government has an extensive interest in whether health care organisations achieve the broad objectives and targets it sets, as it is the major funder of health care and wants to see value for taxpayers’ money. And, as Propper *et al* note, the market is endogenous to the behaviour of the Department of Health (DH): for example, there is an overlap between the pricing policy set by the DH and market configuration (Propper *et al* 2005). It is not appropriate (or realistic) that the DH should hand over all of the functions of economic regulation to an independent body – for example, the setting of national prices (the tariff) – although the independent regulator could provide expert advice and objective evidence to inform decisions. Similarly, the management of financial failure in NHS trusts is heavily influenced by the financial regime set by the DH, and the availability and terms of any transitional funds (Palmer 2005).

Furthermore, as discussed above, there are important social objectives to be achieved in health care. Although the functions listed in Table 1 opposite are very technical, they would have highly political consequences, for example some decisions on ‘exit’ with respect to

providers. Also, because the provision of certain types of care requires extensive capital investment (buildings and equipment), and because equality of access to care is a basic objective, the government is likely to want an active role in encouraging the entry of some providers into the market where necessary. Other functions shown in Table 1 (see p 28) may have fewer political ramifications, such as setting the criteria for, and making decisions on, monopolies and mergers (competition management), and financial monitoring, which could be done by an independent regulator.

There is probably no right or technical answer as to the role of the state in economic regulation – clearly, this will be largely a political choice. In reality, the state of NHS finances, in particular the number of NHS bodies facing deficits, means that there will be – and ought to be – a large role for the DH in economic regulation for at least the next five years, but at the very least this role should be as transparent, objective and predictable as possible. There is a pressing need to develop a better regime for dealing with financial distress and failure in NHS trusts in a way that protects patients (Palmer 2005). In the medium term, as greater plurality develops and as the market matures, it may be possible for the role of the DH to be reduced once the policy framework for economic regulation has been specified and, importantly, once it has been made explicit what its roles and social objectives are and how anticipated conflicts should be solved.

On commissioning, there is a question as to how far the functions shown in Table 1 (see p 28) should be subject to performance management by the state (presumably via strategic health authorities) rather than by an independent regulator. In practice, both have a role. For example, financial monitoring in PCTs is carried out by both the strategic health authority and an independent regulator (the Audit Commission) as part of the annual audit of accounts, and as part of an assessment of value for money that feeds into the annual assessment by the Healthcare Commission. As usually understood, the role of the

independent regulator is to assess performance and provide some challenge to improve it, but not to ‘performance manage’ service deliverers. Whereas in reality the distinction between ‘providing some challenge to improve performance’ and ‘performance management’ may not always be clear (see later), it is possible to draw a line that would allow more functions to be carried out by an independent regulator. Clearly, if commissioning became contestable there would be a greater potential role for an independent economic regulator.

One organisation, and harmonisation with regulation in the private sector?

Many of the functions noted above are clearly linked, and it would make sense to have as many as possible performed by a single organisation to build expertise and avoid duplication. The main functions noted in Table 1 (see p 28) are currently the responsibility of the government, the Audit Commission and, for NHS foundation trusts, Monitor (set up by the Health and Social Care (Community Health and Standards) Act 2003), as well as the Healthcare Commission. Yet there are many functions, principally those of market management, that need urgently to be developed, especially in a sector in which the high cost of market entry, and links between services, can lead to natural monopolies.

There is a pressing need, when developing these functions, to be cognisant of how private providers (or private commissioners) are regulated economically. At present private providers are subject to UK and EU competition law and regulation by the Office of Fair Trading (OFT) and the Competition Commission (that is, a referral is made to OFT if it is suspected that the Competition Act 1998 has been breached by a particular organisation and, if so, action will be taken *ex post*, that is, after the event). The 1998 Competition Act aims to reduce anticompetitive behaviour and the abuse of a dominant market position by organisations. At present it is not totally clear whether NHS foundation trusts will be subject to the Competition Act and hence scrutiny by the OFT. This will need to be clarified. Also, as more NHS

trusts become foundation trusts, and as foundation trust policy develops, if the 1998 Competition Act does not apply it will be important to ensure that there are no inappropriate disparities in *ex post* regulation among NHS and non-NHS providers competing in the same marketplace. If the 1998 Competition Act does apply, then decisions will have to be made as to whether referrals, decisions, and subsequent enforcement of those decisions, are made by the OFT or by a sectoral (health) regulator. With respect to the privatised utilities, the economic regulator is normally concerned with prevention of abuse of the market rather than action taken after the event, which is largely the role of the OFT. But it may be important to learn from the experience of the Office of Telecommunications (OfTel) or other regulators where ‘concurrency’ operates – that is, the Director General of OfTel (now Ofcom) did have some *ex post* regulatory powers (for example, to fine telecommunications companies for breaches of the Competition Act), as does the OFT (Better Regulation Task Force 2001).

It may be, as the Better Regulation Task Force notes in its report *Economic Regulators* (2001), that in the longer term sector-specific regulation may be less necessary if a market becomes sufficiently competitive, but in health care this is a long way off and, given the nature of the sector (Arrow 1963), unlikely.

Economic and quality regulation together?

There may be many overlapping issues of concern to independent ‘economic’ regulators and independent ‘quality’ regulators of health care – the line between economic regulation and consumer protection in Table 1 (see p 28), for example a range of social objectives as specified by government (such as equality of access to care for different population groups, different geographical areas or people with different clinical conditions, and equity of quality of care), and also information to facilitate consumer choice. There may also be strong correlations between market failure and clinical failure. Furthermore, the information

on which good regulation depends may be similar for both economic and quality regulation. There is a danger that such blurred boundaries might encourage duplication of activities if independent regulators concerned with quality and economic regulation were separate. For these reasons it seems logical to propose that economic and quality regulation should be carried out by the same organisation, as is the case with the utilities.

Although this may be an ultimate aim, in the short term there is much to do to develop both types of regulation. Only some of the immediate challenges for economic regulation are outlined above: there are many more. Some of the immediate challenges for quality regulation, leaving aside the issue of merging health and social care regulation, are outlined below. It may be more pragmatic to develop both types of regulation separately in the short term, while encouraging much greater co-ordination and information sharing than has been necessary to date, for the reasons outlined in previous sections, not least to minimise conflict with respect to competing objectives, and to develop activities as market-style incentives are embedded.

Quality regulation in health care

This section concerns the role of the main independent regulator of the quality of health care – the Healthcare Commission, a non-departmental public body set up by the Health and Social Care (Community Health and Standards) Act 2003. The roles of bodies involved in regulating the behaviour of professionals in health care are not discussed.

The role and the statutory duties of the Healthcare Commission in England are as shown in Boxes 4 and 5 opposite.

Clearly there are numerous implications for the Healthcare Commission of an emerging health care market. This section focuses on two: the implications of greater plurality in provision on assessing and improving the quality of care; and the implications for activity focused on commissioners of NHS care.

Implications of greater plurality in provision

At present there are significant differences in the approach to regulating health care providers, both NHS and private, but the implications of allowing a greater plurality are that there should be greater harmonisation of regulatory activity between the two sectors, and a burden of regulation which is similar (although not the same).

The broad approach currently taken to the regulation of NHS bodies (including foundation trusts) is that there should be self-assessment against national standards and criteria, a resulting declaration by the regulated body itself, validation by the regulator against a range of indicators, an annual rating of performance for each NHS body, targeted inspection of bodies performing badly or whose declaration does not

BOX 4 THE ROLE OF THE HEALTHCARE COMMISSION

- **Inspect** To inspect the quality and value for money of health care and public health
- **Inform** To equip patients and the public with the best possible information about the provision of health care
- **Improve** To promote improvements in health care and public health

BOX 5 MAIN STATUTORY DUTIES OF THE HEALTHCARE COMMISSION IN ENGLAND

- To assess the management, provision and quality of NHS health care and public health services
- To review the performance of each NHS trust and award an annual performance rating
- To regulate the independent health care sector through registration, annual inspection, monitoring complaints and enforcement
- To publish information about the state of health care
- To consider complaints about NHS organisations that the organisations themselves have not resolved
- To promote the coordination of reviews and assessments carried out by ourselves and others
- To carry out investigations of serious failures in the provision of health care

Source: Healthcare Commission

appear to be validated, and a suggested improvement plan supported by enforcement powers. In doing so, the Healthcare Commission follows the principles of good regulation set out by the Better Regulation Taskforce, in particular that the regulatory activity be ‘proportionate [to the risk], consistent [predictable, so that people know where they stand], transparent [open, simple and user-friendly], and targeted [focused on the problem, with minimal side effects]’ (Better Regulation Task Force 2003). Core and developmental standards are set by the government (Department of Health 2004) as a means of describing the level of quality of care organisations are expected to achieve, which is not optional (core), or the level they are expected to aspire to (developmental). According to the Department of Health (2004), the core standards ‘serve as a platform or bottom rung for progress... They also serve to assure the public that all services, wherever provided, will be safe and of an acceptable quality’. The standards cover seven domains: safety; clinical and cost-effectiveness; governance; patient focus; accessible and responsive care; care environment and amenities; and public health. There are clearly other regulatory activities performed by the Healthcare Commission, such as special investigations of potentially serious failures of provision, and reviews of second-stage complaints by individuals about care.

The approach to regulating private sector providers is altogether different. At present the Healthcare Commission is required to inspect all independent providers once a year against the national minimum standards for independent health care, using powers set out in the Care Standards Act, its regulations and national minimum standards. Although these standards are incorporated into the core standards applying to the NHS, they are more detailed and onerous to achieve. The intention, as set out in *Standards for Better Health* (Department of Health 2004) is that inspection and review methodologies will be harmonised and aligned between both NHS and private sector providers, and the government intends to legislate ‘to enable an equal approach to inspection of the independent and NHS sectors, when

Parliamentary time allows'. This is sensible, and work by the Healthcare Commission is in progress, but there are four immediate and basic points to make.

First, there is a fundamental debate to be had over the standards that should apply in future to both NHS and non-NHS providers of publicly funded care, if it is the intention that market-style incentives should improve performance. For example, should the standards relating to public health be applied, when clearly public health is not a function of private providers? If they no longer apply to the NHS (in the interests of harmonisation), how is it best to ensure that the public health function is supported? There is a large number of other core standards, worthy in themselves, where it is legitimate to ask whether or not private providers (and hence the NHS, if harmonisation is an aim) should be held to account through regulation, if the assumption is that a market will operate. Possible examples are given in Box 6 overleaf.

Second, the effect of harmonisation may be to reduce the burden of regulation to much nearer a basic core of safety standards. This would change quality regulation to more of an assurance function (or type 2 inspection, according to the Office of Public Services Reform (OPSR) – see Box 7, p39).

This move would go against the grain of the activities and motivation of many regulators. In a review of independent regulators of the public sector, the OPSR noted that 11 out of 13 included some degree of attention to improvement in their activities, and there was widespread support for the mission of improvement (OPSR 2003). But a move further towards assurance only may also be encouraged by the need to demonstrate greater cost-effectiveness by regulators, and the OPSR found that work by the 13 regulators reviewed to assess this was limited. It may also be encouraged by the relatively information-free environment in the private sector, and a reluctance to impose similar burdens for data on it as on the NHS, beyond a core dataset to set and

BOX 6

C9 Healthcare organisations have a systematic and planned approach to the management of records to ensure that, from the moment a record is created until its ultimate disposal, the organisation maintains information so that it serves the purpose it was collected for and disposes of it appropriately when no longer required.

C11 Health care organisations ensure that staff concerned with all aspects of the provision of health care:

- are appropriately recruited, trained and qualified for the work they undertake
- participate in mandatory training programmes
- participate in further professional and occupational development commensurate with their work throughout their working lives.

C17 The views of patients, their carers and others are taken into account in designing, planning, delivering and improving health care services.

C20 Health care services are provided in environments that promote effective care and optimise health outcomes by being well designed and well maintained, with cleanliness levels in clinical and non-clinical areas that meet the national specification for clean NHS premises.

Source : Department of Health (2004)

monitor contracts for the treatment of NHS-funded patients. If that is the case, then the role of the Healthcare Commission with respect to its wider mission of improvement against developmental (or aspirational) standards may well also be significantly reduced. Again, this implication will need to be heavily debated, especially when set alongside the

reduction in direct performance management by the state of NHS trusts (as they achieve foundation status) and the consequent greater reliance on NHS commissioning (and thus contracting) to achieve the improved performance desired (discussed below).

Third, depending on how the market develops, there may be a need to measure the activities (with respect to core and developmental standards) of the Healthcare Commission against the apparent rise in impact of market incentives and better developed economic regulation. There will need to be considerable co-ordination between independent regulators to do so, and much greater clarity from the government as to their future objectives. For example, at what stage of the development of market-style incentives might the activities of the

BOX 7 THREE TYPES OF 'INSPECTION' BY INDEPENDENT REGULATORS ACCORDING TO OPSR

- **Type 1** Inspections give assurance on whether the processes being followed by the provider are reliable and meet basic standards. Inspectors may provide complex information as part of their assessment work. *Assurance*
- **Type 2** Further development of performance indicators has been used to identify the relative achievement of individual providers and a greater specificity of information. Type 2 inspection is more concerned with accountability and presents a challenge to the providers to improve. *Challenge*
- **Type 3** Inspectors are playing a more active part in securing improvement while retaining their independence. Less emphasis is placed on checking compliance and more on the user perspective. *Inspiration*

Source: Office of Public Services Reform (2003)

Healthcare Commission be appropriately reduced or expanded? Where market incentives may not be suitable, or embedded (as detected by the economic regulator) – for example, in emergency care, specialised care, possibly the care of older people, or in more remote geographical areas – should the Healthcare Commission be more active and not curtail its current level of activity?

Fourth, the requirements for information and comparisons of performance are different for different parties, and this will obviously need to be taken into account. A reliance on information about safety or minimum standards is unlikely to be sufficient for NHS (or indeed non-NHS) commissioners of NHS-funded care to discriminate between competing providers. Similarly, patients are likely to make increasingly informed decisions over whether, where, how and by whom they are treated, and to demand better information. A key question, then, is how much information (assessment and comparison of activity) should be mandated to support commissioner and patient choice, and how much left to the market or to self-regulating professional bodies? It may be helpful to think of three possible sets of information:

- Basic information to satisfy safety and other requirements for a licence to operate. This might include considerations about professional standards and working, to ensure that basic health and safety procedures are followed, and adherence to recommendations by, for example, the Health and Safety Executive and the National Patient Safety Agency.
- Information for commissioners that reflects their needs when discriminating between competing providers – a subset of the current set of core standards for the NHS and a limited set of indicators to show performance against key political targets (for example, waiting times).
- A wider set of indicators and information for consumers provided voluntarily by providers. The independent regulator could provide guidance as to the indicators of best practice – providers would

have an incentive to provide these in order to attract patients and commissioners. These indicators could be focused on issues that patients would find helpful.

Implications of focus on NHS commissioners

If, as noted earlier, the state can no longer ‘performance manage’ NHS foundation trusts or conglomerates of practice-based commissioners directly (via strategic health authorities), then its efforts to improve performance will increasingly focus on NHS commissioners such as PCTs. This is likely to have implications for the Healthcare Commission, in particular to develop better metrics to assess and compare the performance of commissioning bodies, partly because it will have the necessary technical expertise to do so. It may be useful to look to other countries to see how the performance of commissioners is assessed, for example, the Health Employers’ Data Information Service (<http://www.ncqa.org/Programs/HEDIS/>) used in the United States. Again, it will be important for the Healthcare Commission to link with the economic regulator if some assessment is to be made about the added value of the commissioner in improving performance over and above other factors, such as the extent to which market forces are helping or hindering the performance of local providers.

In the medium term, as more practices (or, more likely, conglomerates of practices) commission, or if non-NHS commissioners are allowed to commission NHS-funded care on behalf of populations, or if ‘foundation NHS commissioners’ are allowed to develop, the state will no longer be able directly to performance manage commissioners. Again this will have considerable implications with respect to the requirements for quality – and indeed economic – regulation (if competition is allowed between commissioners), depending on the exact details of the reform. It is not the purpose here to discuss options for the regulatory bodies to respond to these hypothetical reforms, merely to underline the fact that reform is dynamic, and the need for regulators constantly to be aware of what might be in the future and to help to shape it.

Conclusions

The NHS is undergoing far-reaching and radical reform. The implication of this reform is that the respective roles of the government and of independent regulators needs to change. Economic regulation needs to be developed, and quality regulation needs to change to respond to the need for greater harmonisation between public and private sectors. The government also needs to make much more explicit the policy framework for regulation, in particular how conflicts between market objectives and social objectives are to be resolved. In doing so it must be more explicit about the scope of its own role versus those of the regulators, in particular with respect to economic regulation and improvement in performance. The actions of government (through the Department of Health) heavily influence the development of the market. This, plus the significant financial instability in the NHS in the short term, means that the Department of Health is likely to have an extensive and legitimate role in economic regulation in the short to medium term.

A preoccupation of government in recent years has been how to reduce the volume of regulation in the public sector. At present it does not assess the total volume of regulation imposed by itself as well as by the external regulators, as regulatory impact assessments apply to a narrow set of regulations. But the total volume should be assessed if public sector organisations are to compete effectively against independent bodies. The government should examine how the principles of the report *Regulation – Less is More* by the Better Regulation Task Force might apply to health care.

Economic regulation for NHS providers and providers offering care to NHS-funded patients must have similar features to those applying to non-NHS providers through the 1998 Competition Act as applied by the

Office of Fair Trading. However, at least in the medium term a separate independent economic regulator for health will be needed.

The performance of NHS commissioners also needs to be better regulated and this may be better undertaken by an external independent regulator such as the Healthcare Commission. If non-NHS bodies take on a commissioning role, then regulation may need to include an economic function; in the short term this may need to be undertaken by a separate body, working closely with the quality regulator.

The increasing use of non-NHS providers, including the private sector, has necessitated work towards the harmonisation of regulation with the public sector. Quality regulation may focus more on the assurance of safety than on improvement of wider performance, but this will depend on how the market develops. In truth, no one knows how far market forces will penetrate into different areas of health care, or what their effects will be. To formulate an appropriate regulatory response will require significant monitoring and sharing of intelligence in the next few years. This will require unprecedented co-ordination between regulatory bodies.

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Appendix I: Terms of reference for the DH wider review of regulation, 2005

The wider review of regulation in health and social care will look at functions first before form. It will include, but not be limited to, the remit of the Healthcare Commission, the Commission for Social Care Inspection, the Mental Health Act Commission, Monitor and the Audit Commission (in respect of its functions for health). It will not include bodies solely responsible for individual professional self-regulation.

The terms of reference for the wider review will be:

- (a) to define our objectives for regulation and inspection in health and social care, striking the right balance between the need to streamline regulation, while ensuring proper stewardship of public funds, and quality and safety in services for patients, users and the public
- (b) to examine the functions needed to achieve these objectives, taking account of current and forthcoming changes in the health and social care sectors, including:
 - changes in the role and organisations of local councils
 - the streamlining of SHAs and PCTs
 - the provision of greater choice and plurality within health
 - payments by results and the price tariff
 - the future direction of travel for policy on social care for adults.
- (c) to review the experience here and in other sectors, and from abroad, and identify predictors of success for added value from regulatory systems
- (d) to identify where changes might have the greatest impact on frontline staff; and improve the assurances for users and the general public
- (e) to put forward proposals for the form in which these functions can be most effectively discharged, taking account of the wider implications of the health and social care systems.

The wider review will be carried out by the Department of Health from September 2005, reporting to Ministers by Christmas 2005. The work will be overseen by a

Regulation Review Panel, chaired by David Currie, the chairman of Ofcom. The other panel members are Dr Dieter Helm from New College, Oxford, and Bob Chilton, acting chair of the National Consumer Council. The role of the Regulation Review Panel will be to act as a 'critical friend' during the process of the review and to challenge emerging findings.

October 2005

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