



# Briefing

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## Regulation of Health Care Provision in England

### Introduction

From April 2009 the new Care Quality Commission will take over the work of three existing health and social care regulators – the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. The government is also introducing new arrangements for regulation of the market in health care.

This briefing examines the recent history of the quality and safety, financial and economic regulation of health care providers in England; describes the new regulatory machinery that is being introduced; and considers how the relationship between these different regulatory systems may develop in the future.

### What is regulation in health care?

At its broadest, regulation of health care in England encompasses the legislative framework within which the NHS and the independent sector operate as well as the more detailed guidance issued by the Department of Health governing the behaviour of organisations within the health care system. In addition, the General Medical Council, the Nursing and Midwifery Council and the Health Professions Council among others regulate individuals as members of particular professions. A briefing on professional regulation is available from The King's Fund website (The King's Fund 2007).

This briefing is concerned with the regulation of health care organisations, rather than of individual professionals. It focuses on three areas: regulation designed to ensure and promote the quality and safety of all health care services; regulation of the financial performance of public sector health care organisations; and regulation of the market in health care services. Organisations currently performing these roles include the Healthcare Commission (whose role will shortly be taken over by the Care Quality Commission), Monitor, the Audit Commission and the Department of Health itself.

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## Quality and safety

### The introduction of quality and safety regulation and the Commission for Health Improvement

The need for a system of regulation on quality and safety was recognised in the Labour government's first health White Paper (Department of Health 1997). At that time there was no national policy covering all aspects of the quality and safety of health care provision.

The government actively intervened to drive through improvements in the NHS by setting targets, such as those for waiting times, requiring trusts to introduce clinical governance systems (Department of Health 1998) and introducing a Performance Assessment Framework, which covered both quality and efficiency in service delivery (Department of Health 1999). A new non-Departmental public body, the Commission for Health Improvement (CHI), was established by the Health Act 1999, primarily to offer guidance to NHS providers in England and Wales on developing clinical governance, but with the broader aim of offering 'an independent guarantee that local systems to monitor assure and improve clinical quality are in place' (Department of Health 1997). Its role was expanded after 2002 to include inspecting NHS organisations and services; publishing annual reports to Parliament on the state of services to NHS patients; and recommending special measures where quality was deemed unacceptably poor (NHS Reform and Health Professions Act 2002).

Responsibility for licensing private sector health care providers was moved from health authorities to a new National Care Standards Commission in 2000 (Care Standards Act 2000). In 2002 the government published a set of National Minimum Standards against which these providers were assessed (Department of Health 2002b).

Even as CHI's powers were expanding, the government was in the process of introducing further changes to the regulatory structure. In *Delivering the NHS Plan* (Department of Health 2002a) the government announced that a new regulator would be established – the Commission for Healthcare Audit and Inspection (CHAI) – that would bring together the NHS quality regulation role of CHI, the health value for money work of the Audit Commission and the private sector health care role of the National Care Standards Commission (Health and Social Care (Community Health and Standards) Act 2003). The new body called itself the Healthcare Commission.

### The work of the Healthcare Commission

The new Commission was more independent of government than any of the organisations it replaced. A key change was that commissioners were to be appointed by the Independent Appointments Commission not by the government and that the Commission was accountable to Parliament.

#### Standards, monitoring and reporting

An annual review of all English NHS trusts (including foundation trusts), called the Annual Health Check, has been the largest part of the Commission's activity. The reviews measure the performance of individual trusts against Department of Health targets and the Department's 'core standards' and 'developmental standards', set out in the document *Standards for Better Health* (Department of Health 2004 (2006)). These describe the level of quality expected from providers in relation to safety; clinical and cost effectiveness; governance; patient focus; the accessibility and responsiveness of care; the care environment and amenities; and public health.

Core standards set out the minimum level of service that must be provided and incorporate requirements that which were already in place before their publication in 2004. Developmental standards are more demanding and are intended to stimulate NHS organisations to improve the quality of the care they provide.

The reviews were originally conducted through inspection visits to all trusts. However, reflecting government-wide concern about the burden of regulation, from 2005 the Healthcare Commission introduced a more selective inspection regime combined with self-certification of data returns by NHS providers.

A similar system of self-assessment exists for independent sector providers, who must meet their minimum standards of practice (the National Minimum Standards) in order to be registered as a legal provider of services. Inspections are carried out when the Healthcare Commission has information to indicate that performance may be falling short of the standards, but those providers who produce information to show they are meeting the standards are visited only every five years.

Foundation trusts are subject to both the Healthcare Commission's assessments and regulation by the foundation trust regulator, Monitor, against their terms of authorisation as foundation trusts. In addition to financial regulation (*see* p 5, Financial regulation), this includes monitoring compliance against standards relating to governance of the trust.

### **Enforcement**

Where 'significant failings' are found in any trust, the Commission reports them to the Secretary of State, or to Monitor in the case of foundation trusts, and can recommend that 'special measures' are taken to remedy the failing. Following the Health Act 2006 the Commission also has the power to issue 'improvement notices', which require improvements from trusts in relation to infection control within a specified time period.

In the case of foundation trusts, if a serious failing is identified in relation to a trust's terms of authorisation or any other legislation, Monitor can require the trust to take action within a specified time period. If that proves unsuccessful, Monitor can (with the permission of the Secretary of State for Health and a magistrate) remove members of the trust board or even dissolve the trust entirely (Monitor 2008b).

In the case of independent sector providers, it is an offence for an organisation to offer health services without being registered by the Healthcare Commission, and the Healthcare Commission can cancel a provider's registration if they are failing to meet the National Minimum Standards.

### **Further reform: The establishment of the Care Quality Commission**

The creation of the Healthcare Commission and the merging of the functions of its three predecessor organisations into one was intended both to strengthen regulation and to reduce the burden it imposed on providers. But while it was being established, pressures developed for further reductions in the number of regulators from a government review of public service regulation (Office of Public Sector Reform 2003) and the Department of Health's own review of its arm's length bodies (Department of Health 2004b).

Following these developments, the 2005 Budget announced a 'long-term strategy' for public service regulation, which would see the number of public service regulators reduced from eleven to four (HM Treasury 2005). This included the merger of the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission (which monitors services and conditions for patients detained in hospital under the Mental Health Act 1983) into a single body by 2008.

A consultation document on the future of health care regulation, published in November 2006, proposed the merger of these three bodies to form a new body called the Care Quality Commission (CQC). This was enshrined in law by the passing of the Health and Social Care Act in July 2008 (Health and Social Care Act 2008).

The CQC came into being in October 2008 on a shadow basis and becomes fully operational from 1 April 2009, when it will be responsible for the regulation of all health and adult social care providers in England.

From April 2010, all providers of health care in England, including NHS providers, foundation trusts and independent providers, will be legally bound to be registered with the Commission in order to provide services. The government has proposed that from 2011 this requirement will include NHS primary care providers, including GPs, who had not previously been subject to regulation by the Healthcare Commission. The case for bringing these into the regulatory system is based on perceived variation in current service quality and a recognition that the policy of moving services out of hospitals and into community-based settings has increased the complexity of some primary care services (Department of Health 2008f).

The task of assuring the quality of *commissioning* rather than of the services commissioned will continue to rest largely with strategic health authorities (Department of Health 2008c). The CQC has said it will provide information on the performance of commissioners (Care Quality Commission 2008a), but it is not yet clear what form this will take.

The Care Quality Commission has defined its mission as ensuring essential quality and safety standards, driving improvement and stamping out bad practice – with a particular emphasis on protecting vulnerable people and those detained under the Mental Health Act (Care Quality Commission 2008a). Its mission statement also includes a commitment to provide accessible information on service quality to patients, commissioners and providers.

### Registration standards

Registration for all health care providers will be conditional on the service provider meeting a series of 'registration requirements' covering areas such as the state of premises, providing information, keeping accounts and records, the management and training of staff and the handling of and learning from complaints (Health and Social Care Act 2008). These will replace the Core Standards from *Standards for Better Health*, which currently apply to NHS providers, and the National Minimum Standards, which apply to the independent sector. The more demanding developmental standards against which NHS trusts and foundation trusts are currently also judged through the Annual Health Check are to be replaced by a revised set of improvement standards.

### Monitoring and reporting

The Department of Health has described this new registration function as being the regulator's 'principal role' (Department of Health 2008c). All providers will need to demonstrate that they can meet the registration requirements in order to be granted registration and, once registered, to demonstrate that they can continue to meet them. How this will be demonstrated and verified has yet to be established. The Care Quality Commission has been tasked with developing 'guidance on the new methodology and compliance criteria, to ensure that providers continue to meet the requirements for essential levels of safety and quality' (Department of Health 2008f).

The Care Quality Commission is required to carry out performance reviews of all NHS trusts and foundation trusts and of care provided and commissioned by PCTs in England. These – formerly known as the Annual Health Check – will be termed Periodic Reviews. The Department of Health's emphasis on registration appears to downplay the significance of these reviews

Like the Healthcare Commission, the CQC must also provide annual reports to Parliament on the state of health care (and adult social care) services and can conduct special reviews or investigations of individual providers or groups of services as they see fit and when requested to do so by the Secretary of State. The Commission can also undertake studies on how to improve the efficiency, economy, effectiveness and management of services – or request that the Audit Commission does so on their behalf.

## Enforcement

The Commission will have a wide range of enforcement powers including fines or imprisonment for failure to register. It can place conditions on an organisation's terms of registration, suspend the registration or, in extreme cases, cancel it. The Commission can also issue warning notices, requiring organisations to take action to remedy a problem within a set time period and issue penalty notices that impose fines. If trusts fail to comply with any enforcement action, then the trust boards will be subject to intervention by the Secretary of State or, in the case of foundation trusts, Monitor. The enforcement powers of Monitor, described above, remain unchanged.

The Commission launched a consultation in October 2008 on how it intends to use its new enforcement powers and has also published guidance for NHS trusts about additional requirements for registering with the new Commission in relation to healthcare-associated infection (Care Quality Commission 2008b).

## User involvement

The Healthcare Commission regularly consults users within its monitoring programme. The Health and Social Care Act 2008 *requires* the new Commission to publish a Statement of User Involvement that should include details of how they will inform service users and carers about their functions and arrange for some of their functions to be 'exercised by and with the assistance of service users and carers'.

The introduction of the Care Quality Commission represents a further major reorganisation of the system of quality and safety regulation introduced after 1997. The common themes running through this and previous reforms are attempts to increase the independence of the regulatory system; to reduce the cost of regulation; and to reduce the burden its activities place on frontline organisations. In addition, the government's most recent changes place an emphasis on an assurance rather than improvement role for the regulator, and begin to harmonise the regulatory regimes applied to non-NHS and NHS providers.

## Financial regulation

In addition to regulation of quality and safety, NHS organisations are subject to a set of financial rules. In recent years, these rules have been developed to allow some providers greater independence from central government and to actively encourage better use of resources by NHS bodies.

When provider trusts for hospital and community health services were established during the 1990s they were required to operate within a quasi-commercial financial structure. The main financial duty imposed on them was to break even, after interest and other capital payments, on a year-by-year basis. In principle neither deficits nor surpluses could be carried forward. In practice, however, inter-trust short-term borrowing – a system known as brokerage – allowed a degree of flexibility. Access to capital was controlled by the Department of Health, and all major schemes had to have central government approval. The Audit Commission was responsible for ensuring

trusts' accounts were audited and any failings drawn to the attention of the trust board. In the first instance the boards were responsible for ensuring the financial stability of each trust. Financial performance was monitored by health authorities.

Essentially the same regime continued up to and after publication of the NHS Plan in 2000. The key indicator of financial performance remained achievement of financial balance.

### The introduction of Monitor

The introduction of foundation trusts from April 2004 changed the system of accountability, with the explicit aim of encouraging greater independence from central government. Foundation trusts were made accountable to local people and Monitor was established both to assess NHS trusts' suitability for foundation status and to oversee their financial performance.

Foundation trusts enjoy greater financial freedom in two main areas: they are allowed to build up surpluses that can then be used for service development – and as a result do not need to balance their books on a year-to-year basis – and they are able to borrow from commercial sources, subject to limits set by Monitor.

To become a foundation trust NHS trusts must demonstrate to Monitor their ability to manage their finances effectively. Subsequently they must conform to a compliance regime set by Monitor (Monitor 2008b). Monitor assigns a risk score to each trust and varies the intensity of its monitoring accordingly. When a trust runs into financial difficulty, Monitor provides support for its recovery.

Foundation trusts are also subject to regulation against their terms of authorisation as a foundation trust, which are set on a case-by-case basis by Monitor. These include stipulations about the maximum amount of money a trust can earn through private income, the maximum amount they can borrow, and data they have to make available (Monitor 2008a). By autumn 2008 45 per cent of acute trusts were foundation trusts (Monitor 2008c), and the government expects that in due course all NHS trusts will attain foundation status.

### The impact of NHS deficits from 2005

Despite the rapid increases in NHS budgets from 2000 onwards, by 2005 many provider trusts were heading for serious deficits. This raised questions about the ability of trusts to manage their finances, the ability of the Department of Health to monitor them effectively and the appropriateness of the financial regime itself.

A series of reports into the situation from the Health Committee, the Audit Commission and the National Audit Office led to further changes in the regulatory regime (House of Commons Health Committee 2006, National Audit Office *et al* 2006). The brokerage system was abolished from 2006/7 onwards to compel trusts to address their underlying financial problems. Trusts that overspend now have to borrow cash and to repay such loans, with interest, in an explicit way. The general aim is to move towards a rules-based regime that does not allow poor performance to be hidden.

The Public Accounts Committee argued in its report into Financial Management in the NHS that the Department of Health was not effective as a financial regulator (House of Commons Committee of Public Accounts 2007). In response the Department made a number of changes, including a commitment to strengthen its own monitoring capacity.

## Economic regulation

The introduction of market mechanisms into the provision of health care for NHS patients has led to the emergence of a new area of regulatory activity.

In 2002 the government announced that it was commissioning new capacity from the private sector to treat patients on NHS waiting lists. In addition, it began to allow patients to choose which hospitals they would be treated in. From 2006 all patients requiring non-urgent treatment should have been offered a choice of hospital from a local menu – a choice extended in April 2008 to include all NHS hospitals and non-NHS providers who meet certain quality and cost requirements (*see* The King's Fund 2008). These developments combined with the freedoms offered to foundation trusts laid the foundation for a market in hospital services.

The introduction of new contractual mechanisms in primary care has also opened up the provision of some primary care services to independent and third sector providers, and the government is pursuing policies intended to make it easier for patients to move their registration between GP practices (Department of Health 2004a, Department of Health 2006).

NHS bodies are not subject to the regulatory regime that applies to other parts of the economy and is enforced by the Office of Fair Trading and the Competition Commission – though non-NHS health contractors, such as dentists and pharmacists are. The government has decided that there needs to be a separate set of mechanisms to create and to regulate this new market in health care. Developments to date include:

- Price setting – a national tariff, which sets out the fixed-price-per-case that hospitals will be reimbursed for treating NHS patients, is set by the Department of Health. This ensures that trusts attracting additional patients gain extra income
- Competition – guidance has been issued on how and when to put services out to tender (Department of Health 2008c). This, like the EU Treaty and subsequent directives, does not place a general requirement on PCTs to submit NHS services to a formal procurement process, but it does require them to have a procurement strategy. They are encouraged to tender in respect of large contracts and where there are a number of potential providers. The guidance also sets out procedural rules, eg, on advertising tenders. A Cooperation and Competition Panel has been established to monitor how commissioners adhere to these rules (Department of Health 2008a). Private sector providers can appeal to the Cooperation and Competition panel if they feel they have not been given a fair chance to compete. Support has been provided to encourage new third sector providers, including social enterprises (Department of Health 2008g).
- Mergers – decisions on whether to permit mergers between trusts, such as the acquisition of Good Hope Hospital by the Heart of England Foundation Trust in Birmingham (Monitor 2007), or vertical integration (takeover of a primary care organisation by a hospital trust) are to be examined locally on a case-by-case basis but remain subject to Department of Health approval (Department of Health 2007).
- Trust failure – procedures are being established (Department of Health 2008c) for identifying poorly performing trusts and taking action to turn round their performance. In the first instance primary care trusts will be responsible for taking action. The Care Quality Commission may intervene in respect of specific services and Monitor in respect of foundation trusts. Strategic health authorities and the Department of Health may also intervene depending on the effectiveness or otherwise of PCT action.

- Market exit – a consultation document on the rules governing provider ‘exit’ from the market (when a provider is no longer able to compete and the interventions described above have failed) was published by the Department of Health in September 2008 (Department of Health 2008b). This envisages the appointment of a special administrator, who would take over control of the trust from the board and subsequently make recommendations to the NHS Chief Executive as to what should happen to the services currently being provided by the trust in question.

## What next for health care regulation?

After 10 years of development, the regulatory system for quality and safety, finances and the market remains in a state of transition. A key question for the years to come is how the three regulatory regimes described above and the various bodies responsible for them will mesh together and with other policies designed to promote better performance.

The Care Quality Commission has yet to determine how it will discharge its new responsibilities. In particular, the relationship between the work of the Care Quality Commission and Monitor has yet to be clearly elaborated. For example, a foundation trust’s terms of authorisation are to continue to be regulated by Monitor, but the CQC’s registration requirements are to form part of these terms, and breaches of these specific requirements are to be assessed by the Care Quality Commission (Department of Health 2008f). This approach seems to create the potential for overlaps in regulatory activity. Ensuring that the processes complement each other will require the two organisations to closely co-ordinate their activities.

The boundary between the role of PCTs in ensuring service quality through contracts and local intervention and the role of Care Quality Commission will also need to be established and carefully managed. The Department of Health has emphasised the quality assurance role of the new regulator, stating that ‘improvements above levels of essential safety and quality will be encouraged and secured by other levers in the system’ (Department of Health 2008f). However, the Care Quality Commission’s own initial manifesto presents quality improvement as a key part of its role (Care Quality Commission 2008a).

Although these features of the new system have yet to be clarified, it is already clear that still further changes can be expected. Lord Darzi’s report *High Quality Care for All* proposed that the role of the National Institute for Health and Clinical Excellence (NICE) should be expanded to allow it to develop a comprehensive set of standards covering all care services and that a National Quality Board should be established to advise Ministers on what the priorities should be for those standards (Department of Health 2008d). All organisations providing services for NHS patients will be required to publish annual Quality Accounts detailing their performance in relation to patient safety, experience and outcomes.

How the new financial and economic regulations will work in practice and how they will dovetail with quality regulation also remains to be seen. Lord Darzi’s report proposes closer links between financial and quality regulation by suggesting that the national tariff be modified to reflect quality differences and that extra payments be made for higher quality performance. How this will be done and by whom is not clear.

However the system develops, there will be a continuing need to ensure that the total burden of regulation on NHS providers is kept in check; that the effectiveness of specific instruments such as registration is monitored; and that the effectiveness of the *combination* of different policies and mechanisms, including professional regulation and broader quality-improvement policies, is kept under review.

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