A consultation on the framework for the registration of health and adult social care providers

The future regulation of health and adult social care in England

Health and social care working together in partnership

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Contents

Foreword

From: Ben Bradshaw

A consultation on the framework for the registration of health and adult social care providers

The public rightly expects that the health and adult social care services they pay for through taxes will be safe and of the highest quality. We also know that people using those services want them to be more personalised in order to meet their individual circumstances and that the "one size fits all" approach is no longer appropriate for the 21st century.

The widespread public engagement that is informing the NHS Next Stage Review has shown that people want services to be seamless and co-ordinated. This is just as true for adult social care as it is for health. Above all, they want care that is:

- fair – treating people with equity and dignity at all times;
- personalised – responding to individual needs and preferences;
- effective – improving people's health, wellbeing and quality of life; and,
- safe – making sure people are not put at risk of harm.

All parts of the system have an important role to play in ensuring that people receive the quality of care they need, expect and deserve. As part of that overall system the Government will set, through legislation, the essential requirements of safety and quality that health and adult social care providers are expected to meet to be registered and therefore allowed to deliver services.

Government will also determine which health and adult social care services will be included within the new system of registration. Primary legislation will set out the sanctions and enforcement powers available to the new regulator when providers do not meet the essential safety and quality requirements of registration. Other parts of the system will build upon the essential levels of safety and quality required through registration to deliver even higher quality services.

So, the registration requirements are not the whole story. We know that frontline clinicians and care staff all aspire to provide world-class quality of

care. The NHS Next Stage Review which Lord Darzi is leading is intended to challenge clinicians to engage with the evidence of best practice and be clearer about what they mean by world-class quality of care for their patients. We know that staff providing adult social care will be equally keen to ensure the best possible care for people using their services.

Subject to Parliamentary approval, the Health and Social Care Bill will establish the Care Quality Commission. From April 2009, the new Commission will take over the functions of the Healthcare Commission, the Commission for Social Care Inspection (CSCI) and the Mental Health Act Commission (MHAC).

The Care Quality Commission will be an organisation responsible for regulating services across the health and social care sectors, which spend over £100bn of public money and involve about 2.9m people employed in delivery of services in over 25,000 establishments.

Integration of care pathways – across different health care providers and between health and social care – and variety in types of service provision are both increasing. Greater joined-up working will provide better outcomes for patients and service users.

This document launches a twelve-week consultation on the proposals for the new system of registration for health and adult social care. Please take this opportunity to give us your views – we welcome contributions from all of those affected by the new system of registration including from individual staff and people using services.

Ben Bradshaw
Minister of State for Health Services

Executive summary

People who use health and adult social care services want to know that those services are safe and that the care they receive will be of good quality, regardless of which organisation is providing that care. The same person may well receive care from both health and social care providers in a range of settings, including primary, community, residential or hospital. This care might be provided by the NHS, local authorities, independent sector organisations,[1] as well as personal carers such as friends, neighbours or relatives. In such a potentially complex care environment, it is important that people are protected from things that could go wrong and that could be a threat to their health, wellbeing and safety.

Quality of care is the responsibility of staff delivering care, and the boards and management of the organisations in which they work. Local authorities, primary care trusts (PCTs) and others who commission services on behalf of local people are also responsible for ensuring they insist on the highest possible quality, holding service providers to account through their contractual arrangements if they fail to meet the required levels of quality. Independent regulators are responsible for ensuring the essential requirements of safety and quality are met by all providers. The new regulator for health and adult social care will be no different. It will develop and consult on the criteria it will use to determine whether providers are meeting those essential requirements. Where they are not, it will decide on the most appropriate action, from a wide range of sanctions and enforcement powers, to ensure that services do meet the required standards.

The independent regulation of health and social care is changing

The current Health and Social Care Bill will, subject to Parliamentary approval, pave the way for the establishment of the proposed new integrated health and adult social care regulator, the Care Quality Commission. From April 2009, it will take over the functions of the Healthcare Commission, the Commission for Social Care Inspection (CSCI) and the Mental Health Act Commission (MHAC).

We have already consulted widely on the overall regulatory framework. The November 2006 consultation document, *The future regulation of health*

1 References to the 'independent sector' include private, third sector and social enterprise providers.

and adult social care in England,[2] set out proposals for aligning the regulation of health and adult social care and making it consistent for providers from all sectors. It described seven regulatory functions and proposed roles for providers, commissioners, strategic health authorities (SHAs) and national regulators within the overall framework. Following extensive consultation, the Government's formal response was published in October 2007.[3] There was broad support for the regulatory framework, which confirmed the Government's intention to legislate for a new national regulator for health and adult social care. Since the respondents sought further information about the new system, this consultation provides a further opportunity to contribute views and ideas on the safety and quality assurance function within the overall regulatory framework.

The functions and powers of the three current commissions will be supplemented by tougher sanctions and enforcement powers that will enable the new Commission to take direct and independent action against service providers which fail to provide care that meets essential requirements on safety and quality. The new Commission will provide a consistent approach to regulation across health and adult social care, reflecting the fact that services are increasingly integrated.

The new Commission will tailor its approach to different care sectors. Legislation will give it the flexibility to adapt its approach in recognition of the fact that there are significant differences in the nature of services, for example hospitals are very different from residential care homes.

Requirements for the registration of providers

Whatever the care setting, the Care Quality Commission will insist that services are safe, people are not put at risk of harm, and that essential levels of service quality are maintained. These requirements (called 'registration requirements') will be set by the Government in secondary legislation and will be monitored and enforced by the Care Quality Commission. They will replace the current core Standards for Better Health (SfBH), which apply to the NHS, and the National Minimum Standards and Regulations, which apply to social care and independent sector health providers.

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2 Policy and Strategy Directorate. *The future regulation of health and adult social care in England*. Department of Health, 2006.
Available at: www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286.

3 Policy and Strategy Directorate. *The future regulation of health and adult social care in England: response to consultation*. Department of Health, 2007.
Available at: www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_078227.

All health and adult social care providers that come within the future scope of registration (see Chapter 3) will be required to register with the Care Quality Commission. In order to be granted registration, care providers will need to demonstrate that they can meet, or are already meeting, the registration requirements. To maintain their registration they will need to demonstrate an ongoing ability to meet the requirements.

A registration system for social care and independent health providers already exists under the Care Standards Act 2000, but there is no such system for the NHS. The new registration system will incorporate providers from all sectors into a single system. In developing the new registration system and its requirements both the Government and the Care Quality Commission will build on the experience of the current commissions and service providers in operating under the existing system and against the current standards.

The new system will evolve from the old and will be introduced from April 2010, with the exception of the new requirements in relation to healthcare-associated infection (HCAI), which will be implemented during 2009/10 for the NHS. This will allow the new Commission time to develop, consult on and test its new guidance on setting criteria and methodology for monitoring compliance with registration requirements. During 2009/10, it will therefore continue to operate the current systems it inherits from the Healthcare Commission and CSCI.

This document begins the process of public consultation on the registration requirements and on the scope of registration. Registration requirements (see Chapter 2) will cover those activities and functions of service provision that, if not well managed, pose most risk of harm to people. Once the registration requirements have been consulted upon and agreed, the Government will turn them into regulations in secondary legislation. Subsequently the Care Quality Commission will develop and consult on the guidance it will use to monitor compliance with registration requirements.

The scope of registration

Providers that offer services and care that inherently present the greatest potential risk of harm to people will be included in the registration system (see Chapter 3). In some of these situations, it will also be necessary for the provider to register a named ‘manager’, in addition to being registered for the activities or services provided that are within scope.

Subject to the outcome of the consultation on the proposed scope of services, as set out in Annex B, we envisage that most independent health and social care providers currently registered with either the Healthcare Commission or CSCI will have their registration transferred to the Care

Quality Commission. In addition, we envisage that most NHS trust, foundation trust and PCT community services will need to become registered, and there will be an initial transfer for them into the new registration system.

Primary care

Given the increasing range of services offered in primary care, including minor operations and other services traditionally provided in hospitals, it is important that patients have the same degree of regulatory protection – regardless of the care setting – whenever these services pose a potentially significant risk. Although GPs and other healthcare professionals are individually registered by their professional governing bodies, this may not be enough to protect people in the future, as services in primary care become ever more complex. In Chapter 4, we invite views on how primary care can be brought within the scope of regulation.

Public information and accountability

The Care Quality Commission will be a powerful and authoritative independent voice on the quality of health and adult social care services. The information it publishes through reviews, reports and investigations will reassure the public that services are safe and let them know where there are problems. It will inform the choices they make about how, when and where they wish to be treated and receive their care. The publication of this information should help to encourage the improvement of services that are already satisfactory or good. The Commission will use its sanctions and enforcement powers where services are unacceptably poor.

This consultation therefore has an important part to play in further promoting the safety and quality of health and adult social care services: we very much hope you engage with it and we look forward to hearing your views. Chapter 5 sets out details of how to reply and the closing date for the consultation.

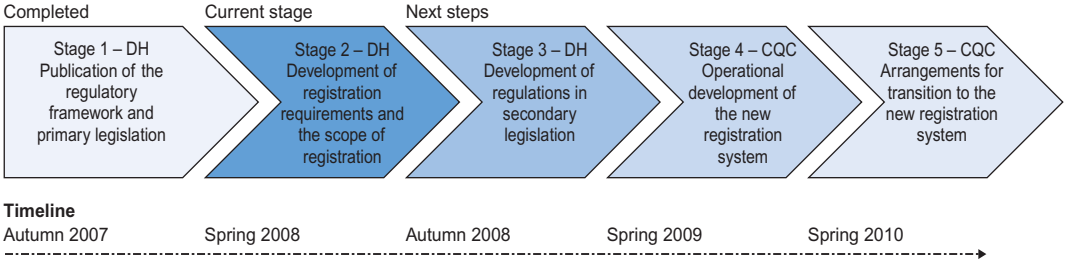
1. Introduction and context

Chapter summary

This chapter sets out why we are seeking to introduce a new approach to the regulatory systems for health and adult social care. To respond to the provision of further integrated health and adult social care we are proposing a single, flexible registration system to replace the current varied systems. From 2009, there will be one health and adult social care regulator, the Care Quality Commission, which will be responsible for this new registration system.

This chapter also summarises the key functions of the Care Quality Commission, including the use of registration to ensure essential levels of safety and quality, and explains how it will work alongside other parts of the system to promote the safety and quality of services. The chapter concludes by setting out the next steps in the process.

Where we are and next steps



Stage 1:

> Consultation by **DH** on the model for the new regulatory framework.
> Published consultation response describing the model set out in the Health and Social Care Bill.

Stage 2:

> **DH** will consult on what is included in the new registration requirements and the scope of registration.
> The response to this consultation will inform the development of regulations, which will be subject to a separate consultation.

Stage 3:

> **DH** will consult on the regulations to be made under the new Act, including registration requirements, scope and more information about the arrangements for transition to the new system.
> New regulations will be set out in secondary legislation.

Stage 4:

> The **Care Quality Commission** will consult on details of the guidance for operating the new registration system, including methodology and criteria for assessing compliance.

Stage 5:

> The **Care Quality Commission** will implement the process for transferring existing providers to the new registration system.

Why are we making changes?

What happens at the moment?

1.1 The existing regulatory framework for health and adult social care has become fragmented over time.[4] In healthcare, there are different regulatory procedures and standards for NHS and independent sector providers, with a variety of sanctions and different enforcement procedures. Adult social care does have a unified regulatory framework across public and independent sector providers, but it lacks the flexibility to address changes and developments as health and social care services become more innovative and integrated.

Why is there a need for change?

1.2 The current legislation is not flexible enough to cope with the increasing pace of change in the delivery of services. This has led to inconsistencies in service regulation, giving rise to a situation in which the same type of care may be registered in some settings, but not in others. For example, wholly private GP practices have to be registered with the Healthcare Commission, but those offering any NHS

4 Providers of independent sector healthcare and adult social care providers from all sectors are required to register with the Healthcare Commission or the Commission for Social Care Inspection respectively (under the Care Standards Act 2000). NHS providers are assessed by the Healthcare Commission's Annual Health Check under a different legislative framework (Health and Social Care (Community Health and Standards) Act 2003).

treatment do not. The lack of flexibility is also problematic because some new forms of care do not fit neatly into the existing legislative models, which specify the type of provider rather than the type of service or care offered.

1.3 Inconsistency is also an issue because the current commissions do not have the same range of sanctions and enforcement powers to address problems in the NHS that they can use with independent health and social care providers. Social care or independent sector health providers required to register with the Commission for Social Care Inspection (CSCI) or the Healthcare Commission can be prosecuted by the relevant commission if they fail to meet the conditions of their registration, whereas the Healthcare Commission has no equivalent direct powers in relation to NHS providers. If NHS providers fail to meet satisfactory safety or quality standards, the Healthcare Commission can only recommend, to the Secretary of State for Health or to Monitor (if it is an NHS foundation trust), that special measures are taken. In addition, in the case of a breach of the code of practice on healthcare associated infection (HCAI), the Healthcare Commission can issue an improvement notice.

What changes are we proposing?

1.4 We intend to develop a coherent system of registration across health and adult social care. This will be based on one set of generic 'registration requirements', which all providers will have to meet for any service they offer that comes within the scope of registration. Providers will need to demonstrate that they can meet the essential levels of safety and quality required for registration and will need to continue to meet them to maintain their registration.

1.5 This new system of registration will replace the one currently operated under the Care Standards Act 2000. In addition, NHS providers will for the first time be within a legally binding system of registration, where the registration requirements will replace the core standards within the current Standards for Better Health (SfBH) assessed by the Healthcare Commission. The Care Quality Commission will develop guidance on a new methodology and compliance criteria, to ensure that providers continue to meet the requirements for essential levels of safety and quality. It will also continue to undertake wider performance assessments (known as 'periodic reviews') of the general quality of services that providers offer, although it will not have any enforcement powers in this respect.

How do we propose to approach this?

1.6 All providers of health and adult social care activities that come within the scope of registration will need to register with the Care Quality Commission to be allowed to deliver services. The new Commission will monitor providers against their terms of registration and take appropriate enforcement action against non-compliance with essential levels of safety and quality. When deciding whether to take enforcement action, the Commission will be able to take account of the provider's compliance with other relevant legislation (for example on health and safety, fire regulations or equality). The powers contained in the Health and Social Care Bill will allow the Commission to take action against providers where, in its opinion, the provider has:

> failed to comply with the registration requirements; or

> failed to comply with the requirements of other legislation that the Commission believes is relevant.

1.7 The main objectives of the registration system for health and adult social care are to:

> assure people using health and adult social care that, no matter which service they choose, their providers are operating to the same requirements of essential safety and quality;

> enable independent and, where necessary, strong enforcement action to be taken against providers of unacceptable services, including suspending or closing services;

> ensure a proportionate approach to monitoring compliance with registration requirements that does not place an unnecessary burden on providers, thus making it difficult for them to innovate, develop and offer improved services; and

> establish a flexible system that can adapt to new and innovative service models.

1.8 Our aim is to ensure that the registration system is fair to all providers, no matter whether they are classed as health or adult social care, or are from the NHS, local authority or independent sectors.

How have we arrived at this approach?

1.9 People who use health and adult social care services want to know that those services are safe and that the care they receive will be of

good quality, regardless of which organisation is providing that care. However, people do not just want good outcomes from their care, they also want a good experience going through the care system. They want seamless, co-ordinated and convenient services that are integrated across care pathways.

1.10 From what we have heard during the widespread public engagement that is informing the NHS Next Stage Review, people want their care to be fair, personalised, effective and safe. We know that this is equally true for people using social services as it is for NHS patients.

1.11 As services further integrate, adapt and develop to meet the needs of a twenty-first-century population, so must the regulatory systems that underpin them. Regulation must continue to offer people the assurance that the services they use are safe and do not put them at risk of harm. This means having strong professional regulatory systems in place for clinicians and professional care workers, so that people know that the staff caring for them are appropriately trained, qualified and supervised.

1.12 The previous consultation, on the proposed regulatory framework for health and adult social care,[5] enabled us to test our planned direction with the people and organisations affected by the proposals. There was broad support for the proposed regulatory framework and the assignment of roles and responsibilities within that framework.

1.13 The consultation response[6] reaffirmed our commitment to the overall framework, proposed changes to some elements of it, and summarised our policy direction. It formed the basis for the primary legislation in the Health and Social Care Bill that will, subject to Parliamentary approval, establish the Care Quality Commission and define its functions in regulating health and adult social care. This will bring together the functions of the Healthcare Commission, the CSCI and the Mental Health Act Commission (MHAC) into a single body. The legislation also sets out the high-level framework for the new registration system.

1.14 In developing our thinking, we have worked closely with the existing commissions, building on their experience and seeking their views on what works and what does not work in the current regulatory systems.

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5 Policy and Strategy Directorate. *The future regulation of health and adult social care in England*. Department of Health, 2006.
Available at: www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286.

6 Policy and Strategy Directorate. *The future regulation of health and adult social care in England: response to consultation*. Department of Health, 2007.
Available at: www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_078227.

We have also sought their advice and input on the approach to registration set out in this document. The proposed approach to the revised regulatory framework is one of evolution, not revolution. We will be looking to ensure that the Care Quality Commission is able to draw upon not only the knowledge and experiences of its predecessors, but also the views and experiences of those who use and provide the services. We want to ensure that, as thinking on the new system develops, the Care Quality Commission has the right tools to do the job it needs to do.

1.15 To test this approach further, we commissioned some independent analysis of how registration of health and social care is handled in other countries. This work was undertaken by Professor Ellie Scrivens of the Health Care Standards Unit at Keele University and can be found on the university's website.[7] The report concluded that many countries have licensing or registration systems of a similar nature to that being proposed for England, even though the responsibility for operating them is often at regional or federal level, rather than through a national body. The report also suggests that the topics that other countries consider as mandatory for essential safety and quality assurance are in line with the proposed registration requirements on which we are now consulting.

How do we think the new system will work?

1.16 The registration system will be a key function of the Care Quality Commission. Chapter 2 sets out the essential aspects of safety and quality that we think the registration requirements should cover, and how they would be monitored and enforced. Chapter 3 sets out what we think the scope of registration should cover. Chapter 4 considers the options for extending the registration system to primary care. The Care Quality Commission will have other important functions, alongside registration, which will contribute to improving the quality of health and adult social care. These include:

> a duty to assess the performance of providers and commissioners (through periodic reviews) and to publish comparable information for public accountability alongside other information sources such as the NHS Choices website. This will help people make informed choices about their care provision;

7 Scrivens, E. *Review of International Issues Relating to the Registration of Health and Social Care*. Health Care Standards Unit, Keele University, 2008. Available at: www.hcsu.org.uk/index.php?option=com_docman&task=doc_download&gid=1192&Itemid=118.

- carrying out general service reviews when there are concerns that patients or users are not being as well served as they might be because of the way in which services are commissioned or provided;
- providing an annual report to Parliament on the state of health and adult social care services and the operation of the Mental Health Act;
- keeping under review, and safeguarding, the rights of patients subject to the Mental Health Act;
- taking a proportionate approach to regulation (in line with principles of good regulation[8]) and having a role in minimising the overall burden of regulation on health and adult social care organisations;
- taking account of the views of people using services and of providers on how it carries out its functions; and
- performing all its functions in a way that encourages improvement of health and adult social care services (noting that its enforcement powers can only be used in relation to providers failing to meet the essential levels of safety and quality covered by the registration requirements).

1.17 The Care Quality Commission will carry out periodic reviews that will build on the good work of the current commissions in developing the NHS Annual Health Check, the periodic reviews of councils with social services functions and the Quality Ratings of care homes. These assessments, of both commissioning and provider organisations, will provide authoritative and independent information to the public, as well as to the organisations themselves, about the broader quality of services. They are likely to include measures of the experience and satisfaction of people using services, of information about access to services, and of the quality of care outcomes.

1.18 The analysis and assessments that the Care Quality Commission makes of commissioning and provider organisations will be fully independent, although it will have first agreed with the Government the issues to be covered by the periodic reviews.

1.19 The periodic reviews of providers are a separate function in legislation from the registration system, because they are not linked to the Care Quality Commission's sanctions and enforcement powers.

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8 As set out in Hampton, P. *Reducing administrative burdens: effective inspection and enforcement*. HM Treasury, 2005. Available at: www.berr.gov.uk/files/file22988.pdf.

However, it is likely that the Commission will develop an integrated system for collecting and analysing data and other information it needs, both to test compliance with essential levels of safety and quality in the registration requirements and to assess wider performance through the periodic reviews. The Commission will consult on its methods and approach once it is established.

1.20 When the Commission highlights relatively poor performance in a provider that is still meeting the essential levels of safety and quality in the registration requirements, it will be for the board or owner of that organisation to take the necessary improvement action. In the case of NHS trusts, the relevant strategic health authority (SHA) may intervene if the board does not satisfy it that sufficient progress is being made. Commissioners may also take action if the provider is failing to deliver services that meet the quality standards set out in its contract.

1.21 However, the Care Quality Commission would take enforcement action if the provider is failing to comply with the essential levels of safety and quality in the registration requirements. Boards would be responsible for ensuring compliance with any enforcement action. Boards of NHS trusts or foundation trusts could be subject to intervention, respectively, from the Secretary of State or Monitor, if they fail to ensure that their organisation complies with the enforcement action.

1.22 The Commission will begin assessing the performance of providers, primary care trusts (PCTs) and local authorities in its first operational year, 2009/10 (using the systems of its predecessors in the first year), as well as publishing during that year the previous year's results inherited from the Healthcare Commission and CSCI.

1.23 Following the comprehensive implementation of the new registration system in 2010/11, the Care Quality Commission will agree with the Government a start date for special thematic or service reviews. This will be an important function, enabling the Commission to select areas for further scrutiny and thus encourage ongoing service improvements. These special reviews will enable it to look across the country at the delivery of particular types of health and adult social care, including:

- integrated health and adult social care services, clinical pathways and general quality;
- particular patient/service user groups to see the overall pattern of services for those people; and
- unmet need or gaps in service provision.

1.24 Just as the new registration system, providing assurance of essential levels of safety and quality, is only one of the functions through which the Care Quality Commission will promote safe, quality treatment and care, the new Commission itself will be only one of several parts of the health and adult social care systems with a responsibility in this area. Other key parts of the health and adult social care systems that will also promote ongoing improvements in the quality of services include:

- **people**, who increasingly can and do exercise choice as to how, when and where they receive their care and thus influence the development of increasingly flexible, responsive and convenient high-quality services from their providers;
- **clinical and care staff in provider organisations**, who work extremely hard to ensure that people receive the quality of care they would want for themselves or their loved ones;
- **professional regulatory bodies for clinical and care staff**, which ensure that all qualified staff are properly trained and competent to carry out their professional duties;
- **boards and management of provider organisations**, which have a general duty of care to their patients and service users, as well as a responsibility to seek to deliver ongoing improvements to the care they offer;
- **commissioners of services (PCTs and local authorities)**, which are responsible for buying the best available services on behalf of their local population. Commissioners will have responsibility for performance management and quality assurance of the services they commission through their contractual arrangements with their providers;
- **SHAs**, which are responsible for the overall management of the healthcare system, taking a strategic view of their areas, managing the performance of PCTs and NHS trusts, and ensuring that world-class commissioning is delivered; and
- **Monitor**, which is responsible for ensuring that NHS foundation trusts maintain the levels of financial management, governance and service performance set out in their terms of authorisation.

1.25 The functions of the MHAC will transfer largely unchanged to the new Commission. These functions, together with the new integrated registration system for health and adult social care, will allow the new Commission to strengthen its assurance of safeguards to protect the rights of people deprived of their liberty in the care of health and social care services. It will retain a strong focus on patients subject to compulsory detention under the Mental Health Act 1983, but will be able to do this alongside action to monitor the operation of safeguards against arbitrary deprivation or restriction of liberty under the Mental Capacity Act 2005.

What will happen next?

1.26 Once contributions to this consultation have been analysed, the Department of Health will publish draft regulations, in particular covering the registration requirements and the scope of registration. Following consultation on the draft regulations, it is anticipated that, subject to the necessary Parliamentary approval, the secondary legislation will be made early in 2009.

1.27 The current intention is that the Care Quality Commission will be established in October 2008 and will become operational in April 2009, when the functions of the Healthcare Commission, CSCI and MHAC will be transferred to the new Commission. Once established, the new Commission will lead on the implementation of the registration system, and consult on the detailed policies and procedures underpinning its operation.

1.28 The new registration system will start to be implemented in full from April 2010. Prior to this, the new Commission will consult on the guidance it will use to assess compliance with the registration requirements. It will also provide information on the transition process into the new system for providers currently offering health and adult social care services.

1.29 As part of a phased approach to transition, the registration requirements concerning HCAI, an integral part of the new registration system, will be implemented during 2009/10 for the NHS. The Government will publish a revised *Code of Practice for the Prevention and Control of Healthcare Associated Infections*, and will set requirements for HCAI in regulations. Social care and non-NHS healthcare providers will have to comply with the Code of Practice too.

1.30 The development of the new regulatory framework is an ongoing process. There will be many opportunities for people using services, service providers, the public at large, Parliament, and other interested parties to influence the development at each stage.

1.31 The next three chapters describe in more detail our proposals for registration requirements and the scope of registration. Chapter 5 provides information about how you can respond to this consultation and a summary of all of the consultation questions.

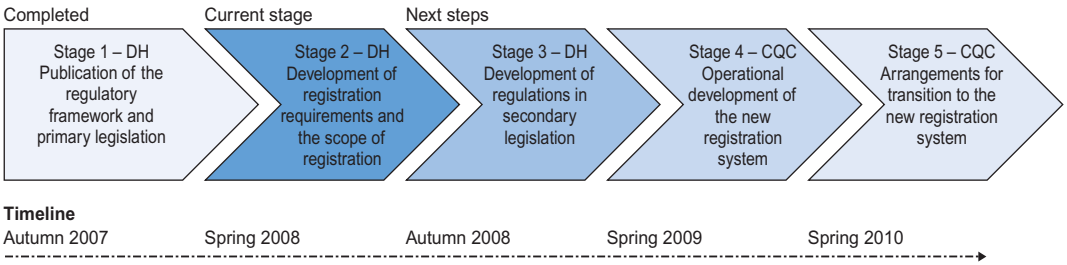
2. Registration requirements for essential safety and quality

Chapter summary

This chapter gives an overview of the different types of standards which currently apply across the health and adult social care sectors. It sets out how the proposed set of generic registration requirements has been developed to cover essential levels of safety and quality. It explains how they will be set out in legally enforceable regulations, and it outlines how the Care Quality Commission will develop a methodology and criteria to monitor the ongoing compliance of providers with the registration requirements.

This chapter also summarises the sanctions and enforcement powers that will be available to the Care Quality Commission. It concludes by outlining the timetable and handling of transition to the new system.

Where we are and next steps



Stage 1:

> **DH** sets out its proposed regulatory framework, including plans for a single registration system for health and adult social care.
> The Health and Social Care Bill makes provision for regulations to be made by **DH** about registration requirements, and for the **Care Quality Commission** to produce guidance about the criteria and methodology for the operation of the registration system.

Stage 2:

> **DH** will consult on what is included in the new registration requirements and which services should be included within the scope of registration.

Stage 3:

> Informed by the responses from this consultation, **DH** will consult on regulations, which will set the registration requirements and the scope of registration in secondary legislation, giving both a legal basis for enforcement.

Stage 4:

> The **Care Quality Commission** will develop and consult on the guidance on criteria and the methodology it will use to assess providers' compliance with registration requirements.

Stage 5:

> The **Care Quality Commission** will implement the process for transferring existing providers into the new registration system from April 2010 for most currently regulated providers.

Why are we making changes?

What happens at the moment?

2.1 In Chapter 1 we explained that currently there are different regulations, standards and assessment processes that apply to health and adult social care services, even though some of the services provided are very similar, if not the same, in nature. In this chapter, we set out the main topic areas for the proposed registration requirements and describe how we developed these. We also set out our initial thinking on the process of transition to the new system.

Why is there a need for change?

2.2 The current commissions have delivered effective regulation and assessment for each of their respective sectors based on the different legislative frameworks. However, the differing systems, regulations, standards and approaches in the regulatory framework have meant inconsistency in the type of enforcement used and the way it works across the system.

2.3 The Standards for Better Health (SfBH) were not developed for use in an enforceable regulatory framework in the same way as the National Minimum Standards arising from the Care Standards Act regulations. However, they have been an important element in the Healthcare Commission's annual performance assessment of NHS bodies, and

have played an important role in helping to promote ongoing quality improvements. They are divided between core and developmental standards, but the core standards are not independently enforceable and the distinction across both types of standard between what is essential and what is desirable is not as clear as it needs to be for the purposes of enforcement.

2.4 When they were first published by the Government in 2004, a commitment was made that the SfBH would be reviewed after a period of time. We now propose that the essential safety and quality elements of the core standards will be transferred into the new registration requirements, while a revised set of improvement standards will be developed to update the developmental standards. These improvement standards will be used by commissioners and providers to set challenging local quality improvement targets, which will be monitored through their contractual arrangements and will not be subject to regulatory sanctions and enforcement.

2.5 The National Minimum Standards which currently apply to social care and independent healthcare, by contrast, are very detailed and precise, and are considered by some to be overly prescriptive in places given the wide range of health and adult social care services. The Care Standards Act system currently sets four layers in relation to compliance: primary legislation, secondary regulation, National Minimum Standards and the current regulators' compliance methodology and criteria. This can make regulation bureaucratic and can give providers problems in understanding what they must comply with, rather than matters that are advisory or aspirational. For children's social care, the Department for Children, Schools and Families believes that the Care Standards Act remains appropriate but it is committed to carrying out a review of the current National Minimum Standards.

2.6 The current focus is often on processes rather than outcomes, which means that providers can achieve the standards without necessarily delivering the outcomes that people want. The system is also disproportionate, in that it duplicates process regardless of risk, for example by requiring registered 'managers' (who have already demonstrated fitness) to reapply and to be reassessed in terms of their fitness each time they change post.

2.7 In moving to a regulatory system which is based on essential safety and quality requirements rather than desirable best practice standards, we propose to put a greater regulatory focus on essential outcomes and on addressing the risks. We also think that this will remove some of the inconsistencies inherent in the current system and

enable the Care Quality Commission, building on the good work of its predecessors, to operate a modern, proportionate approach to regulation.

What changes are we proposing?

2.8 We are proposing a single set of registration requirements, to be applied across all health and adult social care providers that come within the scope of registration. These requirements will concentrate on the essential levels of safety and quality of care that people have the right to expect, and will be enforceable by the Care Quality Commission. They are separate to the revised set of improvement standards that will be developed for the NHS and used to benchmark best practice and promote further improvements in service quality; those improvement standards are not part of this consultation and will not be enforceable by the Care Quality Commission. The registration requirements are built around the main risks inherent in the provision of any health or adult social care service and developed from the most appropriate of the current regulations and standards. They will:

- be consistent across providers from both the independent and public sectors (including NHS trusts and foundation trusts);
- require providers to manage key risks to the safety, quality and governance of the care they provide;
- seek to address the concerns of people using health and adult social care services, and cover the topics on which they want assurance;
- provide clarity about **what** is required to deliver essential levels of safety and quality and so achieve compliance, without being prescriptive about **how** compliance is achieved; and
- allow the Care Quality Commission to judge compliance and, if necessary, to take a range of enforcement actions against non-compliance.

What is our favoured approach?

2.9 A summary of the registration requirements we have developed for consultation is set out in the following table. A more detailed list can be found in Annex A.

Table 1: Topics to be covered by registration requirements – for essential levels of safety and quality

People's health and wellbeing are better because the care and treatment they receive are safe and effective

> Making sure people get the care and treatment that meet their needs safely and effectively
> Safeguarding people when they are vulnerable
> Managing cleanliness, hygiene and infection control
> Managing medicines safely
> Making sure people get the nourishment they need
> Making sure people get care and treatment in safe, suitable places which support their independence, privacy and personal dignity
> Using equipment that is safe and suitable for people's care and treatment and supports people's independence, privacy and personal dignity

People's health and wellbeing are better because the care and treatment they receive are personalised and fair

> Involving people in making informed decisions about their care and treatment
> Getting people's ongoing agreement to care and treatment
> Responding to people's comments and complaints
> Supporting people to be independent
> Respecting people and their families and carers

People get better care and treatment because systems are operated to manage and deliver safe, effective, fair and personalised services

> Having arrangements for risk management, quality assurance and clinical governance
> Keeping records of the provision of care and treatment
> Checking that workers are safe and competent to give people the care and treatment they need
> Having enough competent staff to give people the care and treatment they need
> Supporting workers to give people the care and treatment they need
> Working effectively with other services

2.10 The registration requirements will operate across three levels of legislation and guidance:

- **primary legislation**, which will set the key functions of the Care Quality Commission and the main areas under which regulations in secondary legislation can be made to ensure that the registration requirements set by the Government are enforceable by the new Commission;

- **regulations in secondary legislation**, which will set out the legal expectations placed on service providers, so that failure to comply with the regulations will mean that the Care Quality Commission can impose sanctions or use enforcement powers. They will relate to the essential elements of safety and quality covered by the registration requirements, where people are more likely to be at risk of harm. They will be focused on the outcomes that the person using the service would want to see to be assured that essential levels of safety and quality are being met; and

- **compliance guidance**, which will be developed by the Care Quality Commission to monitor whether or not providers are meeting the registration requirements. The guidance will include the criteria (sources of information and evidence) and the methods the Commission will use to test compliance. Criteria might include performance indicators, other clinical/quality outcomes data, the experience of people using the service, complaints information, the results of site visits and inspections, information on the provider's performance held by third parties (such as commissioners) and evidence of good governance and management systems.

2.11 The proposed registration requirements are deliberately set out in summary form at this stage in the process of developing the revised regulatory framework. Subsequently they will be set in more detail in regulations and supported by the Commission's guidance on compliance. Our intention is that the registration requirements should reflect the main generic areas of risk that people face to the essential safety and quality of their care, across the spectrum of health and adult social care services.

2.12 The registration requirements are generic, but the criteria developed by the Care Quality Commission to assess compliance will be tailored to the type of service being registered. For example, the main risks to safety in a hospital are likely to be identified in different ways from those in a care home. Annex C gives examples which illustrate this in more detail.

How have we arrived at this approach?

2.13 The set of registration requirements proposed in this consultation is intended to protect people using services from the risk of harm involved in the provision of health and social care. They do not seek to enforce best practice that other parts of the system will promote. We have looked at how regulation works in other countries, and in particular at what kind of risks are covered by regulators. In general, other countries also have systems of regulation that include licensing or registration applying to service providers. Of course, these systems vary from country to country, but the risks covered by regulation tend to be consistent with our proposed registration requirements.

How do we think the new system will work?

2.14 We envisage that the registration requirements, along with their supporting regulations and criteria, will be used by the Care Quality Commission to:

- assess if an applicant for registration will be **able to deliver** a service at the required essential levels of safety and quality, and refuse registration where the ability is not proven;
- assess if a registered provider **is delivering** a service at the required essential levels of safety and quality and, where appropriate, take action to ensure that the service meets the requirements; and
- enforce the delivery of those requirements and cancel registration where the service provider cannot – or will not – deliver the required essential levels of safety and quality.

2.15 The Care Quality Commission will take a proportionate approach to assessing compliance with the registration requirements, wherever possible using existing data sources, self-assessment methods and feedback from people using the services. For some services, on-site inspections will always be necessary to assure compliance, but their frequency will be set by the Commission. It will decide on how regularly individual providers will be inspected according to the inherent risks to people using the service, whether the service is used by people at particular risk of being vulnerable, or the existence of other information that leads the Commission to believe there may be a problem with a particular provider.

2.16 Enforcement action will be taken against breaches of the registration requirements, not against specific compliance criteria. The evidence gathered on specific criteria will be used to prompt further investigation

by the Commission if necessary. Where criteria are not being met by a registered provider, that will be a signal for the Commission to investigate further and consider whether enforcement action is required. In situations of a suspected breach of registration requirements, the Commission may ask to see, or the provider may choose to submit, additional evidence that is not part of the published criteria.

2.17 We therefore intend that the Care Quality Commission should carefully consider suspected breaches on a case-by-case basis and judge whether enforcement action is required. 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 sanctions or enforcement powers listed below it judges most appropriate and to make this public. It will also be able to proceed to a more serious enforcement action, if the provider does not comply after sanctions have been imposed.

2.18 Given the range of enforcement actions that the Care Quality Commission will be able to take (listed below), and the potential impact on providers, the appeals process currently run by the Care Standards Tribunal for social care and independent healthcare providers will also be extended to registered NHS bodies.

Sanctions

> a new statutory warning notice, requiring improvement within a specified time;

> a new power to issue a fine in lieu of prosecution (a penalty notice); and

> a formal non-statutory caution.

Enforcement powers

> conditions that place continuing restrictions on registration (for example, preventing the provider from running a particular service, preventing further admissions to a service, or closing a service for a specified period);

> a power to temporarily suspend registration for a specific period;

> prosecution of organisations and/or individuals – resulting in fines or, in extreme cases, imprisonment; and

> cancellation of registration.

Interaction between registration and the NHS foundation trust authorisation process

2.19 Authorisation is a specific process run by Monitor to confirm that NHS trusts meet the standards of governance, financial management and overall performance that are required for them to become NHS foundation trusts. Registration of NHS providers is a function of the Care Quality Commission and will be distinct from the authorisation process to obtain foundation trust status. As registration will be a prerequisite for any provider wishing to offer regulated NHS services, NHS trusts will have been registered before they become foundation trusts.

2.20 On attaining foundation status, the registration requirements will become part of the NHS foundation trust's terms of authorisation. It will be for the Care Quality Commission, not Monitor, to determine whether there has been a breach of registration requirements, taking account of any information it receives from Monitor. Monitor would be able to use its intervention powers, if needed, in an NHS foundation trust that breaches its registration requirements, to ensure that the foundation trust makes the necessary improvements.

2.21 Monitor's powers to authorise NHS foundation trusts will not duplicate the Care Quality Commission's powers to decide: which providers should be registered; how providers should be assessed in terms of compliance with requirements for essential levels of safety and quality; or when breaches of the requirements have happened. 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 – one that recognises Monitor's existing statutory role and intervention powers alongside the statutory functions and enforcement powers of the Care Quality Commission, to ensure that providers from all sectors meet essential safety and quality requirements.

How will existing providers transfer into the new registration system?

2.22 The arrangements for managing the transition to the new system will be set out following the passage of the Bill, using secondary legislation where necessary. This will include how registered providers will have their registration transferred, how NHS organisations will be brought into the registration system, and the arrangements for registering new providers during the transition period.

2.23 The Care Quality Commission will set out how it will manage the process. Before a new provider is granted registration to deliver services, the Commission will need to assure itself that the provider has the policies, processes and systems in place to ensure compliance. Once registered, the provider will be judged on actual compliance based on its track record of service delivery.

2.24 We want to make the transfer process for existing providers as straightforward as possible. To ensure that the transition is balanced and effective, we are currently intending to phase it in over the period from April 2009 to April 2010 for providers currently registered under the Care Standards Act and for NHS providers of services that will come within the scope of registration (which will include PCT provider arms). Registration requirements for HCAI will be prioritised to take effect during 2009/10, with all other registration requirements coming into effect from April 2010.

2.25 The current arrangements for registration of providers under the Care Standards Act 2000 will therefore continue until April 2010, but will be operated from April 2009 by the Care Quality Commission. To ensure that the Care Quality Commission can focus on the operation of the new registration system from April 2010, we envisage that there will be a cut-off point during 2009/10 for new applications for registration under the Care Standards Act. The new Commission will provide more details about this later.

2.26 In the response to this consultation, we will set out a separate transition timetable for primary care services that fall within the scope of the registration system. Please refer to Chapter 4 for more detail.

Providers eligible for direct transition to the new registration system

2.27 It is our intention that the vast majority of current providers will transfer directly into the new registration system. Existing NHS providers will also be registered directly with the Care Quality Commission and will not need to make an application for registration as part of this process. The new Commission will be able to attach conditions to their registration where it decides it is appropriate, for instance if the Healthcare Commission passes on concerns about the essential safety and quality of care in an NHS provider. However, those providers – whatever sector they are from – which are under enforcement action of any kind at the transition date will undergo different transitional arrangements.

Providers under current regulatory action (excluding action to cancel registration)

2.28 These providers will transfer across to the new registration system, but will be required to ensure satisfactory resolution of the issues for which the regulatory action was commenced, with the action redefined legally in the context of the new registration system. This might be achieved, for example, by applying conditions to the provider's registration, such as requiring problems to be addressed within a certain time period.

Providers already under action to cancel registration

2.29 For these providers, the process of cancellation will continue 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 it will at that point be directly transferred into the new system. If a decision is taken to cancel registration, the provider will not be registered under the new system.

What are we consulting on?

2.30 We are asking for your views on the following five questions:

> We propose to introduce a generic set of registration requirements (set out in regulations) for all providers offering services that are within scope. These requirements will be supplemented by compliance criteria, to be developed by the Care Quality Commission, that are specific to the type of activity. These will be consulted on at a later date. Do you agree with this approach?

> Are the areas covered by the registration requirements (set out in Annex A) the right ones to provide the assurance of the essential levels of safety and quality that we are aiming for?

> Does the wording of the registration requirements in Annex A provide appropriate coverage of these areas?

> Are there any overlaps, gaps or unintended consequences that will not be picked up by other parts of the system?

> What are your views on the transition arrangements for existing providers to enter the new registration system?

What will happen next?

2.31 When this consultation has been completed, and once the Health and Social Care Bill has received Royal Assent, the Department of Health plans to finalise draft regulations, which will enshrine the registration requirements in secondary legislation. Those regulations will be consulted on later this year. Following Parliamentary scrutiny, the regulations will be laid early in 2009, but will not come into force until April 2010, with the exception of requirements for HCAI, which will be implemented during 2009/10.

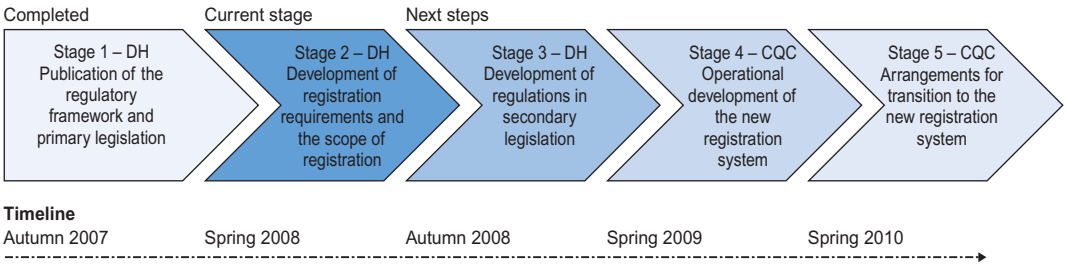
2.32 The Care Quality Commission will then base the implementation of the registration system around the published registration requirements and supporting regulations. The methodology and associated criteria it develops for monitoring and enforcing compliance with registration requirements will be subject to a further consultation by the Care Quality Commission during 2009/10.

3. Scope – which health and adult social care services should be registered?

Chapter summary

This chapter sets out our proposals for the list of health and adult social care services that we believe should come within the scope of registration. This is based around an analysis of those services and care situations that present the greatest potential risk to people. The chapter also describes the way in which we are changing legislation so that we can bring new types of services into registration as they develop. Finally, it sets out our future proposals for more proportionate arrangements on the registration of managers, and gives an outline of the next steps and ongoing timetable for further stages of work on the scope of registration.

Where we are and next steps



Stage 1:

> The primary legislation sets out broad definitions of health and adult social care, the starting point for defining which services are within scope.
> It makes provision to allow for the registration of managers to be required in regulations where appropriate.

Stage 2:

> **DH** will consult on which activities should require a provider to be registered, and for what types of care provision a registered manager is required.
> The consultation sets out a transparent rationale for deciding what falls within the scope of registration.

Stage 3:

> Informed by the responses from this consultation, **DH** will consult on regulations which, subject to Parliamentary approval, will set out in secondary legislation those services requiring providers to register with the **Care Quality Commission**, and the situations where a registered manager is required.

Stage 4:

> The **Care Quality Commission** will develop the process for registering those providers within the scope of registration, as set out in regulations.
> This will include setting out the form and content of applications, the structure and level of fees, and the process that providers must undergo to obtain and maintain registration.

Stage 5:

> The **Care Quality Commission** will develop a process for identifying those existing providers within the scope of the new registration system, and will implement the transfer of providers to the new system.

Why are we making changes?

3.1 Health and adult social care services are continually evolving, with the introduction of new technology, developing roles of care professionals, and changes to the settings in which services are provided. So that people can use new services with confidence, it is important that the system for registering health and adult social care provision is flexible enough to cover any new services that could present a potential risk of harm to people.

What happens at the moment?

3.2 Currently, any non-NHS provider of health and social care that falls within the definitions set out in the Care Standards Act 2000 has to register with either the Healthcare Commission or the Commission for Social Care Inspection, in order to provide services legally.[9] Additionally, if the registered provider of an 'establishment or agency' is not in day-to-day control of delivering the service, then the person who is must register as a manager. There is currently no registration

9 Care Standards Act 2000, Chapter 14, Part I, subsections 1–4. Available at: www.opsi.gov.uk/acts/acts2000/ukpga_20000014_en_1.

system for NHS bodies, which are instead assessed against the Standards for Better Health by the Healthcare Commission.

Why is there a need for change?

3.3 The way the scope of registration was defined for the existing system was right for the time at which it was created and has generally worked well for traditional adult social care and independent health service providers. However, health and adult social care services are continuously evolving, so that some new services (for example nurse-led services) do not easily fit within the organisational definitions set by the current legislation. Similar services are now more often provided in a range of settings, meaning that they are subject to different regulatory regimes. This has a number of disadvantages:

- people cannot be fully confident that the same types of service are always satisfactorily covered by the regulatory system;
- service providers can be left unsure whether they are required to register certain services, particularly when they expand their provision into new service areas; and
- there is no clear reference point for the existing commissions to help determine at what point, if at all, changing services such as new diagnostic techniques or support for people using direct payments to arrange their social care should be brought within the scope of registration.

What changes are we proposing?

3.4 The scope of registration under the new system will be broadly similar to that which currently applies to adult social care and independent health providers. A notable change is that NHS providers will have to register to deliver services that fall within the scope of registration. The other significant difference is that, instead of defining scope in terms of organisational settings, there will be a list of broad service areas or types of care (described in the Bill as 'regulated activities') for which registration will be required.

What is our favoured approach to defining the scope of registration?

3.5 The Health and Social Care Bill sets out broad definitions of health and adult social care in primary legislation. It also provides for the detailed list of health and adult social care activities, for which a provider must register, to be set in secondary legislation. This is different to the current system, which sets out the detail of who must

register in primary legislation. Setting the detail in secondary legislation allows the list to be revised when appropriate, enabling the new registration system to be more responsive to changes in service provision. The definitions in the Bill are as follows:

- **Healthcare** includes all forms of healthcare provided for individuals, whether relating to physical or mental health, and also includes procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition.

- **Social care** includes all forms of personal care and other practical assistance provided for individuals who by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs, or any other similar circumstances, are in need of such care or other assistance.

3.6 The exact definition of any individual regulated activity, when set out in regulations, can refer to any type of service or new model of provision, but must fall within the broad definitions above.

3.7 We propose to define the scope of registration in a way that ensures that:

- all providers are treated fairly regardless of whether they are public or independent sector, or whether services are delivered in secondary, community, primary, residential or domiciliary care settings;

- the Care Quality Commission can operate a proportionate registration system, avoiding unnecessary burdens on providers and on the Commission itself;

- services are registered according to the risk of harm to people using them, after taking into account any other protections offered by other regulatory or management and governance systems;

- the process enables the accommodation of changes and innovations in models of care provision;

- the definitions encompass the increasing integration between health and social care services; and

- it is clear to providers, the public and the new Commission when registration is required.

3.8 Our detailed proposals for the regulated activities that should be included within the scope of registration can be found at Annex B. These proposals describe activities by focusing on the type of care given (for example surgery or personal care), rather than the setting in which the care is given (for example hospital or care home). Separating activities and settings in this way will ensure that the Care Quality Commission can adopt a consistent approach to the way in which activities are registered, irrespective of location and model of care.

3.9 As well as setting out our proposed list of services for registration, Annex B also sets out those services that we think should **not** come within the scope of registration, for example provision of care by family and friends. In addition, Annex B identifies the services that we do not propose to cover by registration because they are overseen by other systems or legislation. For example, fertility and associated services are required to obtain a licence from the Human Fertilisation and Embryology Authority.

How have we arrived at this approach for regulated activities?

3.10 To identify health and adult social care services that present the greatest potential risk to the safety, health, wellbeing and dignity of the people using those services, we devised a set of criteria against which services could be assessed. The criteria were compiled by examining the types of incidents investigated by the current regulators and identifying the inherent potential for a particular service to harm people or to place people in situations where they might be vulnerable to harm. We also considered the circumstances that might lead to a potential imbalance in power between the people most likely to use the service and those providing it, to ensure that those services directed towards people most at risk of being vulnerable because of particular circumstances would be appropriately covered by registration. The criteria are given in the following table.

Table 2: Criteria for determining whether services should be registered

Aspects of activities that have an inherent potential to cause harm because they:	People to whom the inherent potential to cause harm is increased because the balance of power between them and the service provider is affected by their particular circumstances, since they:
> are invasive procedures (risk of trauma, deep infection, etc); > risk compromising dignity through the necessity of intimate personal examination or care; > risk spreading disease; > involve the use of medication; > involve the use of potentially harmful technologies, eg radiation; > risk a reduction in quality of life; > risk psychological harm; > necessitate the use of restraint or seclusion; or > impact on other parts of the care pathway.	> have periods of mental impairment; > lack mental capacity to make decisions about their own health and social care; > are in a state of unconsciousness; > are in a heightened emotional state; > depend on others to support their everyday activities; > depend on others for support with privacy and dignity; or > depend on others to support the exercise of control.

3.11 We assessed services from across all sectors of health and adult social care against these criteria. If a service had the potential to cause significant harm, or was provided for those at risk of being vulnerable, as listed, the service was considered to require inclusion in the registration system. For example, X-rays involve the use of potentially harmful technologies, and people in care homes depend on others for support with privacy, dignity and everyday activities. Both of these services were considered to require inclusion in the registration system. By grouping together similar services that met any of the criteria in Table 2, we have formed proposals for the descriptions of regulated activities that require registration. These are set out in Annex B.

How do we think the new system will work?

3.12 We expect that most existing providers, with establishments or agencies registered under the Care Standards Act 2000, will continue to require registration in the future. For example, care homes and most domiciliary care agencies will continue to be registered due to their provision of personal care. Similarly, in healthcare, independent sector hospitals are likely to continue to be registered, due to their provision of surgical services or other regulated activities.

3.13 By adopting our proposed approach, we will be able to bring new types of providers into the registration system, including NHS trusts, NHS foundation trusts and PCT-provided services. In addition, providers previously exempt by virtue of not being doctor-led will be brought into the scope of registration if they provide regulated activities. Other activities being provided in private prisons or by private ambulance providers are likely to come within the scope of registration via this approach. This will ensure a fair playing field for providers who operate in these sectors.

3.14 Any provider who seeks to provide one or more regulated activity will have to register with the Care Quality Commission. Some providers, such as small care homes, will only wish to provide a single service from a single site. To simplify the process for those providers that offer more than one service or have more than one site, we intend that all the providers' activities that require registration should be combined into a single registration application process. That would mean a single registration for multi-site providers, such as independent companies or NHS trusts, or those that use a variety of settings, such as mobile providers and those that provide care in people's homes.

3.15 We envisage that the registration of a provider will be supported by a 'Statement of Purpose'. This will contain the details of the services that the provider is registered to deliver, and the sites for which it is registered. For example, if a provider is registered to deliver personal care, the Statement of Purpose might show the categories of people that it could care for, for example age range, or details of any particular conditions such as dementia; if a provider is registered to deliver surgical services, the Statement of Purpose might show the surgical specialties it provides, for example general, cardiothoracic or plastic surgery. When providers change the range of services they deliver, or they open new sites, they will not need to re-register but they will need to notify the new Commission so that their Certificate of Registration can be altered. If the change to services is significant, the Commission may ask for additional information to ensure that the provider meets the essential levels of safety and quality required for registration.

3.16 Subcontractors or agencies providing services to a registered provider would also normally need to be registered when they are carrying out a regulated activity. An exception to this would be when they are not directly providing a care service but are supplying equipment, technical assistance or staff to the main provider of the service. In these cases, the main provider would be registered for all the care provided and would need to ensure compliance with the registration requirements.

3.17 Bringing NHS services within the system of registration raises questions as to whether or not other public services delivering health activities of a similar risk should be included in the system, for example prison healthcare or Defence Medical Services (DMS). In the case of DMS delivered in England, hospital care is delivered either by arrangement with the NHS or under contract with the independent sector, and is therefore likely to be covered within the proposals for the new registration system. Nevertheless, there are some activities in community or primary care (such as rehabilitation) that could also come within the scope of registration. For activities that are delivered outside England or do not come within the potential scope of registration, the Care Quality Commission may carry out reviews of those services under agreement with the Ministry of Defence.

3.18 Specific consultation questions on our proposals for the descriptions of regulated activities, as set out in Annex B, are at the end of this chapter. We welcome views on each of the activity topics put forward. As part of this, we are particularly interested to hear your views on the exclusion of non-urgent patient transport services, and on employment agencies. Further questions on how primary care services might be covered by registration can be found at the end of Chapter 4.

What should be the future arrangements for a registered manager?

3.19 Historically, legislation covering adult social care and independent sector healthcare services has included provision for the appointment of a registered 'manager'. This was intended to ensure that, in cases where the registered person (provider) either decided that they did not wish to be responsible for the day-to-day running of the service or was not competent or a fit person to do this, a competent registered manager would be appointed.

3.20 For example, chains of care homes or independent hospitals where the registered person is located perhaps hundreds of miles away would have a registered 'manager' in place for each service. They would share responsibility with the provider for assuring compliance

with the regulatory framework on a day-to-day basis. This is to ensure that there is always someone accountable for what happens to people using registered services. It is not professional registration and it is not intended to apply to all managers who work within health and social care services.

3.21 It is right that there should be clarity about who is responsible for the provision of safe and effective services on a day-to-day basis. However, the current requirement for a registered manager, in every instance where the registered provider is not responsible for the day-to-day management of the service, is potentially very rigid. This can cause duplication when there are other governance and accountability systems in place for the supervision of managers of services. For example, NHS foundation trusts have boards and potentially hundreds of managers with clear chains of accountability, and in most cases it would not be appropriate to extend this requirement in such situations.

3.22 In social care, it is necessary to ensure that there is appropriate accountability in law for the operation of services, and the appointment of a registered manager may be crucial. In addition, for some providers of independent healthcare this may also be necessary, particularly where the chains of accountability are geographically dispersed.

3.23 Good management is crucial to delivering care that is safe and of appropriate quality. It will be important for providers to be able to demonstrate that they can manage their services safely and effectively. For some regulated activities, key components of the assurance of quality will be the Care Quality Commission's assessment and the requirement to have a registered manager.

3.24 To determine which regulated activities should require a registered manager, we think it is important to take into account the nature of the service and the external framework in which the service operates. In some cases, the nature of the provision can mean that a manager has significant control and autonomy in determining the quality of the service provided, and carries the burden of responsibility for controlling any potential harm to people using that service. The risk of people using the service being vulnerable to abuse is also a key consideration when determining which regulated activities should require the registration of a manager.

3.25 Providers of services for people who are at greatest risk of vulnerability and that operate within frameworks with fewer mechanisms to support the management of service delivery are most likely to be smaller organisations, often in social care. As such, we

propose that the social care regulated activities should generally be subject to a condition for the provider to have a registered manager, where the provider is not in day-to-day control of the service. The Commission will also be able to apply this to healthcare services where the lines of day-to-day accountability do not provide adequate assurance in terms of safety and quality. If this power did not apply to those healthcare services, it would represent a deregulation from the position under the Care Standards Act, which may not be in the best interests of people using the services.

3.26 We will be consulting later this year on the detailed regulations the Care Quality Commission will use to regulate managers. In this instance, we propose that these regulations should link the need for registered managers with particular service sectors, ie social care and appropriate healthcare providers of particular regulated activities, rather than all sectors of care. This will allow a more targeted approach to be taken to the registration of managers. We welcome your views on this approach.

3.27 If a provider wants to deliver any regulated activity that the Care Quality Commission decides requires the appointment of a registered manager, it will be the provider's responsibility to ensure that the manager applies for and obtains registration. The new Commission will be able to assess the capability of the manager the provider puts forward and will be able to decline to register the manager if it has good reason. Once registered, the manager will be responsible, in addition to the service provider, for ensuring that all registration requirements are fulfilled for the provision of the service they manage. The CQC will keep to a minimum the further information required from managers when they move elsewhere to run the same type of service as the one for which they were previously registered.

3.28 In common with registered providers, registered managers who do not ensure that registration requirements and other legal requirements are satisfied can be subject to enforcement action from the Care Quality Commission. This can range from warning notices through to penalty notices, or to cancellation of registration where necessary.

What are we consulting on?

3.29 We are asking for your views on the following questions:

> Do you agree with our proposed list of regulated activities in Annex B to be included within the scope of registration?

– Are there any high-risk services not covered?

- Have we proposed any inappropriate registration of lower-risk services?
- What are your views on the exclusion of non-urgent patient transport services under the 'Emergency and urgent care' activity topic?
- What are your views on the proposals for the registration of agencies who supply workers to other registered providers, under the 'Personal care' and 'Nursing care' activity topics?

> Are the activities for registration described at the right level of detail, given that they will be underpinned by more specific and legally enforceable regulations?

> Is there a risk of inappropriately deregulating high-risk activities in this approach?

> Have we determined the right situations in which to register a manager?

What will happen next?

3.30 Once this consultation process has finished, the Department of Health will publish its response to the consultation after the Health and Social Care Bill has received Royal Assent. We will then carry out a further consultation on the draft regulations, which will define and list those health and adult social care activities that require providers to register with the Care Quality Commission in the future. We expect a draft of these regulations to be debated by Parliament early in 2009, but these will not come into force until April 2010. The current regulatory system under the Care Standards Act will be operated by the new Commission from April 2009 until then, with the exception of HCAI in relation to the NHS, where registration will start during 2009/10.

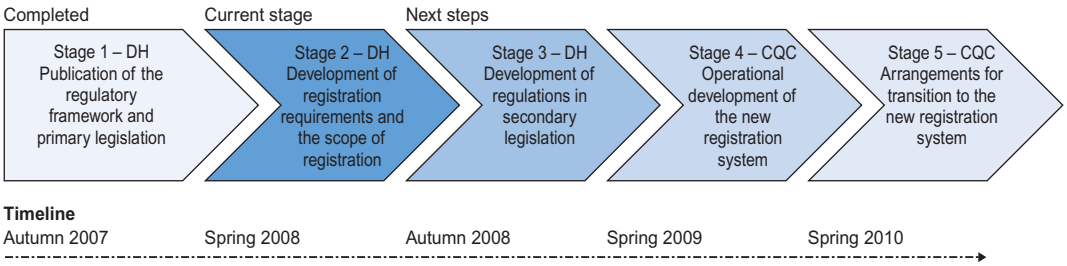
3.31 Once the scope of registration has been defined and set out in regulations, the Care Quality Commission will, during 2009/10, develop and consult on its approach to running the registration application process, setting out the different processes for existing providers transferring into the new registration system and new providers seeking an initial registration.

4. Registration of primary care

Chapter summary

People using services need to be protected if services present a risk, regardless of the setting or type of provider. Chapter 3 makes clear that we intend to consider the risk to people using services, together with existing protections, when determining which services should fall within the remit of the Care Quality Commission. This chapter considers the implications for primary care services, and how they might be regulated.

Where we are and next steps



Stage 1:

> The responses to the previous consultation on the overall regulatory framework gave broad support for inclusion of primary care in registration.
> The response document confirmed that the Government would consult further on how and when to regulate primary care.

Stage 2:

> **DH** will consult on how and when primary care could be brought into the scope of registration.

Stage 3:

> Depending on the outcome of Stage 2, the consultation on draft regulations setting out those activities requiring providers to register will incorporate some or all primary care into the scope of registration.

Stage 4:

> The **Care Quality Commission** will develop the process for registering those providers within the scope of registration, as set out in regulations.
> This will include setting out the form and content of applications, the structure and level of fees, and the process that providers must undergo to obtain and maintain registration.

Stage 5:

> The **Care Quality Commission** will develop a process for identifying those existing providers within the scope of the new registration system, and will implement a process for transferring those providers to the new system.
> Depending on the outcome of Stage 2, these arrangements could include providers of primary care services.

Why are we making changes?

4.1 GPs and dentists, working alongside a range of other professionals, provide services in primary care settings and, when necessary, refer their patients to other parts of the NHS, to social care services and to the independent health sector. Some 80 per cent of the interaction between members of the public and the NHS takes place in primary care settings. Every day 800,000 people use primary care services and some 90 per cent will be diagnosed, treated and receive all the care they need in those settings.

4.2 In primary medical care, the key risk is one of volume. Whilst the individual risk may be small, with approximately 290 million consultations with GPs and an estimated 75 million visits to the dentist each year, the cumulative risk is great.

4.3 Research evidence on error rates in primary care is limited.[10] However, a team at the University of Manchester found that such threats occur between just 5 and 80 times per 100,000 consultations, mainly related to the processes involved in diagnosis and treatment. Prescribing and prescriptions may have a higher error rate – up to 11 per cent of prescriptions – mainly related to errors in dose. Most errors do not

10 Sanders, J, Esmail, A. *Threats to Patient Safety in Primary Care. A review of the research into the frequency and nature of error in primary care*. Patient Safety Research Portfolio. University of Birmingham, 2001.

cause actual patient harm but have the potential to do so, and a registration system could ensure that practices have appropriate clinical governance systems in place to minimise these errors.

4.4 In primary dental care, the Dental Reference Service has reported a range of poor decontamination practices and conditions in surgeries that place patients at risk of infection. Concerns about the risks of blood-borne infections have also grown. Research has demonstrated that infective agents may adhere to dental instruments and transfer infection if these instruments are reused (even if good decontamination practices are in place).

4.5 Registration of primary care practices would help both to drive up the quality of practice-level clinical governance and to enable primary care trusts (PCTs) to concentrate on overseeing a small number of poor-quality practices.

What happens at the moment?

4.6 Most providers of primary care services are not within the scope of registration under the current legislation. As set out in the Care Standards Act 2000 and its associated regulations, only wholly private GPs are required to register. GPs with an NHS contract are not required to register, even for any non-NHS services they provide. All primary care dental services, both NHS and private, are outside the scope of the current registration system. However, any primary care and out-of-hospital services provided directly by PCTs are considered as part of the Healthcare Commission's current assessment of PCTs.

4.7 Existing protection for patients receiving primary care services includes the following:

> all GPs and dentists are subject to individual professional regulation and must comply with the General Medical Council or General Dental Council standards of practice;

> NHS contracts between PCTs and primary care providers require certain things, for example competency of the individual and the suitability of the premises;

> the NHS performers list confirms the competency and suitability of the individual to work in NHS primary care services; and

> the accreditation system for professionals with special interests considers the skills and competence of the individual as well as the supporting infrastructure and accredits them for a three-year period.

4.8 Nevertheless, there is not a set of national essential safety and quality requirements underpinned by clear criteria and, therefore, without the registration of primary care services, where the risk of harm to people is similar or equivalent to that posed by services provided elsewhere, protection will not be as strong as that for other registered providers.

Why is there a need for change?

4.9 The interim report of the NHS Next Stage Review has signalled our intention that more care will be provided closer to home and, as a result, more services are likely to be delivered in the community or in primary care settings, such as local clinics, rather than in acute hospitals. The increasing complexity and widening range of services offered in primary care, combined with an increasing diversity in the types of provider, point to the need for a consistent regulatory framework across both primary and secondary care.

4.10 The current regulatory arrangements for primary care focus mainly on the competence of the individual professional. However, professional regulation can only come into play as a safeguard for patients if an issue has been identified locally. There need to be systems in place, such as effective clinical governance, to enable practices and PCTs to identify doctors whose poor performance is putting patients at risk. The Public Accounts Committee's report on implementing clinical governance in primary care noted serious short-comings, for example only 4 per cent of GPs report untoward events and clinical incidents to the National Patient Safety Agency.[11]

4.11 The ways in which organisations are managed and their systems work, together with factors such as the suitability of premises in which services are provided, also have an impact on the safety and quality of the services provided. This means that highly skilled and competent individuals may be working in organisations that have system weaknesses or in premises that do not meet the needs of their patients and, as a result, patients may be put at risk.

4.12 These wider factors have partially been addressed through requirements in NHS primary care contracts. However, these do not apply consistently across all primary care services and, in the absence

11 House of Commons Committee of Public Accounts. *Improving quality and safety – Progress in implementing clinical governance in primary care: Lessons for the new Primary Care Trusts*. Forty-seventh Report of Session 2006–07. Available at: www.publications.parliament.uk/pa/cm200607/cmselect/cmpubacc/cmpubacc.htm.

of a national set of requirements for essential levels of safety and quality, PCTs have not always found it straightforward to enforce them. Likewise, the Professionals with Special Interests accreditation arrangements include some checks on organisational and system aspects but apply to only a limited proportion of services.

What changes are we proposing?

4.13 As Chapter 3 makes clear, the new registration system will be focused on regulated activities (broad service areas or types of care) rather than on settings. Decisions on the activities that fall within the scope of registration will be based on the risk to those receiving the services. The setting in which the service is provided will be relevant only where this either increases or reduces the potential risk to the service user.

4.14 Providers of services deemed to be regulated activities will need to meet the essential safety and quality registration requirements whether they work in primary, community or secondary care and whether they are providing services in the public or private sector.

What is our favoured approach?

4.15 In November 2006, we consulted on the principle of including primary care within the new regulatory system.[12] The majority of responses put forward convincing arguments for a consistent regulatory framework across all settings. We therefore indicated in our consultation response that we expected to regulate all services on the basis of the risk to patients.[13]

4.16 We expect that providers of regulated activities in primary care settings will be required to register in the same way as providers in any other setting. The proportion of primary care providers required to register will depend upon the final definitions of regulated activities and the numbers carrying out those services and how these develop over time. However, we anticipate that all GP practices will eventually be required to register with the Care Quality Commission. Those responding to the consultation are asked to comment on this and whether we should also aim to bring all 'high street' dentists into the registration system.

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12 Policy and Strategy Directorate. *The future regulation of health and adult social care in England*. Department of Health, November 2006. Available at: www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286.

13 Policy and Strategy Directorate. *The future regulation of health and adult social care in England: response to consultation*. Department of Health, October 2007. Available at: www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_078227.

4.17 Annex B sets out proposals for the categories of services to be covered as regulated activities. The draft includes primary medical care services and primary dental care services. If adopted in regulations, this would bring GP practices and dental practices within the scope of the registration system. Specific consultation questions on these proposals are at the end of this chapter.

4.18 Introducing a system of registration that is consistent with the approach for all other settings would bring a number of benefits. These include:

- improving the performance of the poorest primary care performers, potentially reducing the costs to other parts of the system;
- strengthening assurance for people about safety and quality, especially over the performance of GP practices and dental practices as organisations;
- ensuring that the potential to deliver services closer to people is supported and safety is maintained without introducing a bureaucratic block;
- putting arrangements in place that will be able to address the increasing complexity of primary care services as they develop to meet the challenges of the twenty-first century;
- ensuring that regulation supports the Government's vision for delivering quality, personalised services, which will be set out in due course in a primary and community care strategy paper;
- creating a fair playing field, with primary care settings treated the same as equivalent services provided in other settings (for example when GPs are providing elective surgical services);
- ensuring that key safety guidance is prominent in both NHS and non-NHS primary care services, for example given growing concerns about the risks of transmitting blood-borne infections through dental procedures;
- reducing demands on PCTs to monitor those contractual requirements on primary care providers that are also registration requirements; and
- minimising the administrative burden by streamlining other processes, for example the performers list, contract and Quality and Outcomes Framework.

4.19 A fuller assessment of the benefits has been set out in an impact assessment to accompany this document. The impact assessment considers a range of options and for each option estimates the likely cost to the new Commission and to providers of extending the registration system to some primary care services. The level of costs will largely be determined by the final list of regulated activities and the proportion of providers that will be required to register with the Commission as a result. The impact assessment is available at: www.dh.gov.uk/en/Consultations/Liveconsultations/index.htm.

How have we arrived at this approach?

4.20 Chapter 3 sets out the process we have used to develop the proposed list of regulated activities set out in Annex B. As the list has been developed, we have considered whether the provision of these services in primary care is likely to increase or decrease the risk to patients and how to minimise duplication between the various activities, and we have refined the definitions accordingly. We welcome comments on this through the consultation.

How do we think the new system will work?

4.21 If adopted unchanged, the draft regulated activities set out in Annex B are likely to cover those primary care services provided by GPs and dentists. However, in time, other providers may expand their activity to provide regulated activities in primary care settings. For example, the forthcoming pharmacy White Paper will set out how services are expected to develop in the future.

4.22 As Annex B demonstrates, our initial thinking is that the existing legislative systems in place for services currently provided by pharmacists are sufficient to protect patients. Likewise, our risk analysis suggests that the usual eyecare services provided in the community (such as sight tests by optometrists) do not require registration. However, as indicated previously, the proposals included in Annex B could be extended if we were to identify new risks to patients.

4.23 All providers of regulated activities will be required to apply to the Care Quality Commission for registration. As described in paragraph 2.27, we envisage that existing providers will transfer directly into the new registration system. Once registered, the Commission must then satisfy itself that the essential safety and quality registration requirements have been met. The Commission will be under an obligation to minimise the burden of regulation and we would expect the Commission to adopt a proportionate approach to regulation. For example, requests for providers to supply information will be kept to a

minimum as the Commission will be able to use information from a range of sources when determining whether the registration requirements have been complied with. This should minimise the cost and burden of registering services for providers and for the Commission.

4.24 In both primary medical care and primary dental care, there are a number of existing arrangements that could be used as evidence by the Care Quality Commission when it is considering whether providers are complying with the registration requirements. For example:

- monitoring undertaken by PCTs as commissioners of NHS services, under their contractual arrangements;
- the NHS performers list and information gathered by PCTs to maintain this;
- data gathered by the Government's Information Centre;
- any voluntary accreditation scheme that the practice is involved in;
- the Professionals with Special Interests accreditation framework;
- clinical information such as prescribing data and the Quality and Outcomes Framework;
- performance reviews;
- any monitoring information held by private sector insurers that can be made available; and
- information obtained by the Dental Reference Service when monitoring dental services.

4.25 We will also wish to work with stakeholders to consider further how a new registration system would interact with the existing systems. In particular, we would like to consider the potential for rationalising these to ensure that they are coherent and easily understood and that the burden on providers is minimised.

Implementation arrangements

4.26 We are conscious that, as primary care providers are largely outside the existing registration system, it will be important to ensure that providers understand what is required of them. It will also be important that the Commission is given time to become established before being asked to extend its remit and is then allowed to build up the expertise it needs. Given these concerns, we therefore need to consider further how best to implement the new arrangements. In particular, we need

to determine whether it would be reasonable to expect primary care providers to register when the wider registration system comes into force in April 2010, or if logistically it makes sense to use a phased approach with a slower timetable.

4.27 If registration were to be phased in, we would need to identify which, if any, areas should come into force at the same time as the wider registration system, and which would be captured later. We would also need to agree an appropriate timescale. Any approach would need to be proportionate and focused on the risks to patients. For example, the outcome of this consultation might suggest that initially we should regulate only the most complex interventional services provided in primary care settings. The remaining services listed in Annex B and provided in primary care settings could then be brought in at a later date.

4.28 A phased approach to the introduction of registration would need to be linked to any changes needed to the wider regulatory framework. For example, respondents to this consultation could suggest that if the new registration system includes the same essential levels of safety and quality requirements as those in NHS contracts, then they should be removed from contracts and monitored by the new Commission as part of the registration requirements. If, in the light of this, we were to decide that the requirements in NHS contracts should be streamlined, we would not do this until the registration system had been implemented.

What are we consulting on?

4.29 We would welcome your views on the following questions:

> Does the list of activities in Annex B appropriately capture the services where people might be at risk of harm provided in primary care settings? In particular, do you agree with our proposal that ultimately all GP and primary dental services should be within the scope of registration?

> Does the list of activities in Annex B inappropriately capture some services that are less likely to cause harm when provided in primary care settings?

> What information would you expect the new Commission to draw on when making decisions? How could it best do this?

> What is the scope for rationalising the existing requirements on primary care providers if a registration system is introduced?

> When should services provided in primary care settings be required to register? Should we phase in registration?

> If we do phase in registration, how should we determine the services to be captured?

> Is our assessment of the costs and benefits in our accompanying impact assessment (available at www.dh.gov.uk/en/Consultations/Liveconsultations/index.htm) reasonable? Do you have any additional information on impact that we could use?

What will happen next?

4.30 During the consultation period we welcome the views of everyone with an interest. After considering the consultation responses, we will work with the professions and other key stakeholders to finalise the list of regulated activities and confirm the implications for primary care providers. Once we are clear what proportion of providers will be required to register, we will consider, with stakeholders, how best to implement the registration system and to streamline other requirements. The next stage will then be to develop and consult on regulations in secondary legislation over the autumn/winter.

4.31 The Royal College of General Practitioners will shortly be piloting a proposed scheme for accreditation of primary care medical practices. The Department of Health is arranging for independent evaluation of the scheme, in particular to assess the benefits for patients, the general public, and the practices taking part. Decisions on any wider roll-out will be taken in the light of this evaluation and any wider learning from the pilot.

5. Responding to the consultation

The consultation process and questions

5.1 This document launches a 12-week consultation on the proposals for a new system of registration for providers of health and adult social care services. Your feedback on the consultation will inform the development of secondary legislation, which will set registration requirements and the scope of the new system, as well as informing the general transition.

5.2 Subject to the passage of the Health and Social Care Bill, the Government intends to implement the new system of registration on a phased basis from April 2010, with the exception of requirements for HCAI, which will be implemented during 2009/10 for NHS hospitals.

5.3 We expect to report back during autumn 2008 with our response to this consultation and provide the next stage in the development of the registration system by sharing:

> the draft regulations on registration requirements, scope and associated registration issues, including the outcome of consultation on registration of primary care; and

> more detail about the transition to the new registration system.

5.4 This consultation will run for 12 weeks from 25 March 2008 to 17 June 2008. If you wish to respond to the questions raised in this consultation, summarised at Annex D, responses should be emailed to: registration.consultation@dh.gsi.gov.uk

Conclusion

5.5 The framework described here builds on the existing system and seeks to do so in a way that will deliver a proportionate system of registration that will help to ensure the protection of people using health and adult social care services for years to come.

Criteria for consultation

5.6 This consultation follows the Cabinet Office Code of Practice. In particular, we aim to:

- consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy;
- be clear about what our proposals are, who may be affected, what questions we want to ask and the timescale for responses;
- ensure that our consultation is clear, concise and widely accessible;
- ensure that we provide feedback regarding the responses received and how the consultation process influenced the development of the policy;
- monitor our effectiveness at consultation, including through the use of a designated consultation co-ordinator; and
- ensure that our consultation follows better regulation best practice, including carrying out a regulatory impact assessment if appropriate.

5.7 The full text of the Code of Practice is available at: www.berr.gov.uk/files/file44364.pdf

Comments on the consultation process itself

5.8 If you have concerns or comments that you would like to make relating specifically to the consultation process itself, please contact:

Consultations Co-ordinator
Department of Health
2N16, Quarry House
Leeds LS2 7UE
email: Mb-dh-consultations-coordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

5.9 Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

5.10 If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory code of practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

5.11 The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Annex A. Proposed topics for registration requirements – for essential levels of safety and quality

1. We propose there should be 18 registration requirements, which will cover the essential levels of safety and quality of care that people have a right to expect. They will be independently enforceable by the Care Quality Commission.

2. These registration requirements do not represent the limit of our expectations for the quality of health and adult social care. Improvements above levels of essential safety and quality will be encouraged and secured by other levers in the system – for example, through better commissioning, people exercising choice and the new Commission's review and report functions. A separate, revised set of improvement standards will be developed for the NHS and used to benchmark best practice and promote further improvements in service quality. These improvement standards are not part of this consultation and will not be enforceable by the Care Quality Commission.

3. We have developed the requirements so that the Care Quality Commission can enforce them in line with the spirit of the relevant provisions of the European Convention on Human Rights. These requirements do not confer any individual rights of legal redress under the Human Rights Act on people using registered services, but are there to ensure that the Care Quality Commission has a clear remit to act against providers that fail to comply with other legislation designed to protect people's human rights.

4. When deciding whether to take enforcement action, the Commission will be able to take account of the provider's compliance with any other legislation that the Commission believes is relevant to registration (for example, on health and safety, fire regulations or equality). The requirements of other relevant legislation will not be duplicated in registration requirements and so are not included in the topics described in the topics described in the table below.

5. The text in the table below is intended to help the development of regulations for the registration requirements after completion of this consultation. The three main titles represent the overarching topic area that the requirements might fit within. The 18 numbered sub-titles

represent the key individual subject areas for the requirements, focusing on essential safety and quality under the main topics. The text following them explains what each requirement will cover, and will be the starting point for drafting more specific definitions in regulations after this consultation has been completed. The examples are not exhaustive but are purely illustrative, and are designed to enable a practical understanding of the sorts of things the requirement will cover.

People's health and wellbeing are better because the care and treatment they receive are safe and effective

1. Making sure people get the care and treatment that meet their needs safely and effectively
Ensure that people have their health and/or social care needs assessed, and that care and treatment are planned and delivered to meet those needs appropriately, having regard in particular to ensuring their health, safety and welfare and taking account of current evidence-based guidance from relevant professional or expert bodies.
Explanation: This requirement is about managing risk to ensure that people are not harmed by care which is unsafe or unsuitable for their needs. It is also about managing the risk of a service failing to recognise and respond to people's needs and causing harm as a result. For example: > in social care, using person-centred care planning and individual budget support plans to ensure that care promotes independence and does not result in institutionalised care; and > in healthcare, it will draw evidence, where available, of the essential safety and quality of clinical care from approved quality assurance systems, the outcomes of which are subject to evaluation external to the service provider. It will take account of NICE guidance about safety and efficacy issued through its interventional procedure programme, or other authoritative evidence-based guidance as to safety and effectiveness (where NICE guidance is not relevant), to ensure appropriate treatment is provided safely. It would also include the need for a diagnosis to be made if someone presents with symptoms, and for action to be taken in line with care protocols to ensure appropriate treatment, investigations and onward referral or transfer. In addition, it would include a system to ensure that patients are given advice to maintain their health, safety and welfare, and that relevant health protection measures are taken, for example to guard against the spread of infection.

2. Safeguarding people when they are vulnerable
Ensure that people are protected, and do not experience any form of abuse or neglect or are not otherwise harmed, in circumstances when they are vulnerable to harm. Safeguard against the risk of arbitrary deprivation or restriction of liberty. Have arrangements for the appropriate use of restraint or for where a person may be at risk of self-harm. Respond to any instances of abuse, neglect or harm to stop them being repeated (including, for example, reporting critical incidents, making required referrals and participating in case reviews), to support people affected and to ensure that action is taken, with regard in particular to any guidance issued by the Secretary of State for the protection of children (using healthcare or where for example domiciliary care is provided or other adult social care for children) and the safeguarding of people who are, or are at risk of being, vulnerable.
Explanation: This requirement is about managing the risk of people being harmed in circumstances in which they are vulnerable, and responding appropriately when abuse occurs, both to support the abused, and acting to prevent repetition of the abuse. The circumstances that make people vulnerable will be specific to the type of service provided and the people using that service. This will include groups of people who have traditionally been considered more vulnerable and people made vulnerable by the situation they are in (for example those undergoing surgery, recovering on a ward, or facing life changes). The assessment criteria are likely to be quite specific to the different kinds of service.

3. Managing cleanliness, hygiene and infection control
Have effective systems to maintain premises in a clean and hygienic condition, to prevent and control the spread of infection with regard in particular to any guidance issued by the Secretary of State and to ensure people's health, safety and welfare.
Explanation: This requirement reflects the imperative that services ensure the cleanliness and hygiene of their premises and take decisive action to prevent and control infection.The guidance issued by the Secretary of State as referred to above is the Code of Practice for the prevention and control of healthcare associated infections. A firm decision has been taken to include this topic in the registration requirements and this decision is not subject to consultation. However, the Department will consult later in the year on the precise detail of this requirement, and on a new Code of Practice to support it.

4. Managing medicines safely
Manage the ordering, recording, handling, storage, administration and disposal of medicines used in the delivery of the service, having regard in particular to the nature and type of medicines within the control of the service and to any guidance as to essential levels of safety and quality issued by the Secretary of State or expert bodies relevant to medicines and people's health, safety and welfare.
Explanation: This requirement is about managing the risk of people being harmed by medicines being deliberately or accidentally misused. It is not about the prescribing of medicines, but concerns the safe management of medicines (not limited to prescribed drugs administered orally, and including intravenous medication, medical gases, ointments, drops etc). It is applicable to any setting where patients or users of services take medication, whether as part of their specific treatment or not. It includes ensuring that workers involved in the use of medicines receive medicines training relevant to their role. For example: > in healthcare, striking an appropriate balance between the safe storage and timely availability of medicines; and > in social care, keeping records of medicines coming into a care home, being administered and appropriately disposed of.

5. Making sure people get the nourishment they need
Ensure, where meeting nutritional needs is part of the service, that people have access to safe and sufficient nourishment. This includes: the provision of support for eating, drinking or feeding where required; the provision of a sufficient choice of palatable food to meet religious or cultural needs; and the prevention of harm through lack of access to sufficient nutrition and hydration.
Explanation: This requirement is about managing the risk of people becoming malnourished or dehydrated whilst using health or social care services. It applies across all services where people are dependent on the service for their nutritional wellbeing. It includes help to enable people to eat and drink, including where that help is not a specific part of the care or treatment. Providers must be able to spot people at risk of malnutrition, provide adequate nutrition that meets their cultural or religious requirements, and ensure that they do not suffer from malnutrition or dehydration. For example: > in healthcare, this could involve monitoring food and drink consumption of those at risk of malnutrition or dehydration, providing snacks and drinks outside meal times, ensuring help with eating and drinking is accessible and monitoring patients' weight where there is cause for concern; and > in social care, this could involve ensuring that the mealtime experience, including flexibility of meal times, food choice and presentation, supports eating and drinking.

6. Making sure people get care and treatment in safe, suitable places which support their independence, privacy and personal dignity
Ensure that people receive care and treatment in safe, appropriately maintained premises (including mobile premises, ambulances and any other vehicles used to transport people using services or in which care or treatment is delivered, but excluding people's own homes) that are suitable in their location, design and layout for the delivery of the service. Providers must take account of design, technical and operational standards issued by expert bodies as to essential levels of safety and quality that accord with statutory, mandatory and required practice for such premises or vehicles, having regard in particular to people's health, safety and welfare, including their independence, personal dignity and privacy. Ensure that premises are adequately maintained.
Explanation: This requirement is about managing the risk of people being harmed because premises are unsafe, or not fit to provide the care and treatment they are registered to provide. Providers are expected to ensure they meet building regulations, and satisfy any legal requirements applying to vehicles used for the transport of people using the service. For example: > in healthcare, service providers will need to demonstrate that the safety of operating theatres is ensured through compliance with relevant technical specifications; and > in social care, the requirement would apply (for example) to care homes and could include ensuring the building is accessible to people using the service, and that it provides a homely environment.

7. Using equipment that is safe and suitable for people's care and treatment and supports people's independence, privacy and personal dignity

Ensure that the right equipment and supplies are used to meet people's care and treatment needs. Ensure that equipment and supplies used in providing the service are sufficient in number, suitable and safe in their design and construction, takes account of technical specifications and guidance issued by the manufacturer or by expert bodies relevant to the purchasing, maintenance, and safe and competent use of such supplies and equipment, having regard in particular to health, safety and welfare. Where equipment is used to support the activities of daily living, that it promotes people's independence, personal dignity and comfort.

Explanation: This requirement is about managing the risk to people from the use of incorrect or unsafe equipment in their care or treatment.
All providers must ensure that workers are properly trained to use any specialist equipment.

For example:

> in healthcare, the requirement will focus more upon equipment used in clinical procedures and include the cleaning and decontamination of reusable devices; and
> in social care, it is more likely to relate to telecare devices such as enuresis, epilepsy sensors and call-alarm systems. It could also encompass everyday equipment adapted to make sure people are able to maintain their independence.

People's health and wellbeing are better because the care and treatment they receive are personalised and fair

8. Involving people in making informed decisions about their care and treatment
Ensure that people are involved in decisions about their receipt of care and participation in the service provided. Provide information and practical support for such involvement where it is needed. Where a person is assessed as lacking capacity to make decisions about their treatment and care, ensure that decisions are made in their best interests which take full account of the views of their relatives and carers along with those of professionals. Ensure that the service delivered to people and the manner in which it is provided reflect, as far as reasonably practicable, their aims, wishes and diverse needs, with reference to their age, gender, sexual orientation, religion, culture and impairments.
Explanation: This requirement is about managing the risk of people not being involved in decisions about their care and treatment or not having the information they need to be involved in making decisions. It also requires providers to ensure that people are supported in making decisions in accordance with the Mental Capacity Act and associated code of practice. In addition, providers must ensure that the care and treatment they provide respect diverse needs related to age, gender, sexual orientation, religion, culture and impairments, etc. For example: > in healthcare, the requirement could include the provision of information to enable people to protect their health, safety and welfare, for example relevant information about pre- and post-operative self-care and avoiding risks to recovery and recurrence of poor health; and > in social care, it could mean involving people in the review of their care plan. It could also include making sure people are able to take part in culturally appropriate activities such as attending a relevant place of worship.

9. Getting people's ongoing agreement to care and treatment
Ensure that people consent to treatment and have control over the care they receive. Ensure that people are able to opt out of treatment, where there is no statutory requirement to provide it, having regard in particular to any guidance issued by the Secretary of State.
Explanation: This requirement is about managing the risk of people being subject to care and treatment they do not want. For example: > in healthcare, the requirement is about informed consent. The provider must ensure that people have the information needed to make an informed choice about their treatment, including the risks involved in different treatment options. In particular, the provider should ensure, where appropriate, that decisions about resuscitation are taken with particular regard to any guidance issued by the Secretary of State; and > in social care, the requirement is about people having choice and control and directing the support they receive through person-centred care planning and personal or individual budget support plans. It includes agreeing how risks will be managed and how care may be delivered in a specific manner, for example for religious or cultural reasons.

10. Responding to people's comments and complaints
Ensure that people and their relatives and carers are aware of and can use, with support where needed, and without prejudice to their care and treatment, simple and clear arrangements for handling comments and complaints. Ensure that complaints about failures to ensure people's health, safety and welfare are investigated and resolved promptly and effectively. Learning from complaints is reflected in risk management, quality assurance, clinical governance and training and development arrangements. (See also 5.)
Explanation: This requirement is about managing the risk of providers failing to respond to and learn from complaints about any aspect of the care or treatment they provide, and ensuring that those complaints which relate to people's health, safety and welfare are investigated and resolved, and that lessons are learnt and acted upon. People should be equipped and supported to achieve a reasonable outcome to any complaints and be assured that complaining will not prejudice their future care or treatment.

11. Supporting people to be independent
Provide, where possible, opportunities for people to undertake self-care (including self-management of treatment and medicines) and receive support that promotes their independence, freedom of action and community inclusion. Respect people's choices, informing and supporting them in managing the risks they wish to take to promote their independence.
Explanation: This requirement is about managing the risk of people being institutionalised or receiving care which overprotects them or makes them dependent. This involves providers enabling people to be as independent as their circumstances will allow them to be, responding to their informed decisions about their own treatment and care, and providing support. For example: > in healthcare, this requirement might be about supporting people in managing long-term conditions; and > in social care, it might include enabling people to use local facilities such as shops and public transport. It could also include supporting people in developing independent living skills such as money management or cooking.

12. Respecting people and their families and carers
Ensure that people and their relatives and carers are treated with respect. Ensure that they are able to express their needs and concerns, particularly where they need support to communicate effectively, and have them acted on in a timely manner. People's privacy, autonomy and dignity are safeguarded and their human rights and equality are respected. Where appropriate, ensure that they are assisted to maintain their private and family lives and social support networks.
Explanation: This requirement is about managing the risk of people not being treated with dignity and respect, for example by addressing them in their preferred manner and safeguarding their privacy. It involves treating people as individuals, respecting their human rights and having systems to ensure that they are not discriminated against. It also includes enabling contacts with family and support networks to be maintained. For example: > in healthcare, it is more likely to be concerned with ensuring that clinicians and other workers respect the views, needs and equality of patients, carers and families when delivering clinical care; and > in social care, for example in a care home, it could be about ensuring that there is access to a safe, suitable place to see visitors, respecting privacy and dignity, and ensuring that service users are enabled to go out to access services such as dentistry and personal grooming (hairdressing etc).

People get better care and treatment because systems are operated to manage and deliver safe, effective, fair and personalised services

13. Having arrangements for risk management, quality assurance and clinical governance
Have systems in place to manage, assess and report upon the safety and quality of care and treatment provided, and do so regularly. This includes taking account of the views of people who use or may use the service and the advice of clinical and other professional experts. Systematically, identify and assess risks (including for example analysing reporting errors and reporting adverse incidents) and take action to manage risks to health, safety and welfare. Use reports about the quality of care and treatment provided and learn from events to inform decisions about action needed to secure people's health, safety and welfare.
Explanation: This requirement is about managing the risk of providers not having appropriate policies, procedures, systems and accountability in place to support the assurance of safety and quality. Providers will need to ensure their systems are effective and up-to-date, generate the information needed by the service and the regulator to assure safety and quality, and take account of the views of people using services. For example: > in healthcare, this requirement will reflect the importance of providers having the appropriate safety and clinical governance systems and processes in place for the activities they are providing including where available, approved clinical quality assurance systems, the outcomes of which are subject to evaluation external to the service provider; and > in social care, it will focus particularly on quality assurance systems that could include gathering the views of the people using the service, of their families and of the professionals involved in their care and acting upon this feedback. It could also include self-monitoring and internal audits, and the production and implementation of quality plans.

14. Keeping records of the provision of care and treatment

Keep records to support the delivery of personalised care and treatment and to ensure people's health, safety and welfare.

Ensure information entered into records is accurate and up-to-date and that records (both paper and electronic) are stored securely to ensure confidentiality (including the security and encryption of records, particularly portable records held in electronic media) but in a way that allows timely access to and appropriate sharing of information to support delivery of care and treatment. Ensure people are able to access information about themselves kept in records.

Ensure recorded information is used to review and inform quality assurance and clinical governance processes.

Explanation: This requirement is about managing the risk of providers failing to keep and protect the confidentiality of adequate records about the care and treatment they provide.

For example:

> in healthcare, the records might include information about controlled drugs issued to any individual clinician; and
> in social care, the records might include care plans setting out people's goals and aspirations, assessments of their support needs, how risks will be managed to promote independence and care delivered. People should have access to this information about their care.

All providers will need to keep records relating to health and safety (including, for example the dissemination of safety notices, clinical and other professional practice), complaints made, their investigation and any action taken as a result, and employment.

15. Checking that workers are safe and competent to give people the care and treatment they need

Ensure that people get care and treatment from workers (including temporary, agency and bank workers, locums, secondees, volunteers, subcontractors and professionals working within a service in a private capacity, honorary contract holders, and those with practising privileges) who, before they deliver care or treatment or are granted practising privileges, have been subject to initial checks to confirm as far as possible that they:

> are of integrity and good character and physically and mentally fit for the purposes of the work they are employed to perform (subject to any reasonable adjustments under the provisions of the Disability Discrimination Act). This should include, for example, where there is a statutory requirement, the undertaking of checks through the Criminal Records Bureau (CRB) or Independent Safeguarding Authority to confirm their suitability to work with people in vulnerable circumstances; and
> have qualifications, skills, knowledge and experience and any up-to-date professional, workforce or other registration needed for the role they are employed to perform.

Ensure that such checks are repeated at intervals relevant to the role performed to ensure the continuing suitability and up-to-date competency (including participation in continuing professional development where appropriate) of workers. Where a worker is found to have become unsuitable, the provider takes appropriate action and inform the appropriate governing body. This will include referral to the Independent Safeguarding Authority where the relevant harm test is met.

Such checks are to be performed in accordance with legislative requirements relevant to the role, normally by the service provider or, where the worker does not have a contract of employment with the service provider, confirmation is obtained by the service provider that they have been performed by another relevant body (eg seconding employer, supplying agency or professional regulator).

15. Checking that workers are safe and competent to give people the care and treatment they need (continued)

Explanation: This requirement is about managing the risk of people being exposed to harm from unqualified or unsuitable workers. Providers must ensure that all workers employed to deliver care, treatment or support are appropriately trained and qualified and fit to carry out their role. This is linked to, but distinct from, professional regulation, which is concerned with regulating individuals working in the health and social care sectors.

For example, providers must ensure that: recruitment procedures are robust; references are received and checked; and, where workers are subject to CRB or Independent Safeguarding Authority checks, these are up-to-date and in order. Where professional registration is required for the role, checks should be made with the relevant governing body.

Where necessary, checks should be repeated to ensure that workers continue to be fit to practise.

16. Having enough competent staff to give people the care and treatment they need

Ensure that people receive care and treatment from staff (including temporary, agency and bank workers, locums, secondees, subcontractors, honorary contract holders and professionals with practising privileges) who, at any given time, are sufficient in number to ensure people's health, safety and welfare.

Explanation: This requirement is about managing the risk of people being harmed because of there being insufficient numbers of qualified staff to provide the care or treatment the provider is registered to provide. The Care Quality Commission is not expected to set staffing levels. Providers need to be able to justify their decisions about the adequacy of the staffing levels they are using to ensure the safety and quality of their service, demonstrating the rationale for the sufficiency of their staffing deployment decisions with reference to outcomes for people using the service, risk assessments, authoritative benchmarks and other evidence. The new Commission will investigate further where it has concerns that staffing levels are inappropriate for the activities being provided or that they are unsafe and pose a risk to people.

17. Supporting workers to give people the care and treatment they need

Ensure that people receive care and treatment from workers (including temporary, agency and bank workers, locums, secondees, volunteers, subcontractors, honorary contract holders and professionals with practising privileges) who are safe and supported in their duties and held accountable.

Explanation: This requirement is about managing the risk to people of harm because workers are not supported by the provider to ensure they are able to carry out their duties safely and appropriately.

For example, this requirement will include carrying out management activity including induction, supervision and appraisal which will form part of, but is not limited to, quality assessment or clinical governance processes, to:

> ensure that workers perform their duties in a manner that is consistent with the registration requirements and protects their own health, safety and welfare;
> ensure that workers do not exceed the limits of their responsibility and competency;
> identify training and development needs, including continuing professional development where relevant, and provide appropriate support to workers;
> enable professionally registered workers to provide evidence to their regulators that they continue to be fit to practise;
> address problems faced by workers in performing their duties and encourage workers to raise any concerns they have about people's health, safety and welfare, including the provision of internal whistle-blowing arrangements and advice that public interest disclosures may be made to the regulator.

For example:

> in healthcare, there will be an emphasis on engaging clinicians in clinical governance processes, including appraisal and revalidation, on the use of remediation and mentoring to address any areas of concern about professional practice, and on making reference to professional regulators where appropriate; and
> in social care, the requirement will involve regular supervision and performance appraisal and ensuring that training and development activity is focused on promoting people's independence, supporting choice and control and enabling people to make a positive contribution to their communities.

18. Working effectively with other services

Ensure that people's health, safety and welfare are safeguarded when responsibility for their care and treatment is shared between or transfers to and from the registered provider. For example, by planning for and sharing information to support admission, discharge and transfers; by planning for co-ordinated action in the case of emergencies and to contribute to the protection of public health, safety and welfare; and by supporting people to gain access to other health and social care support they need.

Explanation: This requirement is about managing the risk of harm to people due to services not communicating about the care and treatment they are providing. It is also to ensure that people receive appropriate support to access other services, and that the service can respond to emergencies that need to be tackled on a multi-agency basis.

For example:

> in healthcare, this requirement will ensure that separate providers within a care pathway work together to make certain the workers involved jointly in care have regard to health, safety and welfare. It will also ensure, for example, that the service acts to prevent the spread of infection between people using its services and the wider community; and
> in social care, it will ensure that people are supported to access healthcare services, for example GPs and dentists.

This requirement applies particularly to those working across health and social care.

Annex B. Scope

Proposals for services to be covered by regulated activities

1. The following tables contain our proposals for the scope of the Care Quality Commission's future registration system. We have attempted to keep duplication between the registered activities to a minimum.

2. Please note that the descriptions do not represent regulations at this time. We will be drafting regulations once this consultation is complete, and will base them on the descriptions in this annex and the feedback we receive via this consultation.

3. Using the risk criteria shown in Chapter 3, we have grouped services into 19 potential regulated activities (broad service areas or types of care). Each topic describes the types of care we propose for registration, illustrated with examples of what the Commission would or would not cover, as appropriate. As described in Chapter 3, we propose that providers of any services covered by these descriptions would need to be registered by the Care Quality Commission, regardless of whether they are health or social care, public, private or third sector services.

4. The purpose of the Care Quality Commission, in terms of registration, is to regulate organisations and the systems that operate within them, via the registration requirements. It is not our intention that organisational regulation should replace professional or any other forms of existing regulation, but rather that these systems should work together. With this in mind, we have excluded from the scope of registration types of care where existing regulation provides appropriate coverage. This coverage is illustrated in each table for those activity topics where it exists.

Coverage of primary care

5. Chapter 4 explains that we expect that providers of regulated activities in primary care settings will be required to register in the same way as providers in any other setting. The proposals for services to be covered as regulated activities include a category which, as drafted, would capture all 'high street' dental practices. As set out in Chapter 4, respondents to this consultation are asked to consider when and how the registration system should be extended to include GP practices and whether the scope of the new Commission should include the registration of primary dental services.

Consultation on changes to private and voluntary healthcare regulations

6. On 18 March we published a consultation document on proposed changes to regulations under the Care Standards Act 2000, for private and voluntary healthcare.[14]

7. This consultation contains proposals to amend the regulations governing private and voluntary healthcare to:
   > remove certain private and voluntary healthcare services from regulation by the Healthcare Commission; and
   > ensure that there is clarity about how certain regulations should apply to private and voluntary healthcare.

8. Subject to the outcome of that consultation, these changes will be implemented from October 2008, and operate for the period up to the implementation in 2010 of the new registration system under the Care Quality Commission, as presented for consultation in this document. The future scope of registration will build on these changes made to the Care Standards Act regulations.

14 NHS Medical Directorate. *Private and voluntary health care: Care Standards Act 2000. Regulations and national minimum standards consultation document. Department of Health, 2008.* Available at: www.dh.gov.uk/en/consultations/liveconsultations/DH_083519. The PVH consultation closes on 10 June 2008.

Proposals for services to be covered by regulated activities

Proposed regulated activity name: Personal care

Activity topic description

Except where provided as part of another regulated activity, services providing:

- direct assistance with washing, bathing, dressing or oral, skin or hair care that a person would normally perform for themselves on a day-to-day basis without support;
- direct assistance with eating or drinking;
- administration of medicines;
- direct management of urinary or bowel function or menstruation;
- prompting and supervision where any person lacks mental capacity to perform any of the above personal care tasks for themselves without such support; and
- activities that restrict or deprive liberty or seclude a person, other than as part of a custodial sentence, including for example activities undertaken to manage aggression or behaviour that challenges services.

Examples of care that we propose would need to be registered with CQC

- The provision of personal care in care homes, nursing homes and hospitals.
- Services supplying care workers to provide personal care in people's own homes, for example, domiciliary care agencies, both where the workers are engaged and directed by the registered provider and where they are provided as suitable and competent to deliver personal care under the direction of the person receiving support.
- The provision of personal care, but not accommodation, in supported housing – for example the personal care, but **not** the accommodation, in extra-care housing.
- The provision of personal care in community-based settings where the purpose of the service is the provision of personal care – for example community-based bathing services.

Examples of care that we propose would not need to be registered with CQC

- Private arrangements agreed between individuals, for example personal care provided by family or friends in the course of family or other personal relationships.
- The provision of personal care by a personal assistant engaged and directed by the person receiving their support (whether self-funding or using direct payments or individual personal budgets to fund the arrangement).
- Direct payment or personal individual budget advisory or similar services, for example, support for self-assessment of social care needs and arrangement of services to meet those needs (such as brokerage).
- Counselling services, for example, provision of advice and support for decision making and coming to terms with life changes.
- Advocacy services – services supporting people in getting their voices heard.
- Befriending and mentoring services.

Proposed regulated activity name: Personal care (continued)

Please note that where a person engages and directs a personal assistant to provide their care, this arrangement between individuals cannot be regulated in the same way as a formal service structure. Support is available to help people arranging their own care in this way to manage the flexibility and risks involved by themselves.

Care not proposed for CQC regulation as overseen by other regulatory systems

> The provision of personal care in community-based health and social care, for example, day care services where the primary aim of the service is to provide treatment or support health, welfare, education, employment, social activity or kinship support and where people using the service additionally have their personal care needs met to enable them to access the service (covered by local government assessment).
> The provision of workers to deliver personal care in a service regulated by the Care Quality Commission, for example by employment agencies who provide workers as suitable and competent to deliver personal care in a care home.
> Children's social care.

Please note that some employment agencies who provide nurses and care workers to care homes regulated by the Commission for Social Care Inspection (CSCI) are currently also themselves required to register with CSCI as domiciliary care agencies. They are additionally covered by the Conduct of Employment Agencies and Businesses Regulations 2003, for which the DTI is the lead regulatory authority. We are proposing that the new Commission will not register employment agencies that only supply workers to other registered services. Agencies providing nurses and care workers to people in their own homes would still need to register. **What are your views on the proposals for the registration of agencies who supply workers to other registered services, under this activity topic?**

Proposed regulated activity name: Accommodation together with personal or nursing care

Activity topic description
Services where accommodation is provided together with personal care or nursing care, where the person receiving care does not own the accommodation provided or have the rights and freedoms usually associated with tenancy (except where provided as part of another regulated activity).

Examples of care that we propose would need to be registered with CQC

> The provision of care home and nursing home accommodation, including associated support for daily living in the accommodation – for example management of health and welfare, obtaining food and providing meals, laundry and cleaning, management of personal finances, and planning and pursuit of aims and kinship support.
> The provision of in-patient accommodation and associated support from nursing staff during in-patient treatment and care.

Examples of care that we propose would not need to be registered with CQC

> The provision of accommodation, not as part of residential care, to people who receive separate social care support – for example the housing element of extra-care housing (please note that the personal care element of extra-care housing is covered by the personal care activity topic).

Care not proposed for CQC regulation as overseen by other regulatory systems

> Accommodation provided as part of supported housing arrangements where a person receiving care has the rights and freedoms usually associated with tenancy of the accommodation. In this case the housing corporation concerned would have the primary regulatory role with regard to social housing accommodation.

Proposed regulated activity name: Accommodation together with intensive treatments

Activity topic description
Services where accommodation is provided together with an intensive treatment regime for detoxification or assisted withdrawal for people recovering from addiction, or for people who have eating disorders, where the person receiving care does not own the accommodation provided nor have the rights and freedoms usually associated with tenancy.

Examples of care that we propose would need to be registered with CQC

> Residential treatment for addiction or eating disorders, including associated support for daily living whilst resident – for example management of health and welfare, obtaining food and providing meals, laundry and cleaning, management of personal finances, and planning and pursuit of aims and kinship support.

Proposed regulated activity name: Accommodation together with personal care and further education

Activity topic description
Provision where accommodation is provided together with personal care and further education.

Please note, this type of provision is currently registered with CSCI. We welcome views on whether the Care Quality Commission should fully assume this role, or whether these providers should transfer to Ofsted.

Examples of care that we propose would need to be registered with CQC

> Specialist further education colleges.

Proposed regulated activity name: Palliative care

Activity topic description
Services focused on relieving the emotional, social and physical needs of those approaching the end of life.

Examples of care that we propose would need to be registered with CQC
> Hospices and hospice at-home services, outreach, community-based services and specialist palliative care services in hospitals, excluding services provided by a GP to patients on their registered list (separate registered activity – primary medical services).
> Care homes providing residential and/or nursing care to those at the end of life.
> Respite at home for families of people with life-limiting/life-threatening conditions.

Examples of care that we propose would not need to be registered with CQC
> Counselling services providing advice and support for decision making and coming to terms with life changes.
> Befriending and mentoring services.

Proposed regulated activity name: Surgical services

Activity topic description
All surgical treatment (other than minor surgery) by or under the direction of a consultant on a specialist register or general medical practitioner on the GP register; other services of a similar nature provided by other professionals, for example nurses; and associated support services, such as physiotherapy, including cosmetic surgery and similar procedures, and consultations within those specialties (excluding dental services – separate activity).

Examples of care that we propose would need to be registered with CQC
> All surgical procedures carried out under anaesthesia or sedation, other than minor procedures involving the use of a scalpel and local anaesthetic provided as part of a primary medical service (separate activity). This includes all surgical specialties (for example general surgery, cardiac surgery, cosmetic surgery, cataract extraction etc) carried out by any professional, any of these services in any setting, including primary care and community settings.

Examples of care that we propose would not need to be registered with CQC
> Non-surgical cosmetic procedures, akin to simple clinical procedures but performed for non-clinical reasons, for example, non-surgical use of lasers and intense pulsed light equipment, cosmetic use of botulinum toxin and dermal fillers, and similar cosmetic treatments.

Care not proposed for CQC regulation as overseen by other regulatory systems
> Minor podiatric procedures involving the use of a scalpel and local anaesthetic, for example minor nail bed procedures (covered by professional regulation).

Proposed regulated activity name: Dental services

Activity topic description
All dental and orthodontic treatments by, or under the direction of, a dentist or clinical dental technician.

Examples of care that we propose would need to be registered with CQC
> All 'high street' dentistry and orthodontics, including dental work done by a hygienist or other dental care professional.
> Supply of dental appliances by a clinical dental technician.
> Dental surgical treatments, for example minor oral surgery, dental implants and dental treatment under general anaesthetic.
> Dental diagnostic imaging.

Examples of care that we propose would not need to be registered with CQC
> Dental public health services, oral health promotion and preventive advice in accordance with the Functions of PCTs (Dental Public Health) Regulations 2006 (S.I. No. 2006/185).
> Tooth whitening.

Proposed regulated activity name: Diagnostic services

Activity topic description
Intensive or invasive diagnostic procedures or laboratory diagnostics.

Examples of care that we propose would need to be registered with CQC
> Diagnostic imaging services (excluding dental services – separate activity) including forms of endoscopy, X-ray, MRI, CT scanning, nuclear medicine, ultrasound, fluoroscopy and interventional radiology – to include both undertaking the procedure and reporting on images.
> Diagnostic laboratory services, for example pathology, histopathology, cytology.

Care not proposed for CQC regulation as overseen by other regulatory systems
> Non-invasive or simple diagnostics, for example sight tests, blood pressure checks and 'pin-prick' blood tests (covered by professional regulation).

Proposed regulated activity name: Specialist medical services

Activity topic description
All medical treatment provided by or under the direction of a consultant doctor on a specialist register, and other services of a similar nature provided by other professionals, for example nurses, and associated support services, for example physiotherapy (other than services falling into the categories of surgical services, diagnostics, maternity services, emergency and urgent care, palliative care, primary medical services and mental health services, described separately).

Examples of care that we propose would need to be registered with CQC
> All medical specialties, for example general medicine, rehabilitation medicine, therapeutic radiology, intensive care, dialysis, paediatrics, GU medicine and critical care services carried out by any professional.

Examples of care that we propose would not need to be registered with CQC
> Alternative and complementary medicine, for example acupuncture, Chinese medicine and homeopathy.
> Support and advice by lay voluntary groups.

Proposed regulated activity name: Emergency and urgent care

Activity topic description
Emergency and urgent care services, including transportation.

Examples of care that we propose would need to be registered with CQC
> Accident and emergency services.
> Emergency ambulance services and community first responder schemes.
> High-dependency transfers, for example intensive care transfers.
> Minor injuries units.
> Walk-in centres.
> Out-of-hours services (excluding services provided by GPs to patients on their registered list – separate registered activity – primary medical services).

Examples of care that we propose would not need to be registered with CQC
> Any first aid treatment administered to an injured or sick person before professional clinical care is available, including that provided by non-professional individuals and first aid organisations, excluding community first responder schemes.
> Non-urgent patient transport services, for example non-urgent, planned transportation of patients, including hospital car services.

Please note that these proposals split patient transport services into high-dependency and non-urgent transfers. **What are your views on the exclusion of non-urgent patient transport services under this activity topic?**

Proposed regulated activity name: Maternity services – obstetrics and gynaecology

Activity topic description
Specialist maternity care provided by appropriately qualified professionals and their support staff to women and their babies during pregnancy and birth and post-natally.

Examples of care that we propose would need to be registered with CQC
> Maternity clinical services.
> Gynaecology and uro-gynaecology services.
> This excludes services provided by a GP to patients on their registered list.

Examples of care that we propose would not need to be registered with CQC
> Advice not involving clinical care, such as that given at 'parent craft' classes – for example advice on breast feeding, diet, exercise, baby bathing etc.
> Non-specialist maternity care, for example blood pressure checks or medical examinations unrelated to pregnancy.
> Support and advice by lay voluntary groups.
> Family planning and sexual health advisory services.

Care not proposed for CQC regulation as overseen by other regulatory systems
> Fertility and associated services currently required to obtain a licence from the HFEA under the Human Fertilisation and Embryology Act 1990.
> Social care support during pregnancy and childbirth, for example as part of Sure Start services (covered by local government assessment).

Proposed regulated activity name: Termination of pregnancy

Activity topic description
Termination of pregnancy.

Examples of care that we propose would need to be registered with CQC
> Termination of pregnancy, whether by surgical or medical procedures.

Examples of care that we propose would not need to be registered with CQC
> Pregnancy testing services.
> Support and advice by lay voluntary groups.

Proposed regulated activity name: Specialist mental health services

Activity topic description
All specialist services for treating mental disorders, including mental illness, organic conditions, brain injuries, learning disabilities and personality disorder. Excludes services provided by a GP to patients on their registered list.

Examples of care that we propose would need to be registered with CQC
> The provision of treatment or care by or under the direction or supervision of a psychiatrist, whether on an inpatient, outpatient or community basis.
> The administration of drugs and therapies, and the provision of treatment or nursing (or both).
> Psychotherapists' and psychologists' services as part of an inpatient service, or as part of a package of care that is under the direction or supervision of a psychiatrist.

Examples of care that we propose would not need to be registered with CQC
> Counselling.
> Alternative and complementary medicine, for example acupuncture, Chinese medicine and homeopathy.
> Lay groups providing support, advice, advocacy or service user empowerment.

Care not proposed for CQC regulation as overseen by other regulatory systems
> Stand-alone psychotherapy services (for example cognitive behavioural therapy, psychodynamic therapy, gestalt therapy) not under the direction or supervision of a psychiatrist (see Therapies activity, page 88 – covered by professional regulation).

Proposed regulated activity name: Detention or deprivation of liberty for care or treatment

Activity topic description
Detention of persons under the Mental Health Act, for the purposes of compulsory treatment; and deprivation of liberty under the Mental Capacity Act.

Examples of care that we propose would need to be registered with CQC
> Any service involving detention of persons under the Mental Health Act, for the purposes of compulsory treatment.
> Any service involving deprivation of liberty under the Mental Capacity Act.

Proposed regulated activity name: Nursing care

Activity topic description
Nursing care as a stand-alone service, not provided as part of other separate activities listed.

Examples of care that we propose would need to be registered with CQC
> Nursing care in nursing homes.
> Nursing services in people's own homes, for example district nurse services and PCT community nursing services.
> Services supplying nurses to provide nursing care in people's own homes, for example nursing agencies, both where the nurses are engaged and directed by the registered provider and where they are provided as suitable and competent to deliver nursing care independently.

Care not proposed for CQC regulation as overseen by other regulatory systems
> Community nursing services not in people's homes, for example school nurse services.
> Health visitor services.
> The provision of workers to deliver nursing care in a service regulated by the Care Quality Commission, for example by employment agencies who provide workers as suitable and competent to deliver nursing care in a care home.

Please note that employment agencies supplying nursing care workers to care homes regulated by CSCI are currently also required to register with CSCI as nursing agencies. They are additionally covered by the Conduct of Employment Agencies and Businesses Regulations 2003, for which the DTI is the lead regulatory authority. **What are your views on the proposals for the registration of agencies who supply workers to other registered providers under this activity topic?**

Proposed regulated activity name: Prescribing, administration, sale and supply of medicines

Please note: not proposed to be regulated as a separate group.

Activity topic description
Prescribing, administration, sale and supply of medicines, other than as part of separate activities listed.

Examples of care that we propose would need to be registered with CQC

> We are not proposing to regulate these services as a separate group – only as support to other activities, for example hospital pharmacy services and administration of medicines as part of personal care.

Examples of care that we propose would not need to be registered with CQC

> Private arrangements agreed between individuals, such as the provision of medicines by family or friends in the course of family or other personal relationships – for example collecting a prescription for a family member or friend, or supporting them to remember when to take medication.

Care not proposed for CQC regulation as overseen by other regulatory systems

> The prescription, administration, sale and supply of medicines by registered health professionals (for example doctors and other suitably qualified professionals), pharmacy and similar services (covered by the Medicines Act and professional regulation) other than as part of separate activities listed.

Proposed regulated activity name: Therapies

Please note: not proposed to be regulated as a separate group.

Activity topic description
Care services provided by allied health professionals other than as part of separate activities listed.

Examples of care that we propose would need to be registered with CQC
> We are not proposing to regulate these services as a separate group – only as support to other activities, for example, speech and language therapy as part of a stroke unit under medical services.
> To keep under review as professional practice evolves or service models develop.

Examples of care that we propose would not need to be registered with CQC
> Alternative and complementary medicine, for example acupuncture, Chinese medicine and homeopathy.

Care not proposed for CQC regulation as overseen by other regulatory systems
> 'High street' physiotherapy (covered by professional regulation).
> Optometry (covered by professional regulation).
> Psychotherapy services, for example cognitive behavioural therapy, psychodynamic therapy and gestalt therapy (covered by professional regulation).
> Other stand-alone allied health professional services (covered by professional regulation).

Proposed regulated activity name: Telemedicine and telecare

Please note: not proposed to be regulated as a separate group.

Activity topic description
Services providing support and diagnosis via telephone or other electronic systems, other than as support to activities listed above.

Examples of care that we propose would need to be registered with CQC
> We are not proposing to regulate these services as a separate group immediately as they are not yet widespread in this country – this will be reviewed as the market evolves.

Examples of care that we propose would not need to be registered with CQC
> The provision of services that provide a remote response, via an alert system, to requests for support from people living in their own homes.

Care not proposed for CQC regulation as overseen by other regulatory systems
> Remote advisory services, eg NHS Direct (covered by DH).

Proposed regulated activity name: Primary medical services

Activity topic description
Medical treatment provided by, under the direction of, or under the supervision of a general medical practitioner on the GP register, or equivalent primary medical care provided by another medical professional, including nursing care.

Examples of care that we propose would need to be registered with CQC
> Diagnosis, treatment, prescribing and dispensing provided by or under the direction of a GP.
> Diagnosis and prescribing by a nurse, or any healthcare professional; treatment or supply or administration of medicines by or under the direction of a nurse, or any healthcare professional; and any other nursing care provided as part of a primary medical service.
> Primary medical care equivalent to that provided by a GP, provided by any medical professional, including that provided in prisons, detention centres and immigration removal centres, and services provided in slimming clinics.

Examples of care that we propose would not need to be registered with CQC
> Non-clinical services, such as support and advice – for example counselling services.

Annex C. Examples of how the registration requirements would work

Example 1 – making sure people get the nourishment they need

Rationale
When people do not get the support they need to eat and drink whilst in hospital or receiving residential care, there is a risk of serious harm to their health from malnutrition and dehydration. This in turn can dramatically affect the person's rate of recovery from their treatment and compromise their overall wellbeing, potentially increasing their susceptibility to further ill-health, complications and a delayed discharge from hospital. The requirement for registration reflecting this risk could be as follows:

Requirement
Making sure people get the nourishment they need
Ensure, where meeting nutritional needs is part of the service, that people have access to safe and sufficient nourishment. This includes: the provision of support for eating, drinking or feeding where required; the provision of sufficient choice of palatable food to meet religious or cultural needs; and the prevention of harm through lack of access to sufficient nutrition and hydration.

1. The criteria that will be used to assess compliance with the requirements for registration will be developed by the Care Quality Commission. Some activities or settings may have different priorities or emphasis, and will thus be monitored by the new Commission against a different combination of criteria for each registration requirement. For example, the criteria developed for an acute hospital may have a different feel to those developed for older people's residential care.

2. The criteria might include matters such as those listed below, but the lists of criteria in this annex are purely illustrative. They are included to demonstrate how the link between registration requirements and criteria would work, but will not be for the Department of Health to set and do not pre-empt decisions the new Commission will make about the range and types of criteria it will use. The criteria will be developed by the new Commission, following a separate consultation process, once we have published our registration requirements and regulations.

Compliance criteria could be based on:

- the provider having screening procedures that (i) identify people who are at high risk of, or suffering from, malnutrition and/or dehydration, (ii) ensure that their weight and consumption of food and drink are monitored, and (iii) ensure that nutritional and hydration support is provided;
- where people are at high risk, their need for support being assessed and provided, having regard to relevant guidance;
- having appropriately trained staff to provide people with support with eating, drinking or feeding that is sensitive to their dignity;
- allowing sufficient time for people to finish their meals;
- survey results indicating people's satisfaction with meals;
- the number of people requiring treatment for dehydration or malnutrition, where that was not the reason for their admission or attendance;
- the number of complaints received about nutrition or hydration, support with meals or quality of food;
- reported untoward incidents where nutrition or hydration is a factor;
- where people do not eat meals offered to them, their views or the views of their carers being sought, and nutritional support or alternative food choices being offered where needed;
- people who are not at high risk being offered a choice of sufficient drinks (including water) and sufficient, nutritionally balanced meals (based on average nutritional needs) that they are able to eat, and including healthy options;
- people being offered meal choices that allow them to observe their cultural and religious dietary needs;
- the provider being compliant with other legal requirements relating to food safety, such as health and safety legislation relevant to the storage and preparation of food;
- all staff working on food preparation and serving being trained to comply with food hygiene regulations;
- access to snacks and drinks being made available outside set meal times;
- people's particular dietary needs being taken into account in menu planning; and
- people with health-related specific food needs (for example allergies or digestive disorders) being offered alternative, nutritionally-balanced meals that they are able to eat.

3. Once the new Commission has developed and published its criteria, following consultation with stakeholders, we expect it to use the criteria to assess providers' compliance with the requirements for registration. This does not mean that a provider would be considered to be failing the registration requirement if it performed poorly on particular criteria, but that, taken together, the criteria would provide evidence that the Commission would use in coming to a judgement about whether people were receiving adequate levels of nourishment. This will be decided by the new Commission, and Government will not be involved in this judgement.

Action by the Commission

4. We would then expect the new Commission to investigate further and consider taking appropriate action if assessment against the criteria revealed concerns, for example:

   > if a provider persistently fails to identify people who are at high risk of malnourishment and/or dehydration;
   > if a provider persistently fails to provide appropriate nutritional and/or hydration support to people who are at high risk;
   > if a provider persistently provides insufficient food and drink to meet average nutritional needs or provides unsafe or unsuitable food that people are unable to eat; or
   > if there is an untoward incident, or complaints from patients/residents, relatives or staff where nutrition or hydration may be a factor.

5. If the Commission decided that people were being put at risk by failure of the provider to provide adequate nourishment, it will have a range of enforcement powers at its disposal, such as warning notices, fines, prosecution, temporary suspension of services or cancelling the provider's registration for some or all of its services. The Commission will be required to consult upon and publish an enforcement policy document, setting out in which circumstances it will use its enforcement powers.

6. Action to cancel registration might be appropriate where the provider does not demonstrate the organisational capacity or willingness to put in place, within a reasonable time, systems to identify people at high risk and assess and/or provide them with appropriate nutritional support. The Commission might seek to cancel the provider's registration for that service if there is evidence that people are suffering from unaddressed malnutrition or dehydration.

Example 2 – personalising people's treatment and care

Rationale
If people have no involvement in decisions made about their care and treatment, the care and treatment they receive may not reflect their individual needs and choices. There is a risk of serious harm to their health, safety and welfare from the imposition of unsuitable, unwanted or abusive treatment or care. The requirement for registration reflecting this risk could be as follows:

Requirement
Involving people in making informed decisions about their care and treatment
Ensure that people are involved in decisions about their receipt of care and participation in the service provided. Provide information and practical support for such involvement where it is needed. Where a person is assessed as lacking capacity to make decisions about their treatment and care, ensure that decisions are made in their best interests which take full account of the views of their relatives and carers, along with those of professionals.

Ensure that the service delivered to people and the manner in which it is provided reflect, as far as reasonably practicable, their aims, wishes and diverse needs, with reference to their age, gender, sexual orientation, religion, culture and impairments.

Compliance criteria could be based on:
- evidence that care providers, staff and professionals recognise the right of residents to be in control of their lives;
- evidence that staff seek to understand and respond to the needs, priorities and wishes of people using the service;
- people using the service being actively involved in and influencing decision-making (including risk management) in areas that have a significant impact on the quality of their day-to-day lives, and their views being recorded;
- people using the service being able to discuss changes to the treatment, care or support they receive;
- decisions about people's care and treatment being explained to them in terms they can understand – including any risks and choices they may have;
- survey results indicating people's satisfaction with their care and treatment, in the context of responsiveness to their wishes;
- people using the service being offered a choice of daily activities (including, where appropriate, social, educational and employment opportunities in the local community) and being involved in and influencing decision-making about the choices offered;

Example 2 – personalising people's treatment and care (continued)

- where people lack capacity to make decisions about their care, any decisions the provider makes for them being made in accordance with the Mental Capacity Act and associated code of practice;
- each person using the service having a care plan that reflects their basic support needs and most important life aims and does not contain anything that conflicts with their human rights, or any care that they object to (unless this reflects a decision made in accordance with the Mental Capacity Act and associated code of practice and is in their best interests to protect them from harm);
- reported untoward incidents where restraint or deprivation of liberty is a factor; and
- complaints that people are receiving care or treatment that they do not feel is appropriate to them.

Action by the Commission

7. The new Commission might take enforcement action if assessment against the criteria, or other information, identifies evidence that people have been put at risk by failure of a provider to personalise care, for example:

    - if a provider persistently fails to involve people using the service in decision making about the care they need and receive;
    - if a provider persistently makes decisions about people's care and provides care that is not in their best interests;
    - if a provider's care is abusive, involves arbitrary deprivation of liberty or unacceptable use of restraint; or
    - if a provider persistently fails to reflect people's diverse needs, making the care it provides unsuitable for their needs.

8. Action to cancel registration might be appropriate where the provider does not demonstrate the organisational capacity or willingness to put in place, within a reasonable time, systems to involve people in decisions about their care, or make decisions in their best interests and plan and deliver care in accordance with those decisions. The new Commission might seek to cancel the provider's registration for that service if there is evidence that unsuitable care is being systematically imposed and that this is harming people's health, safety and welfare as a result.

Annex D. Summary of consultation questions

Chapter 2 – Registration requirements for essential safety and quality

2.1 We propose to introduce a generic set of registration requirements (set out in regulations) for all providers offering services that are within scope. These requirements will be supplemented by compliance criteria, to be developed by the Care Quality Commission, that are specific to the type of activity. These will be consulted on at a later date. Do you agree with this approach?

2.2 Are the areas covered by the registration requirements (set out in Annex A) the right ones to provide the assurance of the essential levels of safety and quality that we are aiming for?

2.3 Does the wording of the registration requirements in Annex A provide appropriate coverage of these areas?

2.4 Are there any overlaps, gaps or unintended consequences that will not be picked up by other parts of the system?

2.5 What are your views on the transition arrangements for existing providers to enter the new registration system?

Chapter 3 – Scope – which health and adult social care services should be registered?

3.1 Do you agree with our proposed list of regulated activities in Annex B to be included within the scope of registration?

- Are there any high-risk services not covered?
- Have we proposed any inappropriate registration of lower-risk services?
- What are your views on the exclusion of non-urgent patient transport services under the 'Emergency and urgent care' activity topic?
- What are your views on the proposals for the registration of agencies who supply workers to other registered providers, under the 'Personal care' and 'Nursing care' activity topics?

3.2 Are the activities for registration described at the right level of detail, given that they will be underpinned by more specific and legally enforceable regulations?

3.3 Is there a risk of inappropriately deregulating high-risk activities in this approach?

3.4 Have we determined the right situations in which to register a manager?

Chapter 4 – Registration of primary care

4.1 Does the list of activities in Annex B appropriately capture the services where people might be at risk of harm provided in primary care settings? In particular, do you agree with our proposal that ultimately all GP and primary dental services should be within the scope of registration?

4.2 Does the list of activities in Annex B inappropriately capture some services that are less likely to cause harm when provided in primary care settings?

4.3 What information would you expect the new Commission to draw on when making decisions? How could it best do this?

4.4 What is the scope for rationalising the existing requirements on primary care providers if a registration system is introduced?

4.5 When should services provided in primary care settings be required to register? Should we phase in registration?

4.6 If we do phase in registration, how should we determine the services to be captured?

4.7 Is our assessment of the costs and benefits in our accompanying impact assessment (available at www.dh.gov.uk/en/Consultations/Liveconsultations/index.htm) reasonable? Do you have any additional information on impact that we could use?

Annex E. Glossary

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

Term	Definition
Adult social care	Social care includes all forms of personal care and other practical assistance, provided for individuals who due to age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs or any other similar circumstances, are in need of such assistance. For the purposes of the Care Quality Commission it only includes care provided for, or mainly for, adults in England.
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.
Certificate of Registration	When the Care Quality Commission grants registration to a provider, it will issue a Certificate of Registration to the provider. This may include details of the regulated activities that the provider can provide and any relevant conditions on this provision.
Compliance criteria	For each registration requirement there will be a set of compliance criteria that will be used by the Commission to determine whether the requirement has been met. The criteria will be developed by the Commission through consultation and may include indicators of performance and other evidence and information sources, for example 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.
Fair playing field	Will ensure that different providers (independent sector, 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 foundation trust 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; and > financial and statistical information that the NHS foundation trust is required to provide.
Healthcare	Healthcare includes all forms of healthcare provided for individuals, whether relating to physical or mental health, and includes procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition, for example cosmetic surgery.
Healthcare associated infection (HCAI)	HCAI includes any infection to which an individual may be exposed, made susceptible or more susceptible in circumstances where health or social care is being (or has been) provided to that or another individual and the risk of exposure to the infection, or of susceptibility to it, is directly or indirectly attributable to the provision of that care.
Independent sector	Non-publicly owned providers of services. The sector includes the private and third sectors (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, and interviews with involved individuals) that are deemed by the authority to be relevant to the inspection. It may or may not involve an actual visit to the organisation in question. The Care Quality Commission will establish its inspection policy and consult on this in due course.
Nurse-led services	Services which are organised and run by a nurse or nurse practitioner, including those traditionally provided by another profession, for example GPs.

Performance assessment	A process that uses a range of measures and indicators to judge how well organisations are performing.
Primary care	Primary care is the term for health services primarily based in the local community, including GPs, pharmacists, dentists and opticians. In this consultation we are seeking your views on how and when primary care should be included within the scope of registration.
Proportionate approach to regulation	The 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.
Registered manager	In order to provide certain regulated activities, services must be managed by an individual who is registered, in this case with the Care Quality Commission, in respect of that activity, or to provide it at a particular premises. In this consultation we are seeking advice on which activities should be required to have a registered manager.
Registered provider	Any person or organisation wishing to provide one or more of the regulated activities will need to be registered with the Care Quality Commission, as a registered provider of that service or those services.
Registration	Providers of regulated activities (services) must be registered with the Care Quality Commission in order to operate. Registration is the process by which providers are assessed as able to meet the safety and quality requirements we set in order to deliver health and adult social care services.
Registration requirements	A set of requirements, covering essential levels of safety and quality, that must be met in order to be registered and to maintain registration. In this case, we are consulting on a set of registration requirements that we have developed, based on the risks to people using services that are involved in providing health and adult social care services.
Regulated activities	Broad service areas or types of care that will be set out in regulations. They will include those health and adult social care services which an organisation needs to register with the Care Quality Commission to provide care or treatment in England. In this consultation we are seeking your views on which activities should be regulated by the Commission.

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 the Government, interpreted into clear rules by the regulator. Its purpose is to assure the public that providers of services are fit for purpose.
Regulations	These are the legal basis of regulation and are set out in secondary legislation. The regulations will cover more than the registration requirements and scope of registration, for example penalty notices, and will be subject to separate consultation.
Scope of registration	The Health and Social Care Bill contains a definition of the wider scope of health and social care, so that all providers can be covered. This consultation seeks to determine which activities that providers perform will be subject to registration. These activities will be set out in secondary legislation. We will consult on the proposed regulations later in 2008.
Secondary legislation	The Parliamentary procedure that is commonly used to flesh out an Act in greater detail, without needing to put a completely new Act through Parliament. Often an Act contains only a broad framework of its purpose and more complex content is added through secondary legislation. In this case we are intending to set out the detail of the registration system in secondary legislation subject to the passage of the Health and Social Care Bill through Parliament.
Statement of purpose	A description of the services a provider offers, written by that provider, that the Care Quality Commission may use as part of the information it gathers in order to grant or vary the registration of that provider.
Sole provider	A provider who is an individual and in day-to-day charge of a service.
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 period	The 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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