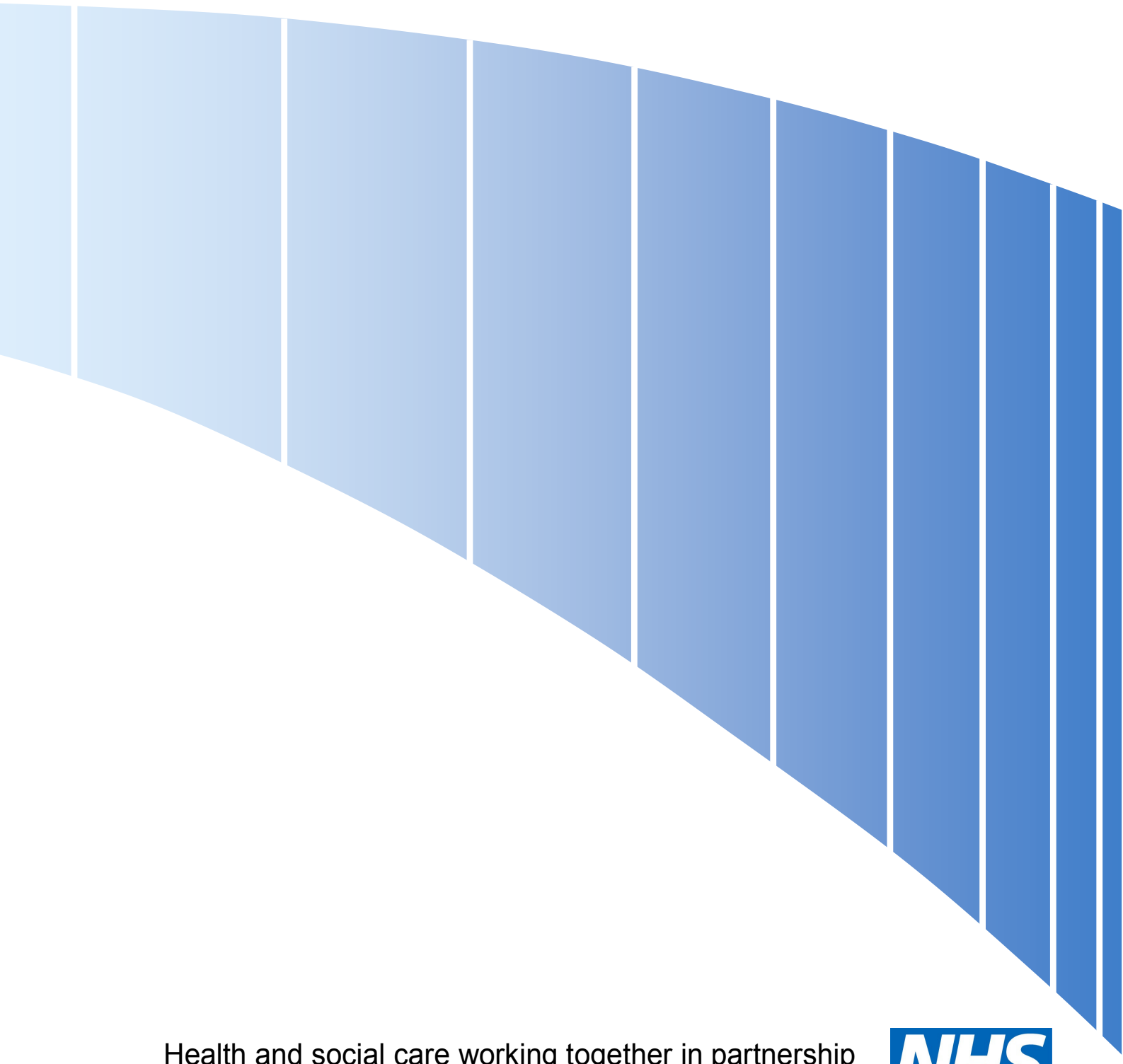
The future regulation of health and adult social care in England: response to consultation



Health and social care working together in partnership

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Foreword

from the Secretary of State for Health

The future regulation of health and adult social care in England: response to consultation

The public rightly expects the health and social care services they pay for through their taxes to be safe and of the highest quality. They also expect there to be a body, independent of Government, responsible for monitoring performance, so people can have confidence in the information about the services they receive.

My ministerial colleague and renowned surgeon, Lord Ara Darzi, recently published his interim report on the long-term future of the NHS[1]. The Government is shortly to publish an important Green Paper on the future of social care. The vision, building on the improvements of recent years, is of high-quality care that is safe, effective and personalised for all. The regulatory framework set out in this document is an essential part of realising that vision.

Flexible and responsive public services need flexible and responsive regulation. The current system has worked well, but is held back by barriers between health and social care and by a lack of flexibility in trying to deal with new and innovative services. As more decisions are devolved to the local level and more choice given to patients and the public the old distinctions will blur further. But people will continue to want clear, credible and transparent information about the services they receive, building on the excellent existing work by the Healthcare Commission and Commission for Social Care Inspection.

Our consultation document, *The future regulation of health and adult social care in England*[2]*,* set out the vision for the overall regulatory framework. It described how management of the system and regulation would give people confidence that, no matter which organisation provides the services they need, those services are safe and of good quality.

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[1] *Our NHS, our future: NHS next stage review – interim report,* Department of Health, October 2007

[2] *The future regulation of health and adult social care in England,* Department of Health, November 2006

The document described the Government's proposals for an integrated health and adult social care regulator, which prioritises the safety and quality of care, and supports a system that continuously seeks to improve services.

We received a large number of responses to the consultation, and these showed widespread support for an integrated and independent regulator. Those responses have helped us to shape this current document. This document provides the Government's response to the consultation.

The new Care Quality Commission will have stronger powers to ensure safety and quality across health and adult social care services. Many people use both health and social care services, so it makes sense to bring them under a common regulatory framework that supports joined-up working. The unprecedented levels of investment across health and social care provide an excellent opportunity to support joint working.

The Care Quality Commission will bring together the expertise of the Commission for Social Care Inspection, the Healthcare Commission and the Mental Health Act Commission. It will apply a consistent approach to regulation for all types of services through a new registration regime, requiring providers of health services and adult social care to be registered.

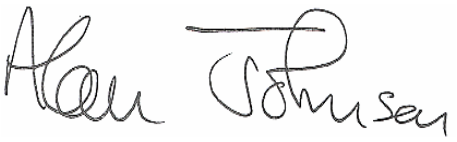
It will take rapid action against any organisation that puts patients or users of services at risk. It will embody the Government's principles of good regulation in the way that it operates to avoid unnecessary or counter-productive burdens being placed on the services it regulates.

The new system will make clear to the public what they should be able to expect in terms of safety and quality from their services and will support the work of those delivering them - such as Primary Care Trusts, hospitals, primary care providers, social care providers, the Strategic Health Authorities and local authorities - in improving standards.

The Care Quality Commission will have specific new powers to tackle the problem of healthcare associated infections. These will include the fining of hospitals and the closing down of wards where hygiene requirements are not being met. High cleanliness and hygiene standards are a priority for the Government and we expect the new regulator to impose a tough cleanliness inspection regime to achieve this.

I would like to thank all the organisations and individuals who responded to the consultation for their input to the development of our proposals.

The Prime Minister announced on 11 July 2007 our intention to introduce a Bill to set up a single new regulator in the next parliamentary session. Stronger regulation, combined with the right incentives at local level, create the right foundation for delivering safe, high-quality services. The publication of this response is an important stage in our reform of the NHS and adult social care services, and it lays the foundations for building confidence in the safety and quality of these services for the future.



Rt Hon Alan Johnson MP
Secretary of State for Health
24 October 2007

Executive summary

Safety and quality is everybody's business. The fundamental responsibility rests with professional and care staff and the organisations they work in. Effective commissioning, increasing choice backed by reliable information and more opportunities for people to influence services will all help improve safety and quality. The particular role of regulation is to provide assurance that systems for safety and quality are in place and working well. Patients, service users and the public as a whole therefore look to staff within the health and adult social care systems and to regulators to ensure the services they use are safe and of good quality.

The overall framework described in this document makes clear that the primary purpose of regulation is to provide an essential safeguard for patients and users of services. The new integrated regulator for health and adult social care will support local system management by:

- have enhanced regulatory powers to provide greater protection for patients and service users;
- bring together in a coherent way the independent regulation of health and adult social care services;
- take a flexible approach to regulating different services as they develop over time, concentrating more of its resources on services that present the biggest risk or where patients and users are most vulnerable;
- ensure the way services are regulated is efficient and effective, thus protecting the taxpayer's interest;
- publish reliable information about the quality of service providers, making it easier for the public to make informed choices;
- publish reliable information about the performance of commissioning bodies that purchase the services that the public needs.

This document reaffirms the Government's approach to regulation and the principles under which it will operate: it will be proportionate, transparent, consistent, accountable and targeted. It follows the consultation on the regulatory framework proposed in *The future regulation of health and adult social care in England*.

The responses to the consultation showed broad support for a single health and adult social care regulator and the functions we have now set out for it in this document; but there was a call for more debate about how some of these

functions would work – particularly a common registration system for all care providers, which will therefore be the subject of a separate consultation.

The regulatory framework described here is largely consistent with the original position in the consultation document, and confirms that the first priority will be the safety and quality of care in hospitals and other care providers. Assurance will be strengthened using a common system of registration, compliance and enforcement that will be applied equally to NHS and independent sector providers. For the first time the new regulator will be able to close NHS services, as well as those provided by the independent sector and adult social care, if they are a threat to the safety of patients or service users. This will be an important part of the Government's drive to tackle serious healthcare associated infections.

This document also highlights important roles for SHAs in the NHS – particularly in holding PCTs to account. It also describes a system for ensuring fair competition in the NHS, where we are proposing a national set of rules that are administered locally.

All the organisations that lead management of the health and adult social care systems locally will need to work closely with the new regulator, which will have an important role within the overall system, focusing on safety and quality assurance, performance assessment of providers and commissioners, safeguarding patients subject to detention under the Mental Health Act[3] and minimising the burden of regulation across the sector as a whole.

The Government will introduce a Bill to establish the integrated health and adult social care regulator, bringing together the Commission for Social Care Inspection, the Healthcare Commission and the Mental Health Act Commission. The final chapter of this document summarises the roles and responsibilities of the new regulator, to be known as the Care Quality Commission.

[3] In this document, references to the Mental Health Act are to the Mental Health Act 1983 as it has been amended since 1983, including, where enacted, by the Mental Health Act 2007.

1. The future of health and adult social care regulation

Summary
This chapter sets the scene on how health and adult social care will be delivered and regulated in the future. It reaffirms the Government's vision for regulation, and summarises the regulatory framework proposed in the consultation document, *The future regulation of health and adult social care in England*, published in November 2006.

The changing landscape of health and adult social care

1.1 Safety and quality is everybody's business: the fundamental responsibility rests with professional and care staff and the organisations in which they work. Other parts of the health and social care system also have a role to play in ensuring good quality: commissioners (PCTs and local authorities) and, for health, Strategic Health Authorities. And patients and service users can influence quality in the choices they make. The particular role of regulation is to provide independent information and assurance that systems for safety and quality are in place and working well.

1.2 Regulation is important to patients, users of social care services, and the wider public. Regulation of individual professionals offers an important safeguard, but it is not enough in itself. There is also a need to make sure that the organisations they work within have appropriate systems and procedures to assure safety and quality, and that controls are in place to ensure continuity of services. Regulation offers assurance that both publicly and privately funded services provide safe, quality care and are delivered in a way that respects individual needs and rights. It gives people confidence that, no matter which provider they choose, they can expect a safe, quality service, and it also gives them reliable information on which to make those choices. In addition, the public expect an independent assessment of whether their taxes are being used effectively and efficiently.

1.3 The public want to influence how services are regulated – they do not want regulation to place an unnecessary burden on public services or to

create a drain on resources with no discernible benefit. All organisations with a regulatory role therefore have to rise to the challenge of listening to service users, and offering them the best possible protection without creating unnecessary bureaucracy.

1.4 Public services are changing, and the regulatory framework needs to adapt to keep up with changing public expectations, new service models and advances in modern medicine. Services are becoming more responsive and more personal, and are increasingly being delivered in a wider range of settings, often more locally based – or even in people's homes. They are also becoming more integrated, with health and social care being jointly commissioned and delivered. There is an increased emphasis on investing in prevention and promoting health and well-being to enable people to stay well and independent. This is becoming just as important as diagnosing, treating and caring when people are unwell or in need.

1.5 In the NHS, while most NHS-funded care will continue to be provided by NHS bodies, the independent sector (private and third sectors) can – and do – play an important part. It can add capacity where there are pressures (e.g. elective surgery), offer a wider range of choices for patients, and bring new and innovative service models (e.g. care for people with long-term conditions). In adult social care, there is a long history of services being delivered by providers from all sectors.

1.6 These changes to service provision, now and in the future, need to be underpinned by a clear framework for managing and regulating health and adult social care systems. This will ensure that high standards of care are maintained and that patients are able to take full advantage of the wider choice of services available to them. In the NHS, strategic health authorities (SHAs) have a key role in managing the local system and holding primary care trusts (PCTs) to account.

1.7 The existing regulatory framework for health and adult social care is fragmented. In healthcare, there are different procedures and standards for NHS providers and independent sector providers, and the current legislation is also not flexible enough to cope with the increasing pace of change in structure and innovation of delivery of services. Although adult social care does have a unified framework across public and independent sector providers, the lack of flexibility is again a significant issue.

1.8 This is why the Government confirmed in *The future regulation of health and adult social care in England* its intention to establish a new integrated health and adult social care regulator, bringing together the existing Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. Subject to

parliamentary approval, we intend to establish this new regulator in 2008, so that it can take over from April 2009. It will be called the Care Quality Commission. Creating this new body will also take forward the Government's commitment to reduce the number of public sector inspectorates.[4]

1.9 The role and functions of this national, independent regulator must be set in the context of an overall system that is led and managed locally by commissioners and providers, and where commissioners and providers take responsibility for continuously driving improvements in quality and safety. The Department of Health will work with these bodies to ensure that the tools needed to secure improvements in the quality and safety of services continue to be developed.

1.10 The Care Quality Commission will bring independence and national oversight. It will build on the effective regulatory models developed by the existing regulators of health and adult social care. It will focus on those things that require national consistency, independence or the economies of scale that come from bringing expertise together in one body.

1.11 It is important for service providers that regulation is proportionate and does not place unreasonable demands on them or distract them from their core business. The Care Quality Commission will therefore work to minimise the cost and impact of on-site inspections and data collections by adhering to the Government's Principles of Good Regulation,[5] which state that regulation should be:

- proportionate – and appropriate to the risk posed;
- transparent;
- consistent;
- accountable;
- targeted only where needed.

1.12 The Care Quality Commission will achieve this by using information and intelligence (including the views of patients, users of services, carers and staff) to target its finite resources on the areas of greatest risk. It will work within an agreed budget and avoid duplicating what others in the system are better placed to do, and will be able to impose sanctions and take enforcement action when patients and users of services are put at risk.

[4] Chancellor's Budget Statement, 16 March 2005.
[5] Available at www.brc.gov.uk/publications/principlesentry.aspx

Our vision for regulation

1.13 In November 2006, we published a consultation document about the regulatory framework that this new regulator would work within. *The future regulation of health and adult social care in England* concluded the 2005 wider regulatory review, and it drew on evidence from a 2006 research study of regulation in other sectors in the UK and regulation of health and adult social care in other countries.[6]

1.14 The consultation document described a framework of seven regulatory functions that are helping health systems in other countries and in other sectors, to work more effectively. Not all the functions need to be carried out by the Care Quality Commission – but they must exist somewhere in the system. The seven functions outlined in the consultation document were:

> safety and quality assurance

Assurance for patients and users of services that providers from all sectors deliver safe and high-quality services. This involves the setting of national requirements and monitoring against them, and the ability to take necessary action where service users are put at risk.

> promoting choice and competition

Ensuring that a range of good-quality services are available, so that patients have real choice and there is a fair playing field for providers. This, in turn, will mean that there are increased incentives in the system to innovate, respond to the needs of patients and users, and improve service quality.

> commissioner assurance

Assuring the public that commissioners are working effectively on their behalf to secure high-quality, good-value services. This will involve holding commissioners to account, managing their performance, and the independent publication of information that compares performance across England.

> information and performance assessment of providers

This function is closely linked to safety and quality assurance, and involves the collection and quality assurance of information from providers. This will mean publishing independent information and

[6] *The future of health and adult social care regulation*, available at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063258

analysis of the performance of providers, so that service users have reliable information to support their choices and commissioners have additional information to support commissioning decisions.

> price setting and allocations

Ensuring a fair and equitable allocation of funds, defining pricing and adjustment rules, and carrying out technical work to calculate actual prices where appropriate. As a result, commissioners and providers will be able to plan to deliver a range of services that meet the needs of their local population.

> stewardship of public assets

Safeguarding public funds by ensuring economic, efficient and effective use of public assets and by monitoring the financial position of publicly owned providers to protect the taxpayer's investment in those organisations. As a result, the public can be assured that services represent good value for money.

> support, intervention and administration of failure

Ensuring that, in the event of a service or provider failure, the public can be assured that a viable alternative will be available. This requires a transparent process for handling distress or failure (and, if appropriate, insolvency) in providers, whatever the sector, and for ensuring continuity of essential services.

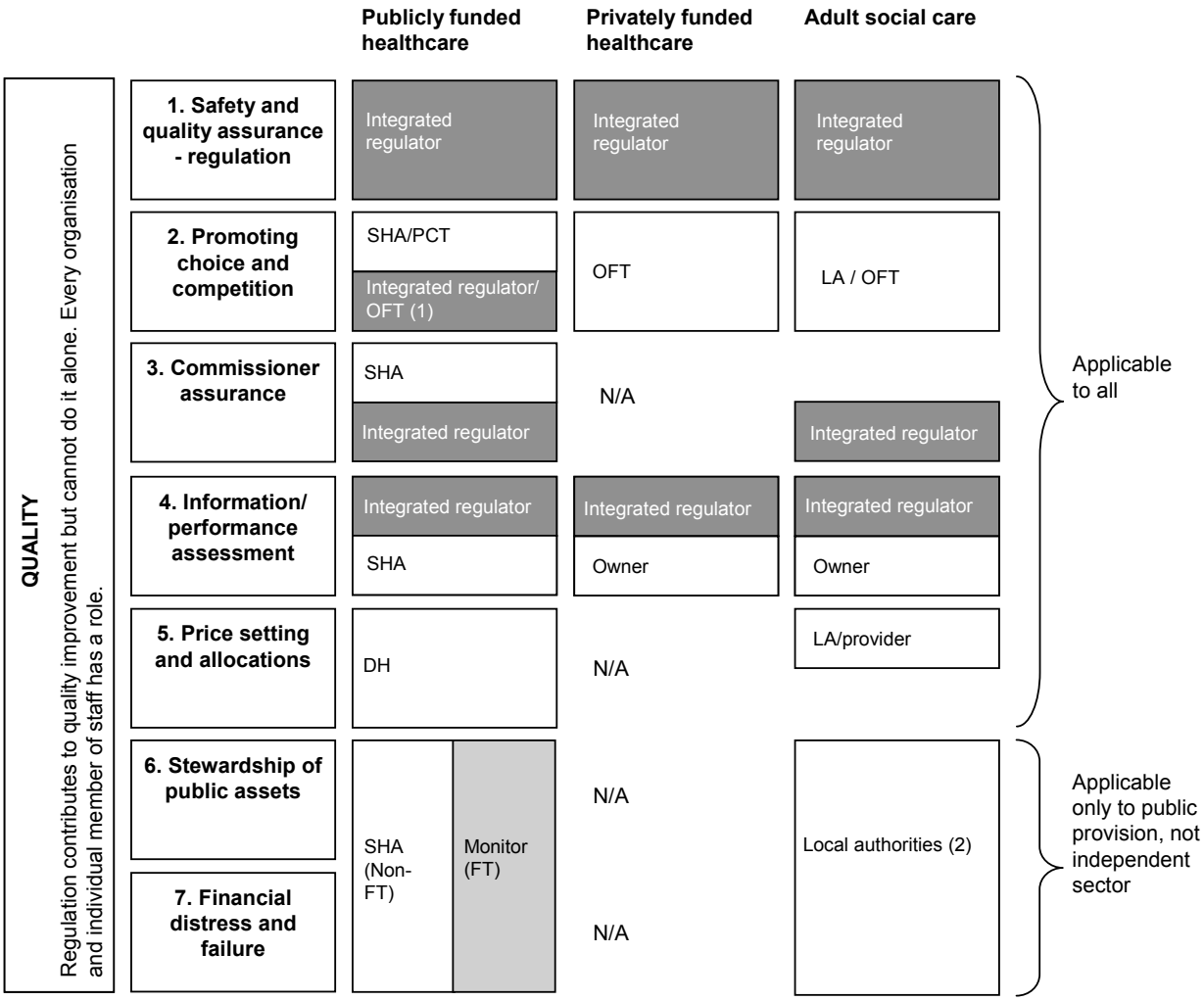
1.15 These seven regulatory functions are integral to the effective operation of health and adult social care systems. The consultation document suggested where these functions might sit within the system, and which of them could sit with the Care Quality Commission. This proposal was summarised in the consultation document in the diagram recreated in Figure 1, and is revised later in Chapter 3 to reflect changes arising from the consultation.

1.16 This document forms the response to the consultation and, as well as setting out the overall framework of responsibilities in the health and adult social care systems, sets out the functions the Government wishes the Care Quality Commission to undertake within that framework. These functions will form the basis of the forthcoming Bill that the Government plans to put before Parliament to create the Care Quality Commission and set out its functions.

1.17 This response will be of interest to all those who contributed to the consultation, as well as to anyone who wants to know how safety and quality will be assured in the future. It will also be of interest to anyone

working within, or in partnership with, health and adult social care organisations who wants to understand roles and responsibilities.

Figure 1. Structure proposed in consultation document (November 2006)



1) Revised following consultation – see Chapter 3.

2) Limited function because relevant only to local authority provision. Commissioner failure is picked up in commissioner assurance.

2. The consultation – what we heard

Summary
This chapter sets out the rationale for consultation and the methods undertaken to ensure full and active participation. It provides information about the type of organisation that responded, and summarises the main themes we heard in response to the consultation.

The consultation process

2.1 The consultation document asked for broad feedback on the proposed regulatory framework. It posed six consultation questions on specific points, and sought views and opinions from stakeholders on the detail of a new regulatory framework and how it could work in practice.

2.2 The consultation period ran for just over 13 weeks, during which time we secured the active participation of people working in the fields of health and social care, of patient and service user representative bodies, the third sector, the private sector, local government and the voluntary and community sectors. In addition to encouraging written consultation responses, we also held workshops and open forums and we have continued this dialogue since the consultation closed.

2.3 We held three workshops in partnership with the NHS Confederation and two with adult social care commissioners, service providers and users of services. Separate open forums were also held with independent sector members affiliated to the NHS Confederation, and we sought input from the third sector via the National Strategic Partnership Forum. We also promoted the consultation document via direct mailings in the Department of Health's Chief Executive's Bulletin, and Social Care Bulletin, the Association of Directors of Social Services bulletin, specialist social care journals and websites, and we targeted a number of approved social enterprise pathfinders and public health stakeholders.

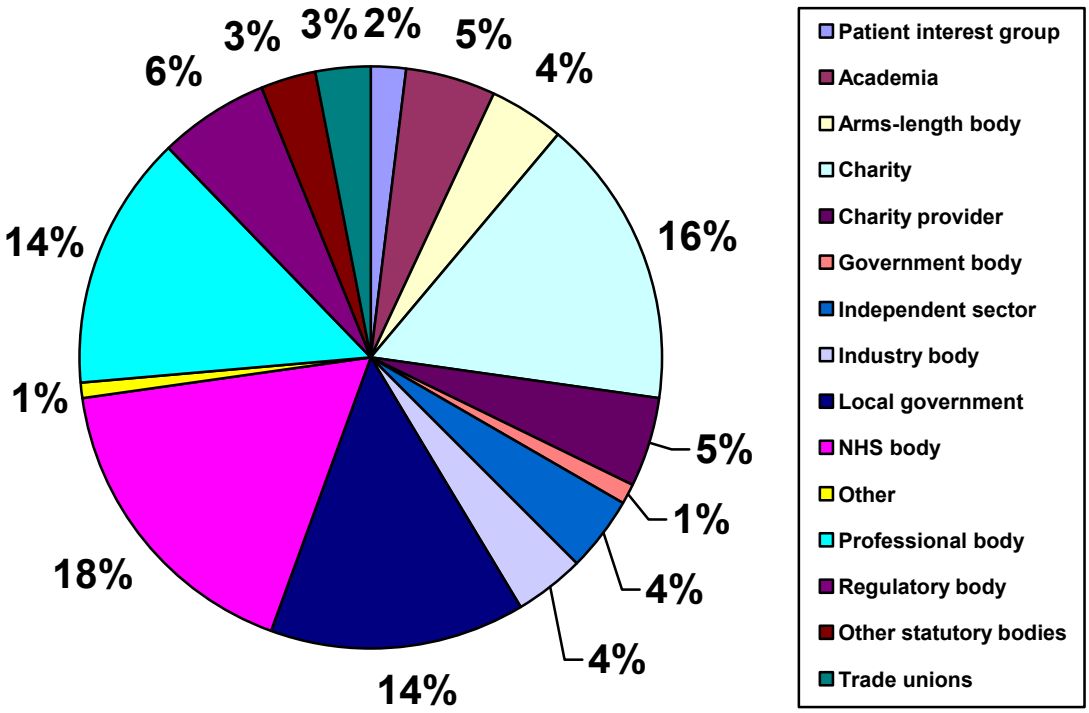
Who responded?

2.4 We received just over 100 written responses to the consultation document, from a wide variety of stakeholders, including all the main inspectorates and regulatory bodies currently involved in health and

social care. Overall, the biggest groups were NHS bodies (18 responses), charities (16 responses), local government bodies (15 responses) and professional bodies (14 responses).

2.5 A copy of the responses can be found on the Department of Health website (www.dh.gov.uk). Figure 2 below shows a breakdown of responses by sector.

Figure 2. A wide range of individuals and organisations from all sectors responded to the consultation



What we heard

2.6 Some of the main themes arising from the consultation and workshops were:

- the importance of involving patients and users of services in regulation – many responses supported the greater input from patients and users of services proposed in the consultation document. Responses were very clear that participation needed to be based around genuine involvement, using a variety of methods in order to promote equality and proper representation of the interests of patients and users of services;

- the regulatory framework and the role of the new regulator – there was broad support for the regulatory framework and the roles and responsibilities within it, including for the idea of bringing together the regulation of health and adult social care. However, further clarity was requested about the new regulator's remit, its statutory powers and its relationship with other organisations in the system (e.g. the Audit Commission, Ofsted, Monitor, commissioners, performance managers and organisations' boards);
- regulating service providers – there was support for a common registration scheme encompassing all care providers. However, a number of respondents called for more detail on how it would work, who it would cover and what standards they would need to meet;
- regulation of public health and health promotion – in the context of the growing emphasis on promoting health and well-being, some stakeholders considered that more emphasis needed to be placed on public health and health promotion, and particularly on joint approaches to commissioner assurance of public health and health promotion functions across the health and local government sectors;
- system management in the NHS – respondents identified a key role for PCTs and SHAs in managing their local systems fairly and in line with nationally agreed principles. Whilst a number of respondents were supportive of the need for an independent body to oversee competition, many were opposed to the new regulator having this role given that it could potentially distract from its core safety and quality assurance role;
- the impact of regulation – there was concern that regulation needed to be proportionate and that any regulator needs to pay close attention to compliance costs. In addition, more should be done to ensure minimal duplication between regulators and to achieve better alignment of their work.

2.7 The Government's response to this consultation and its proposals for legislation in the forthcoming Bill are all contained in the following chapters. For ease of reference, the six consultation questions are listed in Annex A, with links to the relevant paragraphs of this document that address them.

3. Government response to the consultation

Summary
This chapter outlines how the Government intends to take forward the seven regulatory functions from the consultation document, *The future regulation of health and adult social care in England*, taking account of the feedback from the consultation. For each function, it outlines the purpose, any changes arising from the consultation, and how work to clarify further detail will be taken forward. It concludes with a revised diagram of organisational roles and responsibilities. This is largely consistent with the original position in the consultation document, and confirms that the safety and quality assurance of health and adult social care services will be strengthened using a common system of registration, compliance and enforcement that will be applied equally to NHS and independent sector providers. It also describes a system for ensuring fair competition in the NHS, where a national set of guidelines are proposed for local administration.

The seven regulatory functions

3.1 The consultation enabled the Government to test its planned direction with the people and organisations affected by the proposals. As noted in Chapter 2, there was broad support for the proposed regulatory framework and the assignment of roles and responsibilities within that framework, as set out in the consultation document. This consultation response reaffirms our commitment to that overall framework, proposes changes to some elements of it, and summarises the Government's policy direction. It forms the basis for the primary legislation that will, subject to parliamentary approval, establish the Care Quality Commission and define its functions in regulating health and adult social care.

Safety and quality assurance: registration, compliance and enforcement

What is the benefit to patients and users of services?

3.2 With people exercising more personal choice about how they receive treatment and services being offered by a wider range of providers, it is important that there is independent confirmation that providers from all

sectors meet the required levels of safety and quality. This will offer assurance to patients and service users, and help commissioners and other purchasers of services to verify that a given organisation, and the care it provides, meet nationally specified levels of safety and quality.

3.3 It is important for people to know that the system is overseen by an independent regulator with the power to take tough enforcement action against providers that do not meet safety and quality requirements. The Care Quality Commission will be able to draw on a range of sanctions, going as far as closing down services that put patients and users of services at serious risk.

How will this be achieved?

3.4 The responses recognised the key role commissioners and providers have in driving up the quality of services. In addition, most were generally supportive of a national system of registration for providers of health and adult social care services from all sectors, including NHS services, to strengthen safety and quality assurance and make it consistent across health and adult social care. They recognised that information coming out of a registration system would be useful for patients and service users and would help drive improvement.

3.5 Therefore, subject to parliamentary approval, the aim will be to develop a single, coherent registration system for health and adult social care providers. We will consult on the detail of the Care Quality Commission's registration function i.e. the registration requirements to be adhered to, and the scope of registration (which services, organisations and providers will be covered).

3.6 Building on the good work of the existing health and adult social care regulators and on good regulatory practice, the Care Quality Commission will develop a proportionate and risk-based approach to ensuring that different types of provider and service meet nationally specified levels of safety and quality. This will give it the flexibility to adapt its approach and methods over time, as services evolve. To enable it to carry out its functions, the Care Quality Commission will also have rights of access and the power to obtain information. As is currently the case, the Care Quality Commission will have powers to charge fees for regulatory activity.

What types of provider will have to be registered?

3.7 The detail of the scope of registration will be subject to further consultation but we anticipate that service providers currently regulated by the Healthcare Commission or the Commission for Social Care Inspection will be required to be registered. These would include NHS trusts, NHS foundation trusts and PCT community services, as well as

independent sector healthcare providers and providers of adult social care that currently require registration.

3.8 To reduce the potential for excessive bureaucracy, we will ensure that the transfer process for existing providers is as straightforward as possible (see paragraph 3.17). In addition, the new process for first-time applicants for registration will be proportionately and flexibly applied to different kinds of service provision across all sectors of care. There will be a single system for new providers, from whatever sector, to apply for registration before starting to run services that require registration.

3.9 We will seek to define the services that require registration in a flexible way that enables innovation and allows providers to develop new types of service delivery. Decisions on whether to include certain types of service within the scope of registration will be based on the level of risk to users and on whether other regulatory mechanisms already exist that address those risks.

3.10 NHS primary medical care is not currently regulated by the Healthcare Commission. However, respondents to the consultation put forward convincing arguments for including NHS primary medical care providers within the regulatory framework. The increasing complexity of general practice and the widening range of services offered in primary care, combined with the increasing diversity of types of provider, all point to the need for a consistent regulatory framework across secondary and primary care. Changes in the way healthcare is delivered mean that many more services that might once have been provided in hospitals are now being provided in the community or through primary care services. Patients need to know that, whatever type of provider is delivering their care, the same general requirements will apply. We will consult on how registration could be introduced for primary care providers. It is probable that the priority would need to be practices that offer more complex interventions: the inclusion of these services in the registration system would provide assurance to patients and ensure that the system is equally fair to smaller providers as to larger ones.

3.11 One of the principles of good regulation is that it must be proportionate. To avoid duplication, it should take into account professional regulation and the role of commissioners in driving service improvement. It should not create an unnecessary burden on service providers or on the Care Quality Commission itself. The Government will therefore consider how best to regulate NHS primary care, following further discussion with stakeholders and this will form part of the consultation on the scope of registration.

How will the registration system work?

3.12 In line with the Government's principles for good regulation, we would expect the Care Quality Commission to take a proportionate and risk-based approach to the registration of providers, and we intend to build flexibility into the legislation to allow it to do this.

3.13 For example, although the individual sites of a provider will need to be registered, as happens now, we intend that all the activities of an organisation should be combined into one registration, i.e. a single registration for multi-site providers (such as independent companies or NHS trusts), mobile providers and those that provide care in people's homes, and for single-service/site providers (such as a small care home).

3.14 For some services, the Care Quality Commission will be able additionally to require the registration of individual managers, and may impose other conditions specific to certain services or types of provider. The provider will be responsible for complying with the terms of its registration; if it does not, the Care Quality Commission will be able to take action against particular sites or services that are failing, and will do this without compromising the ability of the provider to deliver its other services.

3.15 The Care Quality Commission will also be able to take account of evidence from third parties when it makes registration decisions. Examples might include the use of quality standards, accreditation schemes, or evidence from other scrutiny bodies about compliance or non-compliance with other statutory obligations.

3.16 Registration of NHS providers will be distinct from the authorisation process to obtain foundation trust status. Registration will offer assurance of safety and service quality, and will be a requirement for providers from all sectors that wish to offer health or adult social care services – including NHS trusts. NHS foundation trust authorisation is a specific process run by Monitor to confirm that NHS trusts meet the additional standards of governance, financial management and overall performance that are required for them to become NHS foundation trusts. As such, registration is a prerequisite for NHS foundation trust authorisation, rather than a substitute or subsequent requirement.

3.17 Almost all existing providers of NHS, independent healthcare or adult social care that are not currently under regulatory enforcement action will transfer directly across and continue to operate as now. We will provide more information on how this process will work following the consultation on registration requirements.

3.18 If there are any providers that are in the process of having their registration cancelled at the time the new system is introduced, then the process of cancellation will continue under the Care Standards Act 2000. This is until the enforcement process is complete and a decision has been made to confirm cancellation or to allow the provider to continue to operate. If a decision is made to allow the provider to continue operating, then they will at that point be directly transferred into the new system. Those providers under other forms of enforcement action will transfer to the new framework, subject to sanctions and rights of appeal against the decisions of the Care Quality Commission comparable to those under the current framework.

3.19 In order to ensure that the transition to the new registration system is balanced and effective, it will be phased in over the period April 2009 to April 2010 – with healthcare-associated infections as the first priority. This will allow sufficient time for the Care Quality Commission to develop and consult on its methodology. We therefore expect the current registration regime - for the part of sector currently registered with the Healthcare Commission or with the Commission for Social Care Inspection under the Care Standards Act 2000 - to continue until March 2010. More detail on the transition arrangements will be set out in our consultation on registration requirements.

3.20 The current legislative arrangements have detailed and fixed definitions of the services covered by registration set out in primary legislation. This means there is little flexibility to change the definition when new types of service develop.

3.21 Therefore, subject to parliamentary approval of the planned legislation, we propose to introduce more flexibility to enable the Secretary of State for Health to alter the scope of regulation in the future. Any changes would follow wide consultation with providers and the people using these services, and decisions would be based on the level of risk to users and on whether other regulatory mechanisms already exist to address those risks. Any proposal to extend the scope of regulation to other types of provider would be based on the Government's principles of good regulation.

How will compliance be monitored and enforced?

3.22 The new registration system will be built around a coherent system of registration requirements and compliance criteria.

3.23 We will consult publicly on a revised set of **registration requirements** for providers of health and adult social care. These will focus on safety and quality, and will be used by the Care Quality Commission instead of

the *Standards for Better Health*[7] that currently apply to the NHS, and the Care Standards Act 2000 regulations and *National Minimum Standards*[8] that currently apply to the independent and voluntary health sector and regulated adult social care providers. The new requirements will be simpler, more outcome based and common to health and adult social care. The requirements will be subject to parliamentary scrutiny and will be set out in secondary legislation.

3.24 The Care Quality Commission will develop and consult on **compliance criteria** for assessment of compliance with registration requirements, which will be linked to the secondary legislation. It will take an intelligent, risk-based approach to this by wherever possible using existing data sources, self-assessment methods and feedback from service users so that on-site inspections are only used where visits are necessary to ensure compliance.

3.25 Healthcare-associated infections will be a particular priority for the Care Quality Commission. Registered providers will be expected to comply with registration requirements focused on healthcare-associated infections, and, in a Code of Practice, the Secretary of State for Health will prescribe the criteria that will be used to monitor compliance.

3.26 In support of this, as announced in the NHS Next Stage Review Interim Report,[9] annual infection control inspections will be introduced and matrons will be empowered to report any concerns they have on hygeine direct to the new regulator.

3.27 To assure people that providers from all sectors meet the registration requirements, it is essential that only one regulatory body, the Care Quality Commission, should be responsible for monitoring compliance, and that its enforcement powers, if needed, can be applied equally to all. The Care Quality Commission will complement rather than duplicate the roles of other bodies. Its approach to working with Monitor to ensure that NHS foundation trusts comply with registration requirements is set out in paragraphs 3.32 to 3.36.

3.28 The Care Quality Commission will respond to any evidence of a breach of registration requirements in a health or adult social care provider by investigating further. Where necessary, it will take enforcement action proportionate to the nature of the specific breach or breaches and the degree of risk to patients and users of services. We intend that the Care Quality Commission should carefully consider suspected breaches on a case-by-case basis and judge whether enforcement action is required. It

[7] *Standards for Better Health*, Department of Health, July 2004 (updated April 2006)
[8] National minimum standards and regulations, published under the Care Standards Act 2000
[9] *Our NHS, Our Future,* Department of Health, October 2007

will publish its policy on making these judgements. Initially, it might decide that it is only necessary to increase the frequency of monitoring and inspection visits. Nevertheless, if the situation is of sufficient concern to warrant formal action, the Care Quality Commission will be able to apply whichever of the following sanctions or enforcement powers it judges most appropriate and to make this public. It can also escalate to more serious enforcement action if the provider does not comply after sanctions have been imposed:

Sanctions

- a statutory warning notice, requiring improvement within a specified time (new power);
- imposing a fine in lieu of prosecution (new power);
- formal caution.

Enforcement powers

- conditions that place continuing restrictions on registration (e.g. preventing the provider from running a particular service or preventing further admissions to a service);
- a temporary suspension of registration for a specific period (new power);
- prosecution of organisations and/or individuals (resulting in fines or, in extreme cases, imprisonment);[10]
- cancellation of registration.

3.29 This will also give the Care Quality Commission the powers it needs to effectively tackle healthcare-associated infections. It will be able to inspect, investigate and fine providers that do not comply with the registration requirements. It will also be able to impose conditions that close a ward or prevent further admissions.

3.30 In the consultation document, we stated that if the Care Quality Commission was to take action that resulted in a service or site closing (either temporarily or permanently), then commissioners (PCT or local authority as appropriate) would retain the responsibility for ensuring continuity of service. While the Care Quality Commission will not itself be responsible for ensuring continuity of care for patients and users of services, it will be expected to liaise with PCTs and local authorities, and consider the impact of its actions on patients and users of services.

[10] The Care Quality Commission can only prosecute for the offences set out in this Bill.

3.31 Given the range of enforcement action that the Care Quality Commission can take, and the potential impact on providers, there will be an appeals procedure. The Care Standards Tribunal will extend its jurisdiction to cover appeals from registered NHS bodies (as it does now for social care and independent healthcare providers).

How will the Care Quality Commission work with partners to ensure safety and quality?

3.32 When imposing sanctions or taking enforcement action, the Care Quality Commission will work with different partners, depending on the provider's status – e.g. with Monitor for NHS foundation trusts, with SHAs for NHS trusts and PCT-provided services, and with local authorities for care services. The Care Quality Commission will notify the relevant partner organisation(s) when taking action, to ensure that partner bodies are aware of its concerns.

3.33 NHS foundation trusts will continue to be accountable to Monitor, the independent regulator for NHS foundation trusts. Monitor's role in ensuring that NHS foundation trusts operate in an efficient, effective and economic manner is described in section 3.73 (stewardship of public assets) and is legislated for in the NHS Act 2006. This important role continues and will not be duplicated by the statutory powers given to the Care Quality Commission. Monitor and the Healthcare Commission have established effective arrangements to ensure that NHS foundation trusts meet the standards currently required of NHS organisations. The Care Quality Commission and Monitor will build on these arrangements to ensure an efficient and effective regulatory regime for NHS foundation trusts that recognises Monitor's existing statutory role and intervention powers and the new statutory functions of the Care Quality Commission to ensure that providers from all sectors, including NHS foundation trusts, meet safety and quality requirements.

3.34 At the point of transfer into registration, Monitor will revise the terms of authorisation for NHS foundation trusts to require continued compliance with registration requirements. This will ensure that NHS foundation trusts face a single set of safety and quality requirements, and will enable Monitor to intervene when the Care Quality Commission alerts it to significant breaches of these requirements.

3.35 For example, when the Care Quality Commission responds to a safety or quality failing with a warning notice, the NHS foundation trust will be responsible for delivering the necessary improvements. Monitor will work with the NHS foundation trust to ensure compliance, because it will be concerned about the impact of enforcement action on the NHS foundation trust's ability to operate. Monitor's powers of intervention will be available if required. These include requiring the NHS foundation trust

to take specified actions to improve the service, removing members of the Board of Directors or Board of Governors or even requiring the NHS foundation trust to stop providing a specified service until the necessary steps are taken to comply with the registration requirements.

3.36 The Care Quality Commission will specify a time period within which the issue must be addressed. If the provider fails to correct the problem, with Monitor's input, within that time then, taking account of advice from Monitor, the Care Quality Commission will undertake further enforcement action to protect patients using the services. It will ultimately be able to cancel the registration of the failing service or services. Any such action might trigger wider sustainability issues in the NHS foundation trust that would, in themselves, require further significant intervention by Monitor.

How will further work on this function be taken forward?

3.37 To allow flexibility to revise the registration requirements and the scope of registration as services evolve and improve over time, we propose powers to set them out in regulations. We plan to consult and then lay regulations before Parliament in 2008.

3.38 The Care Quality Commission will base the development of the registration system around the registration requirements. The methodology and associated criteria it develops for monitoring and enforcing compliance with registration requirements will be informed by the consultation, but we would expect that the Care Quality Commission itself would subsequently consult on how compliance with the registration system would work.

3.39 We will also consult separately on related regulations, such as the Care Quality Commission's powers to charge fees.

Promoting choice and competition: managing the system fairly

What is the benefit to patients and users of services?

3.40 Ensuring real choice for people about how, where and when they receive treatment or services is part of a modern health and social care system. Choosing a provider has been a key feature of social services provision for some time. This choice benefits patients and users of services in a number of ways:

- more choice, from a diverse range of providers, means that people are more likely to find services that are convenient for them and that meet their particular needs;

- the fact that people can choose creates strong incentives for service providers to be flexible and innovative, and to respond to patients' and users' expectations;
- whenever commissioners or users of services are negotiating a price for services, choice acts as an incentive for quality and value for money;
- where there is a fixed price, such as for services covered by the NHS tariff, offering choice for NHS services is intended to encourage providers to attract patients by improving quality.

How will this be achieved in the NHS?

3.41 In the consultation document we made clear that, for the NHS, where it is in the interests of meeting patients' healthcare needs, it is the responsibility of commissioners to encourage a diverse range of providers, including NHS bodies and independent sector providers, such as private providers, third sector providers and social enterprises. Commissioners will also be responsible for ensuring that different types of provider are not treated unfairly, either when they are invited to bid for procurements or through choice arrangements. If a provider believes it has evidence that a PCT has not exercised this responsibility appropriately, it will be able to complain in the first instance to the PCT. If it is still dissatisfied, it may ask the relevant SHA to consider the complaint. The SHA will be expected to take action if the provider's claim is substantiated. We will work with PCTs and SHAs to ensure their decisions are fair, transparent and well informed.

3.42 In the consultation document, we went on to propose that the Care Quality Commission would have a role as final arbiter in managing appeals from providers who consider that an SHA has not properly discharged its oversight of this function. In the consultation responses, there was very broad support for the consultation document's proposal that responsibility should lie with PCTs and SHAs. However, there was less support for the Care Quality Commission having a national role in managing final appeals. There was concern that this would be an additional tier of unnecessary bureaucracy; that it would distract the Care Quality Commission from its core function as a quality and safety regulator; that it would undermine SHAs in their local system management role; and that it would encourage the escalation of relatively minor local disputes to a national body.

3.43 Taking these views into account, and recognising that there is now a much clearer appreciation of the developing role of the new SHAs, the Government has decided not to assign this additional role to the Care Quality Commission. In taking this decision, the Government expects SHAs and PCTs to work within national guidelines and act transparently,

proportionately, objectively and without discrimination when dealing with the full range of providers. We would expect PCT and SHA boards to have appropriate governance arrangements that avoid potential conflicts of interest arising from the SHA responsibility for NHS trusts or PCT provision and commissioning functions.

3.44 Where competition issues cannot be resolved locally, providers may legitimately expect there to be a further independent process for reviewing the contentious issues. Therefore, the Government has decided to set up a panel of experts to provide independent advice to SHAs, which they would be expected to follow, working closely with their PCTs. The panel will only consider issues where action to resolve matters locally has been exhausted. More details on how this panel will be established and how it will operate will be set out in due course.

How will we ensure effective local co-operation?

3.45 The Commissioning Framework[11] stated that, for commissioners to secure the best possible services for their population, they would need to work closely with providers, clinicians and other members of the workforce, primary care practices, patients, the public and local government. Close partnership will help commissioners to assess needs, decide priorities and design service models to improve services.

3.46 The evolving nature of healthcare provision means that an increasing range of providers will offer services in different settings. This will require close co-operation and information sharing within the healthcare system to ensure integration and partnership working at all levels. It will optimise the patient experience and prevent patients 'falling into gaps' between services and organisations – for example, between the community and the hospital; urgent and planned care; or health and social care. As such, when providers compete for patients or for contracts, then, once chosen, they will have to co-operate in the interests of patients.

3.47 The increasing availability of choice and alternatives mean that patients will not choose services from providers that do not provide good-quality services that respond to patient needs. The incentive to provide services that meet patient needs and preferences will ensure that patients are able to benefit from the best:

- clinical pathways between providers;
- packages of care designed for individuals;
- continuity of services.

[11] *Health reform in England: update and commissioning framework*, Department of Health, July 2006

3.48 NHS bodies already have a duty to co-operate.[12] In addition, requirements for co-operation between providers will be written into commissioner contracts mandating aspects of practice or co-operation e.g. to require effective integration across a patient pathway.

How will this be achieved for adult social care?

3.49 Plurality of provision has been around longer in adult social care, with the bulk of provision coming from the non-state sector; therefore neither a new set of system management principles nor an appeal mechanism is necessary. Local authorities will continue to be responsible for ensuring fairness in the way they treat social care providers, most of whom may be covered by competition law and the protection that offers.

How will further work on this function be taken forward?

3.50 To ensure a fair and consistent approach, PCTs and SHAs will need to adhere to a national framework of system management. This framework will be developed in stages, starting with preparations for the 2008/09 Operating Framework and followed by further guidance in 2008.

Commissioner assurance

What is the benefit to patients and users of services?

3.51 Commissioners are responsible to their local population for purchasing good-quality services that deliver the best possible health and adult social care outcomes, reduce inequalities and represent good value for money. People will want to be assured, as patients and users of services, that they have access to the best possible services and, as taxpayers, that their money is being spent effectively on their behalf.

How will this be achieved?

3.52 There are two ways in which people can be assured that commissioners are securing the best possible services on their behalf:

- effective performance management of commissioning activity;
- public accountability through publication of an independent assessment of commissioning.

Performance management of commissioning: the role of SHAs

3.53 In the NHS, PCTs are the bodies responsible for commissioning, and they work with practice-based commissioners and other partners to commission services for their population. SHAs will continue the good work they have started in building up commissioning capacity locally. Their continuing strategic oversight of PCTs in relation to commissioning

[12] National Health Service Act 2006 (c. 41) part 2, chapter 6, clause 72.

will become ever more important as commissioning becomes a main driver of improvement and as they work towards truly world-class commissioning. It will be for SHAs to ensure that mechanisms for improvement are put in place if PCTs are not commissioning effectively.

Publishing information on the performance of commissioners

3.54 One of the benefits of the Care Quality Commission covering both health and adult social care will be its ability to take a broad view of commissioning across both sectors and to assess joint commissioning of integrated health and adult social care services. The Care Quality Commission will publish independent, comparative information, including an assessment of the performance of commissioners for both health and adult social care – PCTs and local authorities. Its independent view will maintain public confidence in the transparency and accountability of commissioners and how effectively they use public money.

3.55 In the NHS, it is important that this should not duplicate, or overlap with, the SHA role. As now, the Care Quality Commission will not have powers to intervene with PCTs as commissioners. Intervention, including action to develop PCT capability where necessary, will be part of the performance management role of SHAs.

3.56 Building on the good work to date of the Healthcare Commission and the Commission for Social Care Inspection, there will need to be a new framework (including methodology and format) for the publication of information about commissioners' performance. The indicators and criteria for assessment of PCTs and local authorities will reflect the overall goals for health and adult social care. The assessment of commissioning performance, including an overall rating, will be published at a frequency set by the Care Quality Commission and agreed with the Secretary of State.

3.57 Local authorities commission adult social care services for most of the users of residential and domiciliary care, but a significant minority of people fund and purchase their own care. There is no intermediate tier akin to the SHA role in the NHS, and no equivalent direct performance management of commissioners. This means that the Care Quality Commission's role in publishing information about the performance of adult social care commissioners will be particularly important.

3.58 The assessment will feed into the new Comprehensive Area Assessment (CAA) described in the Local Government White Paper[13], which will be led and co-ordinated by the Audit Commission working together with the Care Quality Commission and other public service

[11] *Strong and prosperous communities – the Local Government White Paper*, Department for Communities and Local Government, October 2006.

inspectorates. Information published on the performance of commissioners of both health and adult social care will need to be consistent for areas covered by joint commissioning or where the same priorities span both services.

3.59 The Care Quality Commission and the Audit Commission will need to work closely together to avoid any duplication in the information they collect and publish on commissioners. In this context, the framework for health and adult social care and CAA are being designed so that for local authorities their information and assessment requirements are aligned. The Audit Commission will continue to be responsible for the annual audit of commissioners' accounts, and will report on their financial statements and its report will include a scored judgement on the use of resources as part of CAA.

How will further work on this function be taken forward?

3.60 The Healthcare Commission and the Commission for Social Care Inspection will start to adapt their current approaches to assessing PCTs and local authorities and the Care Quality Commission will develop this further when it is established.

Information and performance assessment of providers

What is the benefit to patients and users of services?

3.61 Good information about the quality of services is vital in a system that offers the public a range of choices between service providers. This information will come from a variety of formal and informal sources. These include:

- people's own experiences and those of their friends and relatives;
- voluntary and other organisations that represent the interests of specific patient and user groups;
- the media;
- service providers themselves;
- academic and research institutions;
- government bodies;
- independent regulators.

3.62 People need access to information, as well as confidence in the quality of that information. Fundamental responsibility for providing good, accessible information about the quality of services lies with the providers themselves. But a specialist regulator that can additionally provide authoritative and independent information on the performance of

providers has an important role to play both in supporting choice and in promoting accountability for publicly funded services.

How will this be achieved?

3.63 For public accountability and to support choice, the Care Quality Commission will assess and provide information on the performance of providers of adult social care and healthcare. From the outset, the intention is that this will cover NHS providers, independent sector providers that provide significant levels of NHS-funded care, and all registered social care providers, although there is scope to extend the coverage of the assessment in future. A significant minority of people fund and purchase their own adult social care, and information for choice over and above the registration requirements will be key.

3.64 As well as considering whether the provider is complying with registration requirements, the assessment will look broadly at the quality of care provided and will lead to an overall assessment of provider performance. This process will be distinct from the assessment of commissioning.

How will further work on this function be taken forward?

3.65 Building on the good work of the Healthcare Commission in developing the NHS Annual Health Check, and of the Commission for Social Care Inspection in developing the Quality Ratings for adult social care providers, the Care Quality Commission will develop and consult on a framework for publishing its assessment of providers.

3.66 The Secretary of State will have powers to approve the content of the assessment framework and the frequency of assessment.

Price setting and allocations

What is the benefit to patients and users of services?

3.67 Users of services, patients and taxpayers are looking to the system to achieve fair allocation of funds and value for money.

How will this be achieved?

3.68 We said in the consultation document that, because the NHS is funded by taxation, it is important to have a national tariff system, agreed by the Department of Health, that reflects the Secretary of State's accountability to Parliament for the NHS. Some consultation responses suggested that this function should be more independent of the Department of Health because of the greater plurality of providers. But the balance of opinion accepted that the Secretary of State for Health, while basing any decision on expert advice, should retain ultimate responsibility for the

tariff, and for the fair and equitable allocation of funds to commissioners (advised by and drawing on the work of the Advisory Committee on Resource Allocation).

3.69 We can therefore confirm that, for the time being, we will proceed with the proposals in the consultation document. Payment by Results is, however, a relatively new and developing policy, and has recently been the subject of another, separate consultation on options for its future development.

3.70 Social care prices are negotiated locally and this will continue.

How will further work on this function be taken forward?

3.71 *Options for the future of Payment by Results 2008/09 –2010/11*[14] considers the question of greater transparency and accountability in tariff setting. This consultation exercise closed on 22 June 2007, and a response will be published in due course.

Stewardship of public assets

What is the benefit to patients and users of services?

3.72 In addition to ensuring that providers offer a safe service, the Government also has a specific responsibility to make sure that the taxpayer gets good value for money from public assets. This is most significant in the NHS, where NHS trusts and NHS foundation trusts operate from publicly owned assets worth around £37 billion.

How will this be achieved?

3.73 In the consultation document, we set out our view that Monitor, in its role as the regulator of NHS foundation trusts, should retain this function for NHS foundation trusts. It has a specific responsibility for ensuring that those trusts operate in an economic, efficient and effective manner and offer good value for money for the taxpayer. Its role will expand as more NHS trusts become NHS foundation trusts.

3.74 NHS trusts and PCTs are accountable to SHAs, giving SHAs an equivalent responsibility for ensuring good value for money from their assets. SHAs carry out this function in relation to existing NHS trusts, and they will continue this as they support those trusts to become NHS foundation trusts.

3.75 Local authorities perform this for adult social care where they are the provider operating with publicly owned assets.

[14] *Options for the future of Payment by Results 2008/09 – 2010/11,* Department of Health, March 2007

3.76 We can therefore confirm no change from the model described in the consultation document.

How will further work on this function be taken forward?

3.77 This does not require any legislative change. Monitor and SHAs are already taking forward this responsibility to ensure that the bodies for which they are responsible deliver the best possible value from publicly owned assets.

Support, intervention and administration of failure

What is the benefit to patients and users of services?

3.78 Patients and users of services need to know that they will still be able to access the services they need, even if a provider gets into some sort of difficulty – financial failure, termination of a contract or cancellation of registration following a serious safety or quality failure.

How will this be achieved?

3.79 There will be a fair and transparent process for supporting organisations in distress with early and effective interventions. Depending on the type of provider, different organisations will be involved – but the approaches should be consistent and fair.

3.80 The triggers for this intervention are likely to vary in different circumstances. For example, providers themselves may identify financial pressures, or commissioners may identify failures in meeting the performance levels required in the contract. In the NHS, SHA performance management may highlight problems, or Monitor may recognise failures to comply with the terms of foundation trust authorisation. Additionally, the Care Quality Commission may identify safety or quality breaches.

3.81 When these triggers arise, a robust response is needed to turn the situation around and enable the services to continue, if they are still needed. If the services are no longer required, the process should facilitate closure without continuity of service being affected. Decisions about the response to distress need to be approached intelligently, on a case-by-case, site-by-site and service-by-service basis, and with co-operation between providers, commissioners and (where applicable) SHAs and Monitor.

3.82 Providers will lead the response and drive forward a recovery plan – supported by SHAs or Monitor, where applicable. Commissioners need to be made aware of the problem at an early stage, so that they can start taking action to identify alternative services if necessary. In the NHS,

SHAs will oversee this process and ensure that patients are kept informed, and that the solutions maintain adequate patient choice, treat all providers fairly and adhere to the framework of system management.

3.83 Most providers will recover. But if they do not, and if a contract is terminated, a provider fails financially or registration is suspended or cancelled, commissioners are responsible for ensuring continuity of services. When letting contracts, commissioners need to consider how they would ensure service continuity in the event of failure.

How will further work on this function be taken forward?

3.84 This failure regime is relatively well established in social care, where local authorities already have a clear responsibility for ensuring continuity of care for users of services when a provider fails.

3.85 For the NHS, this will be taken forward through the model contracts for acute and out-of-hospital services, the 2008/09 Operating Framework and the national framework of system management (see paragraph 3.50).

3.86 In addition, and subject to parliamentary approval, the legislation and regulations will require the Care Quality Commission to communicate its sanctions and enforcement decisions to commissioners (PCTs and local authorities).

Revised regulatory framework

3.87 Figure 3 overleaf illustrates the revised regulatory framework for health and adult social care, and describes who will carry out each function. It focuses on external assurance, but recognises that the key responsibility for ensuring safety and quality resides with provider organisations and their clinical teams. It also recognises that commissioners have a vital role in improving quality and safety and, in the NHS, the PCT's duty to secure improvements in the quality of services will continue.

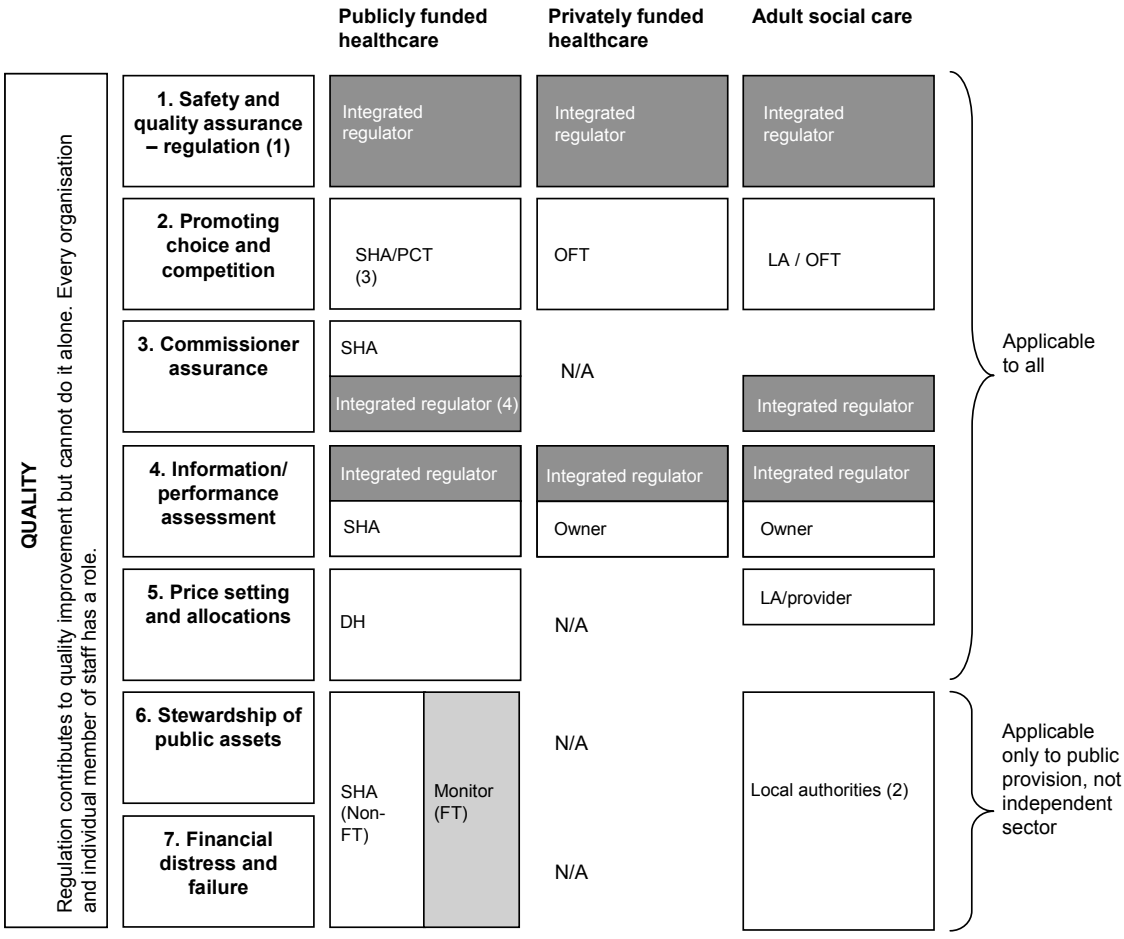
3.88 The functions identified for the integrated health and adult social care regulator (shaded in grey) will be set out in the legislation to create the Care Quality Commission. Further detail on what the new integrated regulator will do, how it will be established and when it will start is outlined in the next chapter.

3.89 There will be a phased transition from the current systems to the new. The first priority will be the safety and quality of care in hospitals and other care providers. The Care Quality Commission's general service reviews, that are not directly concerned with assurance of acceptable levels of safety and quality, will not start until it has fully implemented the

new registration system. The Care Quality Commission will agree this start date for general service reviews with the Secretary of State once it is clear that the new system for checking safety and quality assurance is fully in place.

3.90 There will be further opportunities to participate in the development of the regulatory framework. Over the coming months, we will consult widely on the scope of the registration scheme and the detail of the registration requirements that registered providers will have to meet. We will explore further the place of public health and health promotion in the new regulatory arrangements. And we will further develop the accountability, performance and system management frameworks for the NHS.

Figure 3. Regulatory framework informed by consultation responses



(1) This diagram illustrates external assurance. Primary responsibility for safety and quality will always sit with providers and their clinical and care teams.

(2) Limited function because relevant only to local authority provision. Commissioner failure is picked up in commissioner assurance.

(3) The OFT will continue to have a role for 'undertakings'.

(4) For commissioner assurance, the Audit Commission also has a role in relation to publicly funded health and adult social care.

4. The Care Quality Commission

Summary
The Government is committed to establishing an integrated health and adult social care regulator, bringing together the Commission for Social Care Inspection, the Healthcare Commission and the Mental Health Act Commission. This chapter outlines the roles and responsibilities of the Care Quality Commission. The Care Quality Commission will have an important role within the overall regulatory framework, focusing on safety and quality assurance, performance assessment of providers, commissioner assurance, safeguarding the rights of patients subject to detention under the Mental Health Act and minimising the burden of regulation across the sector as a whole.

The Care Quality Commission – what will it do?

4.1 Historically, the adult social care and healthcare systems have been largely run and managed in different ways. Recently, however, there has been a move to commission services jointly, and increasingly they are delivered in a more integrated manner. The way the new regulator will work must reflect this and realise the opportunity to regulate health and adult social care more consistently and coherently. It will also incorporate the functions of the Mental Health Act Commission to keep the Mental Health Act under review, so that the focus on the particularly vulnerable group of patients covered by this Act can be maintained and strengthened.

4.2 The Care Quality Commission's functions will recognise that it is just one part of a broader, modernised system designed to enhance public confidence in our health and adult social care services, whether they are publicly or privately provided or funded.

4.3 The Care Quality Commission will be a user-focused organisation. Its priority will be to safeguard service users and help improve their experience of health and adult social care services – recognising that it can only do this effectively by involving them. It will be able to build on good work by the Commission for Social Care Inspection, the Healthcare Commission and the Mental Health Act Commission, which all emphasise the importance of involving service users, and their carers, in their work.

4.4 We need to ensure that the new body has the functions and powers to carry out its new role effectively, and to focus its activities within a reduced operating cost budget.

4.5 The proposed functions and roles of the Care Quality Commission are summarised in Table 1 and will all be subject to parliamentary approval.

Table 1. Summary of the functions and roles of the Care Quality Commission

Function	The Care Quality Commission
Safety and quality assurance	> Registering providers of health and adult social care. Flexibility will be created to amend the types of care provider that have to be registered with and regulated by the Care Quality Commission as models of provision continue to evolve. > Monitoring and assessing providers against a set of registration requirements, using information and intelligence, as well as proportionate levels of inspection. It will do this to give people assurance about the safety and quality of care and providers' fitness to provide that care. > Escalating serious service failures, using discretionary sanctions that ultimately lead to enforced closure of a service or of the provider through de-registration, if patients or users of services are seriously at risk. > Conducting further inspections or investigations where there are significant risks to the required levels of safety and quality. > Publishing information and reports using information gathered through carrying out its functions.
Safeguarding patient rights	> Continuing this important role, currently undertaken by the Mental Health Act Commission. It will have the necessary duties and powers to keep under review and safeguard the rights of patients subject to the Mental Health Act. > Fulfilling the role of monitoring the operation of the deprivation of liberty safeguards of the Mental Capacity Act 2005.[15]

[15] Regulations pursuant to Schedule A1 of the Mental Capacity Act 2005 (hospital and care home residents: deprivation of liberty) will make provision for the Care Quality Commission to monitor, and report on, the operation of this schedule.

Commissioner assurance and performance assessment of providers	> Ensuring good-quality information is available to support patient and service user choice. > Publishing an independent assessment of both providers and commissioners for the purpose of public accountability. > Providing an annual report to Parliament on the state of health and adult social care and the operation of the Mental Health Act. > Once the safety and quality assurance systems are fully up and running, the Care Quality Commission will be able to carry out general service reviews, studies and research on issues that arise from carrying out its functions. It will bring forward an annual programme of work for discussion with the Secretary of State; this process will also allow for the need to respond to exceptional circumstances. The aim, ordinarily, will be to ensure that health and social care organisations have plenty of warning about the information to be collected from them. The outcomes and recommendations from such reviews will need to take full account of the potential impact on health and social care organisations.
Minimising the burden of regulation and inspection	> Adhering to the principles of good regulation and carrying out its functions in a way that minimises the burden of regulation and is proportionate, targeted, accountable, consistent and transparent. > Pursuing its remit to co-ordinate and reduce duplication of inspection-related activity across health and adult social care provision. > Consulting other bodies on its work programme. > Taking on new 'gatekeeping' functions which give it powers to prevent duplication/overlap of inspections. This will be in line with the approach being followed by other public sector inspectorates (including Ofsted and the Audit Commission) with the option of extending to other bodies in future.

4.6 In carrying out these functions, the Care Quality Commission will be expected to:

- take account of views and levels of satisfaction among those affected by its activities, particularly service users;
- ensure its actions are proportionate to the risks against which it affords safeguards;
- take account of best practice among other organisations performing similar regulatory functions;
- safeguard and promote the rights and welfare of children and vulnerable adults.

4.7 The Care Quality Commission will be expected to perform all its functions in a way that encourages improvement of health and adult social care services.

4.8 It will consult widely when it develops its methodologies, and will take every opportunity to engage users of services. To strengthen and formalise these processes, it will also be required to appoint advisory committees involving users of services, regulated providers, commissioners and other interested parties. The advisory committees will be concerned to ensure effective protection with minimum cost and impact on providers. They will help the Care Quality Commission to develop a risk-based approach to regulation, with greater focus on care outcomes, using on-site inspections only when they are really needed.

4.9 In carrying out its functions, the Care Quality Commission will work closely with key partners such as health and adult social care commissioners, strategic health authorities, providers, other regulators (e.g. the Audit Commission, Ofsted and Monitor) to enhance its effectiveness and avoid overlap and duplication.

4.10 We do not believe the investigation of complaints from individual patients or users of services sits easily with the functions of a regulatory body. The Care Quality Commission will not therefore take on the Healthcare Commission's current role of dealing with second-stage NHS complaints. The Commission for Social Care Inspection does not hold a corresponding responsibility with regard to social care complaints. The Department of Health has undertaken a public consultation[16] on reform of the health and social care complaints functions. The main proposals are to align the procedures across health and social care, to make those procedures more responsive to the needs of patients and service users,

[16] *Making experiences count: a new approach to responding to complaints – a document for information and comment,* Department of Health, June 2007

and to ensure that information from complaints leads to improvements in service delivery.

The Care Quality Commission – when will it start?

4.11 Working with the current commissions, we remain committed to establishing the new regulator in 2008, subject to the passage of legislation. We plan that the Care Quality Commission will be established in October 2008 and will take on responsibility for the regulation of health and adult social care in April 2009 – working towards full implementation of the new registration system from April 2010 (see paragraph 3.19). This means the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission will continue to fulfil their current statutory functions until the end of March 2009.

4.12 A Bill will be introduced in the next session of Parliament, accompanied by a partial impact assessment (including an equality impact assessment) analysing the costs and benefits of these proposals.

4.13 The appointment of a chair, board members and a chief executive, in shadow or final form, will be made as part of the planning and organisational preparations for the Care Quality Commission's establishment in October 2008, and sufficiently early to maximise its ability to make an effective operational start in April 2009.

4.14 The Care Quality Commission's new board will then have time to become established and prepare to become operational from April 2009.

Conclusion

4.15 The proposals outlined here are designed to build on the best of health and adult social care regulation to create a more flexible, streamlined system, which supports and reinforces the roles of commissioners, of SHAs and of providers themselves for ensuring care is safe and of good quality.

Annex A – Consultation questions

Consultation question[17]	Paragraphs
1. To date, many aspects of health reform have focused on hospital services. What are the implications of the proposals set out in this document for the regulation of other types of service such as: > primary medical care; > community services; > public health and health promotion?	Paragraphs 3.2–3.39 on registration. Also, paragraphs 3.51–3.60 on commissioner assurance are very relevant to public health.
2. What needs to be covered in the rules governing choice and competition in the NHS to clarify expectations and prevent anti-competitive behaviours by commissioners or providers?	Paragraphs 3.40–3.50 on choice and competition.
3. How can the common system for registering all providers be implemented in a way that minimises the burden on providers and the new regulator and is flexible enough to allow for continued innovation in the way services are provided?	Paragraphs 3.2–3.39 on registration.
4. How could Parts I and II of the Care Standards Act 2000, which deal with registration and regulation for independent sector care providers, be improved as part of a new system of regulation?	Paragraphs 3.2–3.39 on registration.
5. How should these roles and responsibilities be carried out to realise the vision of effective partnerships between local public services set out in the Local Government White Paper, *Strong and prosperous communities*?	Paragraphs 3.51–3.60 on commissioner assurance.
6. How could Parts I and II of the Care Standards Act 2000, which deal with registration and regulation for adult social care providers, be improved as part of a new system of regulation?	Paragraphs 3.2–3.39 on registration.

[17] Questions taken from the consultation document, *The future regulation of health and adult social care in England*, Department of Health, November 2006.

Annex B – Glossary

The following table provides working definitions to assist readers in their understanding of the document. They are not legal definitions.

Term	Definition
Care Quality Commission	The Care Quality Commission will be the new, integrated regulator of health and adult social care, replacing the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission.
Compliance criteria	The Care Quality Commission will monitor compliance with registration requirements against a set of measurable criteria. The criteria will be developed through consultation and may include indicators of performance and other evidence and information sources, e.g. accreditation schemes that are relevant to registration requirements.
Compliance monitoring	Compliance monitoring is the methodology that the Care Quality Commission will use to determine whether providers are meeting the requirements of their registration.
Failure regime	Is a rules-based regime which identifies the most appropriate response to failure; ensures continuity of provision of essential services; and enables the management of insolvency of provider organisations.
Fair playing field	Will ensure that different providers (independent sector, third sector and public providers of health or adult social care) are treated in a transparent and non-discriminatory way.
Foundation trust authorisation: the role of Monitor	Monitor negotiates terms of authorisation with each applicant trust that set out the conditions under which an NHS foundation trust is required to operate, covering: > a description of the goods and services related to the provision of healthcare that the NHS foundation trust is authorised to provide; > limits on the amount of income that the NHS foundation trust is allowed to earn from private charges; > limits on the amount of money that the NHS foundation trust is allowed to borrow; > financial and statistical information the NHS foundation trust is required to provide.

Gatekeeping function	The Care Quality Commission will have powers to co-ordinate and reduce duplication of inspection-related activity across health and adult social care.
Governance	Governance describes the mechanisms an organisation uses to ensure that established processes and policies are followed. It is the primary means of maintaining oversight and accountability.
Independent sector	Non-publicly owned providers of services. Includes private and third sector (including voluntary organisations and social enterprises).
Inspection	One of a range of tools used by regulators for the purpose of determining if a body is complying with regulations. A regulatory authority administers an official review of various criteria (such as documents, facilities, records, interviews with involved individuals) that are deemed by the authority to be related to the inspection. It may or may not involve an actual visit to the organisation in question. A report and evaluation follow.
Performance assessment	A process that uses a range of measures and indicators to judge how well organisations are performing.
Performance management	A continuous process of setting outcomes, targets and performance standards for organisations to meet and managing the process of delivery. Organisations are held to account for delivering defined goals and, through ongoing collection of information, performance is monitored and managed.
Registration	The process by which providers are assessed as able to meet the safety and quality requirements in order to deliver health and adult social care services.
Registration requirements	In order to become and remain registered to provide services, providers will need to demonstrate that they meet acceptable levels of safety and quality. These requirements will be set in secondary legislation.
Regulation	The control of a particular market or industry through a system of rule making and adjudication, often managed by an independent organisation within a framework set by government, interpreted into clear rules by the regulator. Its purpose is to assure the public that providers of services are fit for purpose.
Risk-based approach	Method for applying regulation proportionately to the risk posed by the activities of an organisation. This directs regulatory activity to the most high-risk services, where it is most needed.

Scope of registration	Primary legislation will contain a definition of the wider scope of health and social care, such that all providers can be covered. The primary legislation will be supported by secondary legislation, which will specify how the activities that providers perform will be subject to registration.
System management	This is about ensuring that local systems operate effectively and fairly and deliver improved performance.
Stewardship	Stewardship is the responsibility for taking good care of resources – whether they are physical assets, staff or an organisation's reputation.
Third sector	The third sector describes a range of institutions that occupy the space between the state and the private sector, such as social enterprises, charities and voluntary organisations.
Transition	There will be a period of change from the current system of regulation to the new regulatory system under the Care Quality Commission. It is envisaged that this will be a period of a year or so, during which time the functions of the Care Quality Commission will replace those of the existing commissions.

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