DH Department of Health

Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations

The future regulation of health and adult social care in England

Health and social care working together in partnership

Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations

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Foreword

From: Ben Bradshaw

Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations

From 1 April 2009, the new Care Quality Commission, established under the Health and Social Care Act 2008, will take over from the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. The new Commission will, for the first time, provide coherent regulation across both health and adult social care, reflecting the growing integration of those services.

All parts of the system have an important part to play in ensuring that people receive the quality of care that they need. Regulation plays a vital role within our drive to make quality the organising principle of care. *High quality care for all: NHS Next Stage Review final report*[1] sets out that vision for the NHS, but the underpinning ambition and principles apply equally across all forms of health and adult social care. The 2006 White Paper *Our health, our care, our say: a new direction for community services*[2] described the framework that is now used for promoting quality in adult social care services and set out the seven key outcomes that adult social care should deliver. The Care Quality Commission will have a vital role in providing assurance that all health and adult social care services meet essential levels of safety and quality, and will contribute to the wider drive for ongoing service improvement.

From April 2010 we are introducing a new registration framework. The main purpose of the registration framework is independent assurance of the safety and quality of care. The new framework will be proportionate in that decisions on who needs to register with the new Commission (the scope of registration) will be based on the level of risk to the people who use services, where the risk lies, and what contribution the Commission can make to ensure those risks are managed. It will bring with it a fair playing field, as all providers of regulated activities will need to register with the new Commission and meet the same essential standards, whether they are public, private or third sector.

These essential standards, known as registration requirements, and the scope of registration were the subject of the previous consultation and our

1 High quality care for all: NHS Next Stage Review final report (DH, June 2008), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825

2 Our health, our care, our say: a new direction for community services (DH, January 2006), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127453

decisions are set out in the following chapters. Subject to Parliamentary approval, the Government will set these in secondary legislation. The registration requirements set out what patients and users of services can expect in terms of quality and safety of care. For patients receiving NHS care, many of these are aligned with the patient rights set out recently in the NHS Constitution.

The Care Quality Commission will develop and consult on the principles of its own methodology and guidance about compliance, which it will use to determine whether providers are meeting the registration requirements. This will allow the Commission to take enforcement action against providers who fail to meet the registration requirements, using the same powers it will have in its first year to enforce against breaches of the healthcare associated infections requirement by NHS organisations.

This document sets out the services that will require registration with the new Commission and the registration requirements that service providers will need to meet, and launches a consultation seeking your views on whether the draft Regulations attached will establish the framework we have described. It is part of an ongoing process of engagement with people who use health and adult social care services, and the people who provide them, to develop a coherent and overarching regulatory framework. I very much welcome your views.

Ben Bradshaw
Minister of State for Health Services

Executive summary

1. This document serves two main purposes:

    a. it provides the Government's response to the consultation we held during spring 2008[3] on the new registration framework to be introduced from 2010; and
    b. it launches a consultation on the wording of the draft Regulations on the scope of registration and the registration requirements that we are planning to set before Parliament this year. The consultation will run from 30 March to 29 May 2009.

2. The consultation also seeks views on a number of other policy proposals that will support the registration framework. Following the consultation, we will draft Regulations on these policies and lay them before Parliament.

The Care Quality Commission

3. Regulation plays a vital role within the Government's drive to make quality the organising principle of care. *High quality care for all: NHS Next Stage Review final report*[4] sets out that vision for the NHS, but the underpinning ambition and principles apply equally across all forms of health and adult social care. The 2006 White Paper *Our health, our care, our say: a new direction for community services*[5] described the framework that is now used for promoting quality in adult social care services and set out the seven key outcomes that adult social care should deliver.

4. From 1 April 2009, there will be a new independent regulator of health and adult social care in England. The Care Quality Commission will take over from the Healthcare Commission, the Commission for Social Care Inspection (CSCI) and the Mental Health Act Commission (MHAC).

5. During 2009/10, the Commission will continue to regulate private and voluntary healthcare and adult social care under the Care Standards

3 A consultation on the framework for the registration of health and adult social care providers (DH, March 2008), available at: www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625
4 High quality care for all: NHS Next Stage Review final report (DH, June 2008), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825
5 Our health, our care, our say: a new direction for community services (DH, January 2006), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127453

Act 2000[6] (CSA). For the first time, NHS providers will be registered with the new Commission and regulated against the requirement relating to healthcare associated infection.[7]

6. From April 2010, we are introducing a new registration framework. All providers of health and adult social care regulated activities, including NHS, local authority, private and third sector providers, will need to register with the Care Quality Commission.

High quality care for all

7. The new Commission will have a vital role in the overall assurance of the safety and quality of health and adult social care services – linking with and complementing other levers in the system to drive continuous improvements for people who use those services. The Care Quality Commission has a statutory obligation to carry out its functions in a way that encourages improvement. It has already begun to develop this role. The consultation document published by the Commission in December 2008 sets out how it intends to carry out its periodic and special reviews in 2009/10[8].

8. The Commission will monitor providers on an ongoing basis to ensure they continue to meet the essential levels of safety and quality set out in the registration requirements. Where providers are not meeting these requirements, the Commission will have the flexibility to use its independent enforcement powers to bring poor providers back into compliance or to prevent people who use services from being exposed to serious risk of harm.

9. Chapter 1 sets out how the Commission fits in with the wider quality framework and performance regime in more detail.

Overview of the previous consultation

10. There was broad support, from a wide cross section of respondents, for the overall approach set out in the registration framework consultation. In particular, there was general support for the proposal to have a single regulatory framework for health and adult social care, with a coherent set of registration requirements, and for a proportionate approach to the scope of registration. Some responses suggested

6 www.opsi.gov.uk/acts/acts2000/ukpga_20000014_en_1
7 Regulation 5 of the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009 (Statutory Instrument 2009/660), available at www.opsi.gov.uk/si/si2009/uksi_20090660_en_1
8 Care Quality Commission reviews in 2009/10 (Care Quality Commission, December 2008), available at: www.cqc.org.uk/consultations/reviews_in_0910.aspx

changes to the detail of the registration requirements or the specific descriptions of activities within the scope of registration. These are discussed in Chapters 3 and 5 and Annexes A and C. Chapter 2 sets out more detail about the consultation process and the responses.

The scope of registration

11. One of the key changes to the system is that the requirement to register with the new Commission will be based on the kind of activity being provided, rather than the organisation or setting that it is provided in. The scope of registration will be proportionate to risk and the added value that independent system regulation can bring. In other words, decisions on which activities require registration are based on the level of risk to the patient or person using the service and whether the national regulatory body for health and adult social care services is the best part of the assurance system to address this risk, so that we avoid placing an unnecessary burden on the providers or the regulator.

12. We intend the scope of regulation to be broadly similar to that which currently applies to providers of adult social care, independent healthcare and equivalent NHS services. The consultation proposed a range of services that we thought should be within the scope of registration and sought views on whether the proposals captured the right activities. We have made a number of changes to the list of activities we are setting in the Regulations as a result of the consultation responses. For example, we have revised the definition of patient transport services that are within the scope of registration following further discussions with internal and external stakeholders. These are discussed in detail in Chapter 3 and Annex A and a set of draft Regulations is attached for consultation at Annex B.

Registered managers

13. Good management is crucial to delivering care that is safe and of appropriate quality. The consultation proposed that ‘registered managers’ (ie someone who is in day-to-day control of the service and can be held accountable for the quality of it) should be required in most adult social care settings and for some providers of independent healthcare. Responses to the consultation supported the principle of a ‘registered manager’ with a wide range of views as to the best model. These are discussed in more detail in Chapter 3 along with our response.

Primary care

14. In order to ensure there is a coherent and fair approach across all providers of health and adult social care, we intend to bring primary care providers of regulated activities into the scope of regulation. There was strong support for the inclusion of primary medical and dental services within the registration framework but respondents made clear that requiring such providers to register needed to avoid duplicating existing arrangements and make best use of existing information.

15. Primary medical and dental care providers will be brought within the scope of registration. However, they will need time to prepare. Therefore, with the exception of doctors who solely provide services to private patients and are already required to register, GP practices and high street dental practices will be excluded from the registration system in 2010/11. Chapter 4 discusses this in more detail.

Registration requirements

16. There will be a single, coherent set of registration requirements which all providers of regulated activities will need to meet in order to be registered with the Commission. That will mean that patients and people using services will have the same level of assurance of the quality and safety of their care and treatment, whether the NHS, local authorities, or the independent sector is providing it. The requirements address the concerns of people using health and adult social care services, covering the topics on which they want assurance. They provide clarity about the essential levels of safety and quality that must be met without being prescriptive about how compliance is achieved.

17. The consultation proposed a set of registration requirements. There was very strong support for the proposed approach and the set of requirements, but there were a number of comments on the detailed wording of the requirements. As a result of the consultation, we have changed the overall structure of the requirements and refined the emphasis within each requirement. These are discussed in more detail in Chapter 5 and Annex C, and a set of draft Regulations for consultation is attached in Annex D.

Consultation on policy related to supporting the registration framework

18. In addition to the draft Regulations on scope and registration requirements, which are set out in Annexes B and D, we need to make other Regulations covering: the registration process; fitness

of registered person; provision of information; financial position; and enforcement action. Chapter 6 sets out our policy proposals and seeks views to help us to produce draft Regulations to lay before Parliament.

Next steps

19. Chapter 7 sets out the timetable and process for going forward towards full implementation of the new registration framework, and explains our plans for transition to the new system. We want to make this as straightforward as possible.

20. Chapter 8 explains the consultation process and how to respond, including contact details. Annex E sets out a list of the questions we are seeking views on.

1. Setting the scene

Replacing the current system of regulation for health and adult social care

1.1 Regulation plays a vital role within the Government's drive to make quality the organising principle of care. *High quality care for all* set out that vision for the NHS, but the underpinning ambition and principles apply equally across all forms of health and adult social care. The 2006 White Paper *Our health, our care, our say: a new direction for community services* (January 2006)[9] described the framework that is now used for promoting quality in adult social care services and set out the seven key outcomes that adult social care should deliver.

1.2 The existing regulatory framework for health and adult social care has become fragmented over time. In healthcare, there are different regulatory procedures and standards for NHS and independent 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 services become more innovative and integrated.

1.3 We are developing a coherent registration system across health and adult social care, based on a single set of registration requirements, which all providers will have to meet for any service they provide 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 comply with the requirements to maintain their registration.

1.4 For NHS services, many of the registration requirements are aligned with the patient rights set out in the NHS Constitution. For example, the Constitution emphasises that patients have the right to be treated with dignity and respect. This is also an important element of the registration requirements.

9 Our health, our care, our say: a new direction for community services (DH, January 2006), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127453

Care Quality Commission

1.5 The new Commission has a key responsibility in the overall assurance of the safety and quality of health and adult social care services – independent, but linking with and complementing other levers in the system to drive continuous improvements for people that use those services. The Commission's main objective is to protect and promote the health, safety and welfare of people who use health and adult social care services. In addition to this, it has a statutory obligation under Section 3[10] of the Health and Social Care Act 2008[11] to perform its functions in a way that encourages improvement.

1.6 The Commission will form an integral part of the wider quality framework, having responsibility for:

- providing independent assurance and publishing information on the safety and quality of services;
- registering care providers (including NHS, adult social care and independent sector healthcare providers);
- monitoring compliance with a set of registration requirements;
- using enhanced enforcement powers (if necessary) to ensure service providers meet requirements;
- assessing the performance of providers and commissioners;
- undertaking special reviews of particular services at a national level, looking across providers and commissioners of health and adult social care;
- monitoring the use of the Mental Health Act; and
- helping manage the impact of regulation on service providers and commissioners.

1.7 During 2009/10, the new Commission will continue to operate under the current regulatory system, with the addition of the arrangements for regulating NHS providers in relation to healthcare associated infections (HCAI). From April 2010, the new Commission will start to implement a new system of registration for all providers of regulated health and adult social care services.

1.8 The key features of the new registration system will be:

- consistency across health and adult social care providers from both independent and public sectors (including NHS trusts and NHS foundation trusts);

10 Unless otherwise stated, Sections referred to in the text are Sections of the Health and Social Care Act 2008

11 www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/HealthandSocialCareBill/index.htm.

- a single coherent set of registration requirements across both health and adult social care;
- providers will be required to manage key risks to the safety, quality and governance of the care they provide;
- registration requirements will address the concerns of people using health and adult social care services;
- 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
- a more extensive and flexible range of enforcement powers.

1.9 In previous publications[12] we have consulted on, and outlined our reasons for, introducing a new approach to regulating health and adult social care. While the current system and the Commissions have served their purpose well, as services have developed and become more integrated it makes sense to move to a single aligned regulatory framework.

Quality improvement and the Quality Framework

1.10 The registration system will provide a safeguard, but will also provide a solid foundation for providers to build on. It will have an important part to play in delivery of quality services, but is not alone. It will work alongside other parts of the system.

1.11 For the NHS, *High quality care for all* set out an ambitious vision for making quality improvement the organising principle of everything it does. The consultation on the registration framework was published before *High quality care for all*. This consultation response, therefore, takes account of the vision set out in the NHS Next Stage Review and sets the registration framework in that context.

1.12 For adult social care, the Ministerial concordat and protocol: *Putting people first: a shared vision and commitment to the transformation of adult social care*[13] confirmed the collaboration of various parties, including the Healthcare Commission and the Commission for Social Care Inspection, in radically changing people's experience of social care. Signatories included six Secretaries of State, the Chief Executive of the NHS and a range of bodies in social care. This supports and

12 The future regulation of health and adult social care in England (DH, November 2006), available at: www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286, and The future regulation of health and adult social care in England: response to consultation (DH, October 2007), available at: www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_078227

13 Putting people first: a shared vision and commitment to the transformation of adult social care (DH, December 2007), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081118

takes forward the framework for improved outcomes of care set out in *Our health, our care, our say*.

1.13 It is in this context that the Care Quality Commission is being established and it will have an essential role in encouraging, supporting and ensuring quality improvement. The Commission has already begun to develop this role, as can be seen in the consultation it published in December 2008 on how it intends to carry out its periodic and special reviews in 2009/10[14]. This document firmly sets out the Commission's focus on both ensuring that essential levels of quality and safety are met, but also encouraging continuous quality improvement in all services.

1.14 The Care Quality Commission will contribute to the wider drive for quality improvement through:

- its registration of providers;
- its powers to conduct investigations and take enforcement action;
- its periodic reviews of commissioners and providers; and
- its programme of special reviews.

1.15 *High quality care for all* set out seven key aspects which are needed to enable increased quality of services as follows:

a. Bringing clarity to quality
b. Measuring quality
c. Publishing data on quality performance
d. Recognising and rewarding quality
e. Clinical/service leadership and management
f. Safeguarding quality
g. Support for innovation in care

1.16 While these were focused on NHS care, they are generic steps, which can be applied to all health and adult social care. Various partners will play a part in delivering this quality framework, including professional clinicians, other staff and carers, providers of services, commissioners and regulators.

1.17 Alongside its registration functions, the Commission's separate periodic review function will also help to incentivise quality improvement. In its periodic reviews of providers, the Commission will publish independent, accessible and relevant information about the broader quality of services, against indicators determined by the Secretary of State. As

14 Care Quality Commission reviews in 2009/10 – Consultation (Care Quality Commission, December 2008) available at: www.cqc.org.uk/consultation/reviews_in_0910.aspx

well as informing the decisions of commissioners, the comparative information in periodic reviews will help people who use services make choices. The information that the Commission publishes on performance will be a strong incentive for providers to focus on quality improvement, and will recognise when services improve and identify good practice. The Commission's enforcement powers cannot be used in relation to its review functions unless, of course, these demonstrate that a provider is not meeting its registration requirements.

1.18 A special review or study is a one-off review to look at a specific topic or area and can be about virtually any aspect of health and adult social care. The Commission will use special reviews and studies to report on how services are commissioned or provided across organisations, areas or care pathways, either across both health and adult social care or within one sector. The Commission can use its special reviews to look at areas of particular interest or concern. This will help to identify poor practice or areas where improvements could be made.

Managing performance in the NHS

1.19 *Developing the NHS Performance Regime*[15] outlined the Government's vision for: affording greater consistency and transparency in how the NHS identifies underperformance; how the NHS intervenes to support recovery; and how organisations will be managed through a failure regime, where services are not clinically or financially sustainable.

1.20 The new NHS Performance Framework forms part of this regime. It will set clear thresholds for intervention in underperforming organisations and a rules-based process for escalation, including defined timescales for demonstrating performance improvements. Organisational performance will be assessed against a series of metrics using the most current data available, and the results will trigger intervention by strategic health authorities (SHAs) and primary care trust (PCT) commissioners using powers in their contracts in the case of underperformance.

1.21 The Performance Framework will be applied to NHS providers and commissioners will be introduced in three phases:

- From April 2009 for acute and ambulance trusts;
- From October 2009 for PCT-provided services and mental health trusts;
- From April 2010 for PCT commissioners.

15 Developing the NHS Performance Regime (DH, June 2008), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085215

1.22 The NHS Performance Framework will not apply to NHS foundation trusts. NHS foundation trusts are accountable to their commissioners for the delivery of their contractual commitments and to Monitor for compliance with their terms of authorisation. As registration with the Care Quality Commission will be a prerequisite for any provider wishing to offer regulated activities, NHS foundation trusts will need to register and meet the registration requirements. The registration requirements will be part of the NHS foundation trust's terms of authorisation.

1.23 If the Care Quality Commission has concerns about a provider's ability to meet the registration requirements, or takes enforcement action against a provider, this will inform the results of the NHS Performance Framework. In the case of NHS trusts (but not NHS foundation trusts – see below), the relevant SHA or PCT commissioners will intervene to facilitate recovery, especially if it is not satisfied that sufficient progress is already being made.

1.24 In the case of persistent underperformance, or where a provider is found to be clinically or financially unsustainable, the new statutory regime for unsustainable NHS providers (introduced in the Health Bill[16], and therefore subject to Parliamentary approval) could be triggered. The objective of this regime is to secure sustainable, high quality provision of services for the local community and to protect public assets (NHS land and buildings).

1.25 The application of the broader range of enforcement powers available to the Care Quality Commission will make it possible for it to suspend or cancel a provider's registration on the grounds of clinical quality. This may render the provider unsustainable and trigger the new regime.

1.26 The NHS Performance Framework will not apply to NHS foundation trusts. NHS foundation trusts are accountable to their commissioners for the delivery of their contractual commitments and to Monitor for compliance with their terms of authorisation. As registration with the Care Quality Commission will be a prerequisite for any provider wishing to offer regulated activities, NHS foundation trusts will need to register and continue to meet registration requirements. The registration requirements will be part of the NHS foundation trust's terms of authorisation. Monitor will intervene if the trust is in breach of its terms of authorisation.

16 www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_093280

Local Performance Framework for councils and their partners

1.27 Where improvements in local services require partnership working between local councils and the NHS, the NHS Performance Framework will align with the Local Performance Framework[17] which applies to local authorities and their partners. The Local Performance Framework applies to anything done by local authorities acting alone or in partnership and includes Local Area Agreements, the National Indicator Set, the new Comprehensive Area Assessment[18] (CAA) and the National Improvement and Efficiency Strategy. The Care Quality Commission will be a major contributor to CAA.

1.28 Improvement and intervention activity for local authorities including their work with partners is undertaken within the Local Performance Framework and is coordinated by Government Offices for the Regions. This will be aligned with any related improvement or intervention activity by SHAs and PCTs (or Monitor in the case of NHS foundation trusts) in areas of partnership working involving the NHS.

Conclusion

1.29 The Government's vision for health and adult social care services is that quality of service should be at the centre of everything that we do. This document describes how the Commission's registration system will work, and how this will be an integral part of the wider quality agenda. The Commission will register providers and take enforcement action to stamp out bad practice where care does not meet essential levels of safety and quality. Any action that the Commission takes will be coordinated with other levers in the system, for example, with Monitor's work, or that of the NHS performance framework, or the Local Performance Framework, to ensure that quality of services meet the acceptable level. This aims to provide a firm base upon which to work for continuous quality improvement. The Commission's periodic review function will complement other measures set out in the Quality Framework, described in *High Quality Care for All*, to support continuous improvement in the quality of services.

17 The local performance framework – delivering the vision (Department for Communities and Local Government, 2008), available at: www.communities.gov.uk/documents/localgovernment/pdf/1126522.pdf

18 CAA framework (Audit Commission, February 2009) available at: www.audit-commission.gov.uk/caa/framework.asp

2. Consultation process and responses

Introduction

2.1 We published the registration framework consultation document on 25 March 2008. The formal consultation period lasted for 12 weeks, closing on 17 June.

2.2 The consultation followed earlier consultation on the model for the new regulatory framework and the Health and Social Care Bill[19]. Our position for consultation was developed following close work with a range of stakeholders, including national and local health and adult social care bodies and bodies representing people who use services.

2.3 This consultation specifically sought views on:

- which health and adult social care activities should require registration (the scope of registration) with the Care Quality Commission; and
- what the requirements for registration should be.

2.4 The scope and requirements for registration will be set in secondary legislation to populate the statutory framework set out in Sections 8, 13, 16 and 20 of the Health and Social Care Act 2008, following a further consultation on the wording of the draft Regulations discussed in Chapters 3 and 5, and Annexes A and C and set out in Annexes B and D.

2.5 The consultation also sought views on whether some kinds of providers of activities that are within the scope of registration (regulated activities) should be required to have a 'registered manager' as an additional requirement, and how primary care activities should be included in the new registration system. These issues are covered in Chapters 3 and 4 respectively. The document also set out plans and asked for views on the transition to the new registration system. This is covered in chapters 6 and 7.

19 Now the Health and Social Care Act 2008

Publication

2.6 The consultation document was published electronically on the Department's website on 25 March 2008 and hard copies were available on request. The Minister of State for Health Services, Ben Bradshaw MP, made a Written Ministerial Statement to Parliament announcing the launch of the consultation.

2.7 We had already published an impact assessment prepared for the Health and Social Care Bill. At the time of the launch of the consultation, we also published a partial impact assessment, specifically relating the impact of the proposals around the regulation of primary care. A set of slides summarising the consultation was added to the website later.

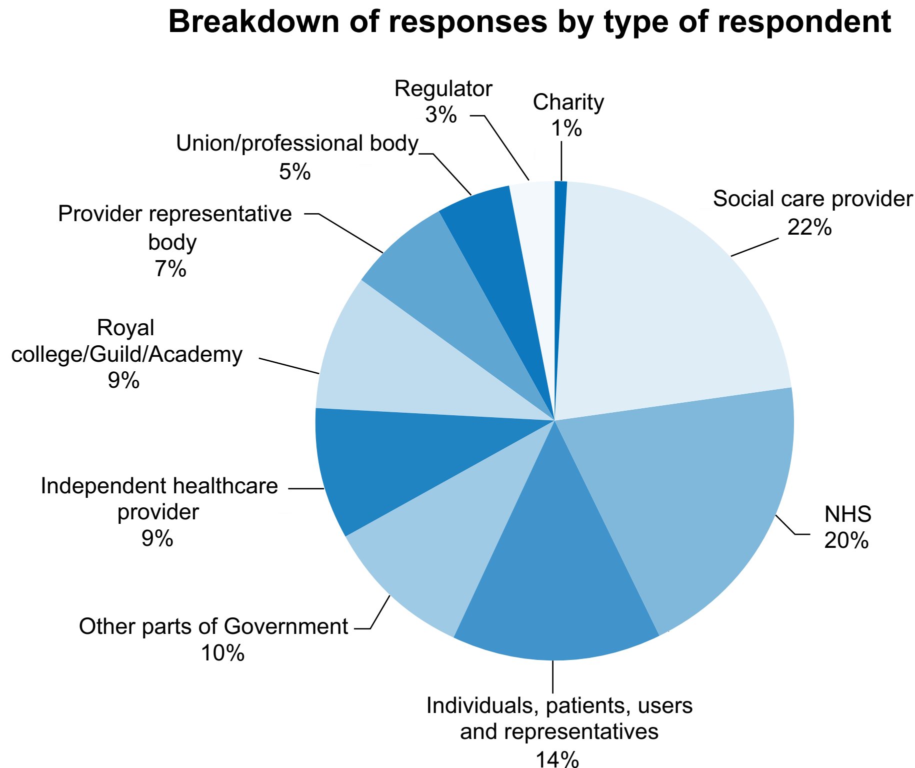
Consultation events

2.8 We held a number of stakeholder events to raise awareness of the consultation, to set the consultation in context and to gather early views. The events included events for:

- health and adult social care stakeholders;
- organisations and groups representing patients and people who use health and adult social care services;
- commissioners and providers of primary care services;
- representatives of third sector organisations;
- people who use services.

2.9 We received 230 written responses to the consultation.

2.10 This chart shows the breakdown of responses by type of respondent.



Overview of what we heard

2.11 We received a large number of very useful comments and suggestions, both at the consultation events and in the responses. There was broad support for the overall approach set out in the consultation document. In particular, there was general support for the approach of having a single regulatory framework for health and adult social care, and including the NHS within the registration system.

Scope – who will have to register?

2.12 The consultation document set out a list of 19 broad service areas and gave examples of the kind of activities we thought should be within the scope of registration. There was general agreement that all the service areas listed should be regulated, but also some suggestions of amendments to the wording and definitions that would improve them. Respondents tended to suggest additional services that should be registered rather than services that should not be registered.

2.13 The responses on scope are summarised, alongside our response, in Chapter 3 and Annex A.

Registered managers

2.14 The consultation document set out our proposals for 'registered managers', ie someone who is in day-to-day control of the service and can be held accountable for the quality of the service. The responses were generally supportive, but there were many suggestions of variations on how the system should be implemented. These are discussed in Chapter 3.

Primary care

2.15 The consultation sought views on how and when primary medical care and primary dental care providers should be brought within the scope of registration. It also made it clear that we would work with stakeholders to give more consideration to how a new registration system would interact with the existing requirements and the potential for rationalisation. The overwhelming majority of respondents supported primary medical and dental care being included within the registration scheme. Our decisions on the regulation of primary care are set out in Chapter 4.

Registration requirements – what requirements will registered providers have to meet?

2.16 The approach of having a broad set of generic registration requirements covering both health and adult social care was also strongly supported. The set of requirements we proposed in the consultation document were well received. In general, respondents did not think there were any major omissions in the set of requirements we proposed, and there were no requirements included that were felt to be inappropriate. There were many comments and queries about the detail of how this would work in practice and the wording of the actual requirements. These are discussed in Chapter 5 and Annex C.

Transition arrangements

2.17 The consultation document set out proposals for the transition arrangements for existing providers to enter the new registration framework and asked for views.

2.18 Responses to the proposed transition arrangements were largely positive, with many respondents supporting a smooth process for transfer into the new registration system for NHS providers and currently registered bodies not under enforcement action. However,

some responses cautioned against registration of existing providers becoming a 'rubber-stamping' exercise, fearing this would devalue registration.

2.19 Some concerns were raised over the proposed time-scale for transition, although a similar number of respondents thought a one-year period was appropriate.

2.20 Several respondents requested further clarity on the proposed transition arrangements, and others highlighted the need for timely and clear guidance to be made available to help providers during the transition.

2.21 We are working with the Care Quality Commission to set out a transition process that is fair, but not bureaucratic, and that provides assurance that the process is not a 'rubber-stamping' exercise. Further details of the transition process are set out in Chapter 7.

3. Who will have to register?

The scope of registration

3.1 Any provider of a regulated activity will be required to register with the new Commission. It is the provider's responsibility to ensure that it applies to register in line with the law. Organisations that are only providing staff or services to a registered provider, but not directly providing services themselves, will not be required to register.

3.2 It is our intention that the system we are developing defines who is required to register with the Care Quality Commission in a way that ensures:

- 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 the Commission itself;
- decisions on which services are to require registration are based on the risk of harm to people using them, after taking into account any other protections offered by other regulatory or management and governance systems, and how much system regulation would effectively reduce those risks;
- flexibility to accommodate changes and innovations in models of care provision;
- the definitions encompass the increasing integration between health and adult social care services;
- it is clear to providers, the public and the new Commission when registration is required;
- decisions on which activities require registration take into account inequalities, so that we do not inadvertently remove protective regulation from activities that will have an adverse effect on particular populations.

Regulating activities rather than settings

3.3 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 come within scope. The other significant difference is that instead of defining scope in terms of organisational types, there will be a list of broad service areas or types of care (described in the Health and Social Care Act as 'regulated activities') for which registration will be required.

3.4 This will give the new Commission more flexibility to regulate new types of services, and to base regulation on risk of harm to those receiving the care or treatment.

3.5 The Commission will look at all ancillary services and activities that support, or have a bearing on, the regulated activity. For example, a requirement to register for surgical procedures will include associated pre- and post-operative care, as well as the specific surgical procedures themselves.

3.6 Following the consultation we have finalised a set of activities that will be regulated by the Care Quality Commission. These are discussed below. The draft Regulations that will set these activities in legislation are at Annex B. We are now seeking views on whether the wording of the draft Regulations will achieve our policy intentions.

Link to professional and workforce regulation

3.7 System regulation by the new Commission does not replace professional regulation. The two systems should work together to assure the safety and quality of care for patients and people who use services, without unnecessarily adding to the burden. With this in mind, we have taken the current coverage of professional or workforce regulation into account when considering the scope of system registration.

Children's health and social care

3.8 We are working with Ofsted, the Care Quality Commission and the Department for Children, Schools and Families (DCSF) to ensure that children's health and social care is appropriately regulated. Establishments and agencies registered by Ofsted under the Care Standards Act 2000 (for example children's homes and fostering agencies) are not within scope of the Care Quality Commission. Our starting principle is that Ofsted will continue to inspect and regulate those children's establishments and services which it inspects currently. All parties are committed to ensuring that the two regulators work together in a way that: does not overlap or unduly increase the burden

of regulation on service providers; does not allow services to fall through the gap; and provides continuity in the assurance of the safety and quality of services.

Consultation response

3.9 The consultation document set out a list of 19 broad service areas or types of care, together with examples of the kinds of activities we thought should be within the scope of regulation. We sought views on whether we had the right set of service areas and which activities within each one should be regulated activities. While there was general agreement with the proposed list of service areas to be included within the scope of registration, there were many comments and suggestions around the detail of what should and should not be within scope.

3.10 A number of issues were raised about the definitions of particular regulated activities. These ranged from queries and comments about the specific wording to whether the description was inappropriately or inadvertently including or excluding services. There were also concerns raised about the need to ensure informal arrangements, for example, arrangements with friends or neighbours, including any made using direct payments, were not inadvertently included within the scope of regulation.

3.11 One of the strongest points made in the consultation on the issue of scope was that we should develop a more rigorous evidence base for determining whether activities should be within scope.

3.12 Following further research and discussions with existing regulators and other experts in the field, we looked at the following evidence, where available:

- the types of suffering people experience as a result of poor quality or inappropriate care;
- the likelihood that the people experience such care;
- the severity of suffering that people experience;
- the circumstances of patients or people using services and their vulnerability;
- the change in suffering that system regulation would deliver; and
- the cost of regulation, including administration costs and indirect costs arising from providers ceasing to provide certain services to avoid regulation.

3.13 This information has been a useful indicator that has made it easier to compare activities that create different risks to patients and people who

use services. However, we have not been able to find detailed data to make a calculation of the effect of system regulation for every activity. For example, data on adverse incidents often does not separate avoidable incidents from unavoidable ones. We have therefore used this information, along with other information provided during the course of the consultation as an aid to decision making.

The questions we asked in Chapter 3 of the consultation document on scope of registration

3.14 The following paragraphs relate to the questions we asked in Chapter 3 of the previous consultation document and the responses we received. Annex A sets out our analysis of comments on our proposals on individual activities, and our response, including more detail on what services are within each of the activities. Annex B sets out the draft Regulations that will set these in legislation.

We asked: Do you agree with our proposed list of regulated activities to be included within the scope of registration?

What we heard

3.15 A majority of respondents said they agreed with the list of activities we proposed in the consultation document. However, many respondents, both those who agreed with the list and those who did not, went on to make comments on the detail of the descriptions of services that should be within scope. There was a view from some that there needs to be greater clarity on the criteria for inclusion in scope, which would help to avoid providers labelling services differently to avoid regulation. There were also concerns that some of the definitions in the consultation tended to reflect current service configuration, or even, as in the case of mental health services, based on out-of-date configuration, rather than being adaptable to potential new and innovative models.

Our response

3.16 Our responses on the different activity topics are discussed in more detail in Annex A under separate headings. We have also set out our description of what is within scope and the further consultation on draft Regulations at Annex B seeks views on whether the draft Regulations effectively bring in those activities that we intend to bring into registration.

3.17 We have designed the Regulations to be flexible enough to respond to service development over time by describing regulated activities at a high level.

We asked: Are there any high-risk services not covered? and

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

What we heard

3.18 While a number of respondents thought that all high-risk services were covered by the proposed scope, other respondents picked out services that they considered high risk but were not covered by the proposed list of services to be included. Some of the most commonly cited were:

- personal assistants;
- counselling and psychotherapy services;
- day care;
- shared lives (adult placement) services;
- NHS Direct;
- tooth whitening.

Our response

3.19 While we understand that no activity is completely risk free, we need to make decisions on the scope of regulation in the context of the principles of better regulation. Therefore, we have considered the severity and likelihood of suffering as a result of bad practice in each of the activity headings, alongside the possible benefits of system regulation, the interaction of other regulatory or licensing bodies and the burden of regulation. In arriving at decisions on the scope of registration, we have also considered the circumstances of patients and people using services and their vulnerability. Our conclusions are set out in Annex A, under the separate activity headings.

We asked: Have we proposed any inappropriate registration of lower-risk services?

What we heard

3.20 The vast majority of responses to this question felt that no low-risk services were inappropriately included. It was also noted that it is difficult to judge what 'low risk' is for vulnerable people.

3.21 A number of responses expressed concerns about specific activities. The most commonly cited issue was that the Regulations need to avoid bringing ordinary members of the community within scope and that there is a risk that extending the definition of personal care will bring low-risk services into scope.

Our response

3.22 The services that respondents had concerns about are discussed in Annex A under the separate activity headings. We have included consideration of the relative vulnerability of people using specific services and the role system regulation might have in assuring their safety, when making decisions around whether services should be within scope. We have placed a general exclusion in the draft Regulations at Annex B (Regulation 19) to avoid regulating activities carried out by family members, friends or neighbours etc in the course of that relationship.

We asked: What are your views on the exclusion of non-urgent patient transport services under the 'emergency and urgent care' activity topic?

What we heard

3.23 Most people who responded to this question argued that all patient transport services (including non-urgent ones) should be included within scope because of the impact that these services can have on people's lives, especially those with long-term conditions. It was pointed out that while the service itself may not involve great risks, it was often provided for vulnerable people and non-regulation would increase the risk to those people. However, some responses did see non-urgent patient transport as low risk and argued for it not to be included.

3.24 A number of respondents made more detailed comments and recommendations. For example, some responses suggested that non-urgent patient transport services should be registered where the ability to provide medical intervention en route is required, or that non-urgent transport should not be registered as long as the staff involved are subject to checks, and the commissioners ensure that the service is appropriate. On the other hand a number of responses suggested that it would be difficult to split off patient transport services that may not need registration because the services provided by ambulance service providers overlap.

3.25 A number of responses suggested that the policy position should be reviewed in future as services develop, and a number of responses

suggested that there should be more discussion before a decision is taken.

Our response

3.26 We have discussed this issue further with a range of stakeholders. We agree that to exclude non-urgent patient transport services would have excluded some providers that should be within scope. However, to bring in all providers of transport services that take people to and from places where they receive care or treatment would mean that transport such as taxis would need to be registered with the Care Quality Commission. Following further discussion with stakeholders, we decided to avoid use of the terminology of patient transport services, which has a specific contractual meaning within the NHS. Instead, we have decided to define transport services along the lines of medical need. We want the dividing line to be related to whether or not the patient being transported needs transport which is designed for the primary purpose of carrying persons for the purposes of treatment.

3.27 We considered the argument that we should extend regulation beyond transport that was required for medical need, because of the vulnerability of people being transported, but concluded that it would be unlikely that system regulation would add to the controls and safeguards that should already be in place. It would also create a situation where a healthcare provider could not commission transport to or from hospital in taxis or volunteer cars unless they were registered with the Commission. This would be counter-productive, and could lead to unnecessary long waits for transport.

3.28 The description of what we are aiming to capture within the scope of regulation is set out in Annex A in the section on emergency and urgent care.

We asked: 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?

What we heard

3.29 The majority of consultation responses supported including agencies within registration. Views were divided on whether employment agencies should be included within scope. Some felt that there was a need to register those agencies who only supplied staff to other registered providers. Others felt that this was not necessary, was duplication and that the responsibility should rest with the service provider that the staff were working for. There was overwhelming

support for the inclusion of agencies who supplied staff direct to people in their own homes where they are carrying out personal care. A number of responses suggested that if the Care Quality Commission did not regulate agencies, an alternative method of regulating them would need to be developed.

3.30 It was suggested that not regulating agencies would put an additional burden on providers. It was also suggested that regulation of businesses would need to be strengthened if agencies were not registered with the Care Quality Commission.

Our response

3.31 The consultation response was inconclusive in this area. As a result, our decisions have been made in line with the principles of better regulation, and having considered the potential benefits and burden of regulation. We have concluded that agencies that do not carry out regulated activities should not be required to register with the new Commission.

3.32 Providers of regulated activities will be required to register with the Commission, and will therefore be required to meet the registration requirements, including those around ensuring their staff are appropriately qualified. Agencies that carry out regulated activities will be required to register, as will nurse-led provision of regulated activities, which were not included under the Care Standards Act 2008[20](CSA). We feel that this provides the necessary assurance for patients and people who use services. Agencies that only supply staff to registered providers, rather than providing care directly, will not be subject to registration with the new Commission. However, they are already subject to legislation governing the regulation of employment agencies (Employment Agencies Act 1973).

3.33 It is the responsibility of the service provider to ensure its contracts with agencies are fit for that purpose. For example, the provider must be sure the agency only sends appropriately qualified and trained staff. It would be an unreasonable expectation of the registration framework to regulate employment agencies, in order to remove responsibility from the service provider for ensuring its staff are safe and appropriately qualified.

20 www.opsi.gov.uk/acts/acts2000/ukpga_20000014_en_1

We asked: 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?

What we heard

3.34 The vast majority of those that responded to this question agreed that the level of detail was appropriate. However, a number of responses said that it was difficult to judge without more details, for example, of how the new Commission will operate, and what the guidance about compliance with the requirements of Regulations will be. It was pointed out that the descriptions would have to be clear and unambiguous, to avoid local interpretation, and that we should ensure that they include new and developing services, but also that they should be reviewed regularly as services develop.

Our response

3.35 We agree that the descriptions need to be as clear and unambiguous as we can make them so that it will be clear to providers whether they need to register with the new Commission or not. We also intend to keep the scope of registration under review to ensure it keeps up with developing services.

Registered managers

3.36 Good management is crucial to delivering care that is safe and of appropriate quality. It will be important for registered providers to be able to demonstrate that they can manage their service safely and effectively. Under the CSA, registered providers must have a 'registered manager' for each establishment or agency if the provider is not able to take responsibility for the day-to-day management and supervision of the care they are registered to deliver. This is different from professional regulation, where individuals are registered for their overall professional competence.

3.37 For some regulated activities, this commitment to the assurance of quality will continue through the Care Quality Commission's assessment against a requirement for some kinds of provider to have a 'registered manager' (as set out in Section 13 of the Health and Social Care Act 2008). Our conclusions on which activities will require a 'registered manager' are set out below.

We asked: Have we determined the right situations in which to register a manager?

What we heard

3.38 Responses were generally supportive of the principle of ‘registered managers’ as an additional requirement for some types of registered activity, but there were many suggestions of variations on how the system should be implemented.

3.39 A number of responses said that the decision on whether a ‘registered manager’ is required should be based on a set of criteria applied consistently. There were suggestions for what the criteria should be based on. These included:

- whether there are adequate mechanisms in place to support management of service delivery;
- risk of harm; and
- concerns about governance, or services with little external scrutiny.

3.40 Some said that the requirement to have a ‘registered manager’ should be extended to the NHS or that adult social care providers should have a ‘registered manager’ at each site. A number of responses took this further and said that every registered service should have a ‘registered manager’ working in the service, whereas other responses suggested a narrower range of services should be required to have a ‘registered manager’. It was suggested that registration with the General Social Care Council (GSCC) should be used as evidence of suitability for ‘registered managers’ in adult social care.

3.41 There were suggestions that multiple site providers should be able to have a single ‘registered manager’ where they can demonstrate effective management of services.

3.42 A number of responses advised caution. For example, it was pointed out that cancelling the registration of a ‘registered manager’ rarely solves underlying problems and the system should ensure that ‘registered managers’ do not become scapegoats for wider organisational shortcomings. A number of responses suggested that there should be a proportionate approach to what is required of a ‘registered manager’, particularly in the case of small providers.

Our response

3.43 Requiring a manager to be registered with the Care Quality Commission ensures that someone who is in day-to-day control of the service can be held accountable for the quality of the service and supervision of the care delivered. This is different from professional regulation where individuals are registered for their overall professional competence. The Commission's role is to ensure that the person applying is fit to manage the particular service.

3.44 The responses to the consultation strongly supported there continuing to be a requirement to have a 'registered manager' for adult social care-related regulated activities, where the registered provider is not in direct day-to-day control of the service on each particular site. In relation to healthcare services, consultation responses were varied and inconclusive, with a range of suggestions put forward by respondents. There is insufficient clear evidence from the consultation to justify changes to the current model for 'registered managers'.

3.45 We have therefore decided that we should maintain the current position and continue to require all providers of regulated adult social care services and private and voluntary providers of regulated health services to appoint a 'registered manager' where the registered provider is not in direct day-to-day control of the service. This means that NHS providers of healthcare will not be required to appoint a 'registered manager'. NHS trust boards are accountable to the Strategic Health Authority or Monitor if they fail to ensure appropriate management of services on each of their sites. We will continue to monitor the requirements for a 'registered manager'.

3.46 The Care Quality Commission will be able to use a proportionate approach to judging provider compliance with the 'registered manager' condition and will be able to exercise its discretion in deciding the type and range of compliance checks required. The Commission will also have the flexibility to decide whether a manager can be registered in respect of more than one regulated activity. In doing so, the Commission will need to be assured that the 'registered manager' is the person in day-to-day control of the regulated activity.

Individual activity topics

3.47 The final list of activities we have decided to include within the scope of registration is as follows:

- Personal care
- Accommodation for persons who require nursing or personal care
- Accommodation for persons who require treatment for drug and alcohol misuse
- Accommodation and nursing or personal care in the further education sector
- Surgical procedures
- Diagnostic procedures
- Treatment of disease, disorder or injury
- Services in slimming clinics
- Transport services, triage and medical advice provided remotely
- Maternity and midwifery services
- Termination of pregnancy
- Assessment or medical treatment for persons detained under the Mental Health Act 1983
- Nursing care
- Management and supply of blood and blood derived products

Other issues

Regulation of non-surgical lasers and intense pulsed light equipment

3.48 Last year, the Department of Health launched a consultation covering private and voluntary healthcare Regulations[21], which proposed the deregulation of non-surgical use of class 3B and class 4 lasers and intense pulsed light equipment. The responses were generally unsupportive of the proposal to de-regulate, citing that the risks the procedures posed to people were too great to support removing it from the scope of registration under the CSA.

3.49 In response to this feedback, we have done further work on collecting and analysing the available information. This included taking advice from other regulatory bodies, and further considering risks posed by these services, and the extent to which regulation by the Care Quality Commission could mitigate these risks. This has enabled us to not only assess relative risks to people using services, set against the costs of

21 The response to that consultation is on the Department's website at: www.dh.gov.uk/en/Consultations/ResponsestoConsultations/DH_096990

regulation, but also which type of regulation (if any) would bring most benefit.

3.50 Our conclusion is that system regulation under the Care Quality Commission is not the most appropriate approach to regulation in this area. Firstly, although these procedures pose some risks, based on the evidence available this does not appear to be high. Secondly, the people who use these procedures are less vulnerable than those accessing many other services, particularly in that they have more freedom to choose whether to undertake the risk or not. Thirdly, the main risks to people receiving non-surgical lasers and lights procedures arise principally from the ability of the provider to use the equipment appropriately. Although system regulation could reduce this risk to a degree by checking that appropriate training had been undertaken, most of the other registration requirements would be irrelevant, which makes system regulation a heavy-handed approach in this field.

3.51 Therefore, we do not intend to include non-surgical uses of lasers and intense pulsed light procedures within the scope of registration under the new system introduced by the 2008 Act. Instead, we will work with the sector and representative bodies on an alternative approach that better targets the specific risks associated with these activities.

3.52 This development will occur over the next 18 months, so that alternative forms of regulation will be developed to support the provision of non-surgical lasers and lights procedures, once the CSA Regulations are repealed and replaced by the scope Regulations made under the 2008 Act.

Services delivered by doctors who provide treatment to NHS and private patients

3.53 Under the CSA, doctors who undertake private work are only required to register with the Healthcare Commission if they work entirely outside of the NHS. Recent reforms in the system, such as introducing a fair playing field, competition policy and patient choice need to feed into any future approach to regulation of private practice. We are considering these policy developments further, in line with our general approach to regulation, ie capturing those areas where the risk to the patient is such that system regulation provides a benefit, whilst not placing an unwarranted regulatory burden on providers or the regulator itself by bringing lower risk areas into regulation. We will continue to work on policy in this area, with a view to introducing an appropriate replacement system in due course.

3.54 However, in the interim we will carry forward the existing provision relating to the registration of doctors who provide treatment to NHS and/or private patients. Therefore those doctors solely providing services to private patients will require registration with the new Commission. In addition, we will make regulatory provision for exemptions to mirror those that currently exist for providers who have a mixture of private and NHS work.

Prison and immigration services

3.55 In the registration framework consultation, we proposed that prison and immigration services should be included in the scope of registration if they are providing a regulated activity. The responses to the consultation on this topic agreed with this proposal. Therefore, where the provision of care as part of prison or immigration services is within scope of any of the above activities, they will need to be registered.

3.56 Forensic medical examiners were also flagged in the consultation document as providing an important high-risk service to vulnerable people with varying levels of external scrutiny through their contractual arrangements. We will work with the professions, police and criminal justice system, Home Office and the new Commission to look at bringing these services into the scope of registration in the future.

Defence Medical Services

3.57 For Defence Medical Services (DMS) delivered in England, hospital care delivered either by arrangement with the NHS or under contract with the independent sector would be covered by the appropriate definitions of regulated activities and, as such, would already be covered by registration with the Care Quality Commission.

3.58 There are some DMS activities which are directly provided by the Ministry of Defence in community or primary care (such as rehabilitation) where the Care Quality Commission could be well placed to provide independent assurance or review whether these services are meeting the levels of safety and quality of equivalent non-DMS services. We are working with the Ministry of Defence on the most appropriate way of assuring these services.

3.59 For DMS activities, including those that are delivered outside England or do not come within the scope of registration, the Care Quality Commission may carry out reviews of those services under agreement with the Ministry of Defence under provisions in Section 73 of the Health and Social Care Act 2008.

What are we consulting on?

Q3.1 Do the draft Regulations set out at Annex B accurately reflect the policy set out in this Chapter and Annex A?

Q3.2 If not, what changes are needed to the draft Regulations to ensure they reflect the policy set out in this Chapter and Annex A?

4. Will primary care be part of registration?

Registering primary care providers

4.1 The consultation sought views on how and when primary medical care and primary dental care providers should be brought within the scope of registration. It also made it clear that we will work with stakeholders to give more consideration to how a new registration system will interact with the existing requirements for primary care providers and the potential for rationalisation.

4.2 There was overwhelming support for the registration of primary medical and dental care providers with the Care Quality Commission. Roughly half of the consultation responses commented directly on primary care. A large percentage of these were from NHS organisations but comments were also made by representative organisations, including: the Royal College of General Practitioners; the Royal College of Nursing; the General Medical Council; the General Dental Council; the British Medical Association; and the British Dental Association.

Primary and Community Care Strategy

4.3 Primary and community care services are regarded with pride at home and admiration abroad. Thanks to the dedication of family doctors, community nurses, health visitors, allied health professionals, adult social care professionals, pharmacists, dentists and opticians, most patients enjoy good quality care close to home.

4.4 There are high levels of satisfaction with services and trust in the staff who provide them. We need to ensure that high quality care is a consistent part of everyone's experience of primary and community care. Services need to evolve to reflect the changes in healthcare and society described in the *NHS Next Stage Review*: rising expectations; the 'information age'; advances in treatments; the changing nature of disease; and the evolving nature of the workplace.

4.5 The vision and strategy in the Primary and Community Care Strategy[22] informed, and has been informed by, the wider *NHS Next Stage Review*. The Department and the Primary and Community Care Advisory Board have discussed how we can raise and realise our ambitions for primary and community care, extensively with members of the public, with clinicians across the NHS including many involved in the regional reviews, and with colleagues from local government and other sectors.

4.6 The conclusions in the strategy fell across four areas:

- people shaping services;
- promoting healthy lives;
- continuously improving quality; and
- leading local change.

4.7 The strategy promised that the Care Quality Commission would, subject to the outcome of this consultation, register all GP and dental services and help tackle persistent poor performance whilst assuring standards for all.

Questions in the consultation document on primary care on registering primary care providers

4.8 The following paragraphs relate to the questions we asked in Chapter 4 of the previous consultation document and the responses we received.

We asked: Do you agree with our proposal that ultimately all GP and primary dental services should be within the scope of registration? and

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

22 NHS Next Stage Review: Our vision for primary and community care (DH, July 2008), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085937

What we heard

Primary medical care

4.9 The overwhelming majority of respondents supported primary medical care being included within the new registration system.

Primary dental care

4.10 The vast majority of those who commented supported primary dental care being included within the new registration system given the risks associated with decontamination and infection control. However, this was not welcomed as universally as the inclusion of primary medical care. It was suggested by some that professional regulation should be sufficient.

General comments

4.11 Respondents sought clarity about where registration would sit in the regulatory framework for primary care. Some respondents wanted clarification on how system regulation would differ from professional regulation and contract management.

4.12 Some respondents also made clear that the extension of registration should not replace the PCT performance management role. Conversely, it was suggested that we should also ensure that the registration system does not result in PCTs diverting a disproportionate level of their resources to a small number of poorly performing practices.

4.13 Some respondents also suggested that extending registration to primary care settings could risk preventing some providers (eg pharmacists) from agreeing to extend the range of services they provide if this results in bringing them into registration.

4.14 The majority of respondents who commented stated that the main risks to be addressed through regulation related to the volume of consultations and to the provision of new services in primary care settings that had previously been provided only in hospitals. Most respondents who commented agreed that it was important to have a level playing field and felt that regulating all settings in the same way was the best way to achieve this.

Other services

4.15 Although the majority of respondents agreed with the suggested scope of registration of primary care, a number of respondents felt that the scope was too limited. Some respondents felt that the principles of

registering services on risk meant there should be further additions to the scope of primary care registration. However, some acknowledged that it might be sensible to begin with primary medical care and primary dental care and keep the need to extend to other services under review.

4.16 Suggested additions to the primary medical services and dental services categories included services sometimes provided in primary care settings and sometimes elsewhere (eg counselling, audiology services, botulinum toxin injections, and dermal fillers). These were considered as part of the wider scope analysis (see Chapter 3 and Annex A). There were a number of services specific to primary care that respondents suggested we needed either to ensure were captured in the existing definitions or else create new definitions to add them in. These were:

- tooth whitening;
- services provided by dental hygienists, dental therapists, dental nurses and dental technicians, as well as those provided by dentists and clinical dental technicians;
- optical services where providing services more complex than sight tests (eg the management of glaucoma patients in the community); and
- pharmacy, particularly if the services they offer extend to include those traditionally offered in a GP practice.

Our response

4.17 The Government intends to bring primary medical and dental care providers within the scope of the registration system. This means that, for the first time, all the approximately 8,500 GP practices and 9,000 high street dental practices will be required to register with the Care Quality Commission, regardless of whether they provide wholly private or wholly NHS services, or a mix of both.

4.18 The Commission's role in registering providers of services will complement and help strengthen PCTs' core responsibility for managing primary care contracts, provide broader information about primary care services to the public, and tackle unacceptably poor or unsafe performance.

4.19 The NHS Next Stage Review Primary and Community Care Strategy set out a framework for managing poor performance and driving up quality in primary and community care services. The registration of primary medical and dental care providers by the Commission will form an important element of our wider strategy for improving quality in

primary care. This wider strategy brings together local action by PCTs and primary care clinicians/practices to improve the measurement of quality improvement with national action to improve key quality metrics such as the Quality and Outcomes Framework (QOF), the GP patient survey, and practice accreditation and to improve incentives for practices and information for the public. Additionally it will bring private sector dentistry within the quality and safety regime for the first time.

4.20 The definitions of regulated activities in the draft Regulations are likely to bring most primary medical and dental care providers into the registration system.

4.21 As set out in the consultation document, we do not currently expect to bring other primary care providers into the registration system, but this may well change if they expand their services. We are committed to keeping the list of regulated activities under review and, in particular, expect to look again at the ophthalmic and audiology services being provided in the community so we can better understand the types of new services being delivered locally and the level of risk they present. We also intend to keep under review the types of services provided by pharmacists as they expand their local role and determine whether or not they are captured by the existing definitions or if these definitions should be revised to ensure that the services that are being developed are included within the registration scheme.

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

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

What we heard

<u>Information</u>

4.22 On the whole, respondents did not comment on the possible information sources that the Care Quality Commission could draw upon in primary care. Those who did were clear that existing information and data sources needed to be used and duplicatory requests avoided. It was suggested that a mapping exercise would be needed to identify the information currently collected before identifying which would be suitable for use by the Care Quality Commission.

4.23 Some respondents asked whether it might be possible for the Care Quality Commission to put arrangements in place to allow it to validate

information that is collected by other organisations. It was also suggested that the Care Quality Commission could work with others in the regulatory system to develop a set of minimum data requirements which all providers would collect and use locally and which all those assessing performance could use.

Rationalising requirements

4.24 Most respondents who commented suggested that the registration system should avoid duplicating any existing arrangements in primary care.

4.25 There was general support from those who commented for rationalising requirements but respondents were uncertain that this would prove to be possible. Several respondents suggested work was needed to map the requirements in order to identify any overlaps and potential for rationalisation. It was felt that there could be scope for a memorandum of understanding to be developed between the Care Quality Commission and other organisations within the regulatory system.

4.26 Rather than talking about rationalising, most responses to this question talked about the concept of information being used in more than one way. For example, it was suggested that should the Commission undertake practice visits, a single visit could perhaps be arranged to simultaneously gather the evidence required to meet the requirements of the Care Quality Commission, PCT, the Dental Reference Service, Denplan and the General Dental Council.

4.27 Many responses made clear that it was important to clarify the role of PCTs and how they would work together with the Care Quality Commission. It was felt the relationship between the Commission and the PCT would be key in the new regulatory framework for primary care.

4.28 There were also some concerns that the new system could be bureaucratic and impose an unnecessary burden on providers. In particular, there was some anxiety about the lack of capacity in small practices to respond to this new agenda, and the likely cost to providers both if fees were charged and in complying with the registration scheme itself. Respondents also suggested that registration could reduce the numbers of those providing services if the standards for new entrants were too high.

Our response

4.29 The registration requirements set out in Chapter 5 will apply to all providers that come within scope of Care Quality Commission registration. The Commission will develop and consult on the principles of its methodology and guidance about compliance with the requirements of Regulations. It is required to work in a risk-based and proportionate way and the Commission has already committed to working closely with partner organisations to develop an approach to registration which draws on existing systems of assurance and sources of information that are relevant to the registration requirements.

4.30 In the case of primary medical care, the Commission will be able to draw on a range of information directly comparable across all practices, such as QOF data, any practice accreditation or teaching practice information and GP patient survey results, in addition to local information gathered by PCTs on areas such as prescribing, referrals, clinical governance and complaints.

4.31 In the case of primary dental care, the Commission could draw on information from the ongoing monitoring and risk assessment process undertaken by the Dental Reference Service (DRS) (part of the Dental Services Division (DSD) of the NHS Business Services Authority) on behalf of all PCTs, together with other information from PCT contract management, patient complaints and other schemes.

4.32 We will work with the Commission as it develops its proposals to ensure that the views expressed as part of the consultation are taken into account.

4.33 We will also work with the Commission, other relevant regulators, and representative groups to ensure that we effectively communicate to providers what the Commission's role is in relation to primary care and explain how this fits within the wider primary care quality framework.

We asked: When should services provided in primary care settings be required to register? Should we phase in registration? and

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

What we heard

Start date

4.34 Nearly all respondents who commented were in favour of bringing all primary care providers into registration at the earliest possible opportunity. There was a concern that unless there was a consistent approach the registration system could influence commissioning decisions and patients could be put at risk.

4.35 However, respondents were clear that it would be important to spend enough time to develop the new system/requirements with all those with an interest in it and to allow time to prepare providers, commissioners, and the Care Quality Commission.

4.36 There were some questions raised about the ability of the Care Quality Commission to develop the necessary expertise and capacity in primary care that it would need to have quickly if it was to have credibility with the providers. It was felt that it was important to allow both the Care Quality Commission and providers themselves time to prepare for the registration of primary medical and dental care. There were also a few concerns about the potential for the Care Quality Commission to develop a secondary healthcare/social care bias if primary care was brought in later.

4.37 The General Medical Council and the General Dental Council, among others, suggested that it would make sense to tie in the rollout of the Care Quality Commission registration scheme for GP practices and high street dentists to the implementation of revalidation and responsible officers for the medical and dental professions. It was also suggested that there should be links with the new Royal College of GPs (RCGP) accreditation system for GP practices.

Phasing

4.38 The majority of respondents to the phasing question felt that this should only be attempted if it was necessary for logistical reasons (due to the scale of the task of bringing providers in) and that it should take place over as short a timescale as possible. Most felt that it would be better to bring all providers in at the same time.

4.39 Some responses suggested that phasing could cause confusion with providers, commissioners, and the general public who could be unclear of which providers would need to register and which would not. However, the suggestion was made that it might help if we pilot implementing the new arrangements.

4.40 If it was necessary to phase, suggestions were to:

- try phasing by area;
- focus on the highest risks first;
- begin in the areas with the least regulation;
- register only single handed practices initially;
- start by registering high risk, high volume services; and
- begin with services with high levels of complaints.

Our response

Start date

4.41 To extend registration to primary medical care and primary dental care providers, the Commission will need to undertake a further work programme to develop a robust methodology and a set of guidance specifically for primary care providers to underpin its registration criteria as well as ensuring providers are aware of the changes. The Department of Health will also have to review the *Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance* to ensure that the criteria are applicable to primary care providers.

4.42 The Commission already has a significant work programme to bring the new registration system on line from 2010. Given this, the scale of the task to develop arrangements for primary care, and the need to ensure providers are adequately informed of the changes and have time to prepare for them, it will not be possible to complete this work in time for primary care to be brought into the registration system in 2010. Therefore, the earliest it will be possible to begin registering GP and dental practices is from April 2011.

4.43 We are working closely with the Commission to explore how it could register dental and GP practices beginning from April 2011. As part of this the Commission will consider how the initial registration and ongoing monitoring processes might be assisted by the availability of existing sources of practice level data, information held on NHS dental practices by the DSD of the NHS BSA, information held by PCTs, and information gathered as part of any practice accreditation scheme. Should a phased approach be necessary, we will ensure that, in the

light of respondents' concerns, any approach taken is unambiguous and fair (see below).

4.44 The draft Regulations in Annex B therefore include an exclusion for those whose sole or main purpose is the delivery of services under GMS, PMS and APMS contracts and dental services provided outside hospitals. This will ensure that GP practices and high street dental practices are not required to register in 2010/11. We will work with stakeholders during the consultation period and subsequently in order to clarify the timetable and process for removing this exclusion and bringing providers into registration. We will also develop the definitions in the draft Regulations further if necessary to ensure all providers of primary medical and dental care are required to register and will consult on any revisions prior to introducing them into Parliament.

4.45 The only exceptions to this exclusion relate to wholly private GPs, who are currently the only primary care providers registered by the Healthcare Commission and to services directly provided by PCTs as these are already considered as part of the Healthcare Commission's annual health check and, in common with all NHS bodies, will be required to register with the Care Quality Commission in relation to HCAI from 1 April 2009. They will be required to continue to register from the start of the new registration system in April 2010 to avoid the burdensome process of taking them out of registration and then requiring them to register again a short while afterwards.

4.46 It is expected that GP and dental practices will be required to register for any regulated activities that they provide in the same way as any other provider. The Commission will work with stakeholders as it develops its methodology and determines how best to handle both the initial registration process and the ongoing monitoring arrangements.

Phasing

4.47 Further work on how to handle the registration of primary medical and primary dental care providers will be undertaken with the Commission and other stakeholders. Given the amount of information held by the Dental Services Division of the NHS Business Services Authority on NHS dental practices it should not be necessary to phase the registration of primary dental care. All providers will be required to be registered from April 2011. However in the case of primary medical care, while we expect the registration process to begin in 2011, we are still working with key stakeholders to confirm when it will be possible to bring all providers into registration. It may be necessary to find a way to phase implementation rather than bringing all providers

into registration on one date. The latest that all GP practices will be registered by the Commission will be April 2012. We will work with all the key stakeholders to ensure that the approach adopted meets the main concerns raised by those responding to the consultation. In particular, with the Commission, we will ensure that any approach works effectively, is unambiguous and fair, will promote improvement, and will balance the need to tackle poor and unsafe practice with continued service provision.

We asked: Is our assessment of the costs and benefits in our accompanying impact assessment reasonable? and

Do you have any additional information on impact that we could use?

What we heard

4.48 Respondents were keen that the extension of regulation to primary care should be properly resourced and should not divert resources from other areas the Care Quality Commission will need to regulate. There was also a general perception that the suggested costs were too low for both PCTs and the Commission and that further work was needed.

4.49 While the majority of responses did not comment on the detailed costings in the impact assessment (IA), a small number of respondents made general comments suggesting that:

- PCT savings were unlikely;
- there could be an increase in the cost to PCTs if registration were brought in and they needed to gather additional information or take more performance management action;
- costs to providers could be higher than suggested if there was a need to complete long forms and provide lots of information for the regulator;
- the IA needed to include the costs of training providers, Care Quality Commission staff, and PCT staff in the new arrangements; and
- the IA needed to cover the costs of enforcement work to the Care Quality Commission.

Our response

4.50 We have considered the comments received and are now undertaking further work with the Commission and provider representatives to develop the detail of our costings further. We are considering the information provided as part of the consultation itself and by

stakeholders subsequently and we will also take into account new information as it becomes available, including information from the pilots of the RCGP primary care accreditation scheme. A further IA will be published in advance of primary medical and dental care providers being brought into the registration system.

4.51 We will also work with the Commission as it develops its methodology, feeding in the comments made and contributing as appropriate to assessments of the costs of implementation.

5. What requirements will registered bodies have to meet?

Registration requirements

5.1 There will be a single, coherent set of registration requirements, which all providers of regulated activities will have to meet. These have been built around the main risks inherent in the provision of health and adult social care services, and developed from the most appropriate of the current Regulations and standards. This includes the core standards within the current Standards for Better Health[23] assessed by the Healthcare Commission and the Regulations under the CSA and National Minimum Standards, which the registration requirements and guidance about compliance with them will replace. The registration requirements are concentrated on the essential levels of safety and quality of care that people should be able to expect, and will be enforceable by the Care Quality Commission.

5.2 The registration requirements are additional to the requirements of other relevant enactments such as human rights and equalities legislation and health and safety at work legislation, compliance with which the Care Quality Commission can take into account when making decisions about registration.

5.3 Providers will need to demonstrate that they are meeting the registration requirements in order to be registered, and continue to meet them in order to maintain their registration. We have finalised the requirements following the consultation, and have now written them into draft legislation (attached at Annex D). The Regulations should be clear about what is required to meet the registration requirements, without being prescriptive about how compliance is achieved. We are now seeking views on whether the wording of the draft Regulations will achieve our intentions set out below.

23 Standards for Better Health (DH, July 2004), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086665

Guidance about compliance with registration requirements

5.4 The Commission is currently developing the principles of its methodology and guidance about compliance, which it will use to judge compliance with the registration requirements, and will be consulting on them later this year. The exception to this is the guidance covering HCAI, which is set by the Secretary of State[24].

5.5 Where necessary, the guidance about compliance with registration requirements will provide more activity specific detail to reflect clear differences in how services are run and delivered. For example, the risks associated with premises where people live, such as a care home, may need to be identified in different ways to an environment that people use only when they require care or treatment, such as a hospital.

5.6 Guidance about compliance with registration requirements will be outcome focused, and based on people's experience of using, or living in, a social or healthcare service. The guidance will set out a means of compliance, but there may be other ways of complying with the Regulations. The most important thing is that the provider runs their service safely and in accordance with the law. The way in which they achieve this must allow for flexibility within different settings.

Human rights and equalities

5.7 Section 23(2) of the Health and Social Care Act 2008 enables the Care Quality Commission to take account of other enactments, including human rights and equalities legislation, in reaching decisions on registration. It will be able to address equality, respect for diversity and other human rights. Therefore, these do not need to be duplicated in registration requirements.

5.8 Section 4 of the 2008 Act requires the Care Quality Commission to have regard to the rights of people who use services, particularly detained people and those that lack mental capacity. We have designed the registration requirements in order to ensure that they support a human rights approach in relation to the provision of health and adult social care.

NHS Constitution

5.9 Many of the registration requirements are aligned with the patient rights set out in the NHS Constitution. For example, the registration requirements around respecting and involving users of services in

24 See Section 20(5), Section 21 and Section 22 of the 2008 Act

decisions about their treatment and care correspond with the patient rights in the Constitution to be treated with dignity and respect, and to be involved in decisions about their healthcare. Similarly, the patient right not to be unlawfully discriminated against in the provision of NHS services is reflected in the registration reqiurements around equal treatment. Subject to the passage of legislation, the new Commission, along with all providers of NHS care, will be required to have regard for the NHS Constitution in its actions.

Consultation response

5.10 More than half of the total consultation responses commented on our proposals for registration requirements. Responses came from all types of respondent, from health and adult social care sectors, from providers and commissioners and from people who use services. We welcome the high level of interest shown in our proposals for safety and quality registration requirements, and value the contributions a very wide range of stakeholders has made to their development.

5.11 Some respondents found it difficult to comment on the registration requirements without seeing the detail of the Care Quality Commission's criteria and methodology for judging compliance. We appreciate respondents' need to understand how registration requirements will work in practice and, in particular, detail about how the Care Quality Commission will judge and enforce compliance. The Commission has a statutory duty to consult upon the way in which it will judge compliance and on its enforcement policy. However, before it develops its approach, the Commission needs to know what legal requirements the Regulations are likely to contain.

5.12 The Care Quality Commission has now started to engage with a range of stakeholders in developing its guidance about compliance with the requirements of Regulations and will consult formally in summer 2009. Information about respondents' comments and queries are being shared with the Care Quality Commission so that it will be aware of them as it develops its approach to registration.

The questions we asked in Chapter 2 of the consultation document on registration requirements

5.13 The following paragraphs relate to the questions we asked in Chapter 2 of the previous consultation document and the responses we received. Annex C sets out our analysis of comments on our proposals on

individual registration requirements, and our response. Annex D sets out the draft Regulations that will set these in legislation.

We asked: 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. Do you agree with this approach?

What we heard

5.14 There was very strong support for the proposed approach to registration requirements, with many responses welcoming a single set of registration requirements spanning health and adult social care. This was welcomed as encouraging co-operation and shared values between different services. Several responses explicitly expressed support for a fair-playing field between NHS and independent sector providers.

5.15 Although the approach to registration requirements was widely welcomed, there were a lot of comments and queries about the detail of how this would work in practice.

5.16 Some respondents felt that there was a need to ensure that providers were not just meeting the essential levels of safety and quality required by registration, but that they were also improving their services. Some feared that the proposals were a backwards move from other initiatives to promote improvements in safety and quality, and they were anxious that these drivers should not be lost.

5.17 Some social care providers in particular questioned the wording of both the proposed areas for registration requirements and their accompanying examples, which they believed failed to emphasise the specific needs of people who use adult social care services. Many noted that the consultation's emphasis on risk failed to consider that some risk has a role in promoting the independence of people who use adult social care services. Overall, many respondents called for more emphasis to be placed on the promotion of independence for people using services, and on the need for social inclusion and the provision of meaningful activities for people who use adult and social care services.

5.18 Some responses considered the wording of the requirements to place insufficient emphasis on the range of ways services are delivered, with too much focus on institutional-based care relative to domiciliary care.

5.19 A number of respondents stressed the need for the Care Quality Commission's guidance about compliance to be specific to the service

provided, and proportional to the size of the provider. This reflected queries from respondents about how the new regulator should ensure it does not place a disproportionate burden on smaller providers.

5.20 There were mixed views about the aim to focus on outcomes and to prevent an unnecessarily prescriptive approach to regulation. Some felt the registration requirements were still too focused on processes. However, others pointed out that reducing the prescription in Regulations, may leave them too open to interpretation with the result that the parameters for the Care Quality Commission's development of guidance about compliance are unclear.

Our response

5.21 We welcome the very strong support for our proposals for a coherent set of registration requirements, clearly set out in Regulations, which will apply across health and adult social care services.

5.22 In developing a coherent set of requirements that applies across health and adult social care, it is inevitable that the different nuances of approach in specific types of care and for different sizes of provider are not fully explicit in Regulations. To attempt to tailor Regulations to different types of service would result in a very large volume of Regulations. This would dilute the impact of a concise set of requirements, clearly setting out what people can expect regardless of who provides the specific care they need. A more specific approach would also lose flexibility to adapt requirements to new integrated care services as they evolve.

5.23 We have therefore prepared Regulations that are flexible enough to allow the Care Quality Commission to develop guidance about compliance with the requirements of Regulations that can, where relevant, reflect the important differences of emphasis between activities. So for example, where the requirement is to manage risk, there is scope for the Commission to focus on appropriate risk-taking to promote independence in services that provide longer-term care, but in activities such as surgery to focus more on patient safety and reducing risk. Where a service provider is a small business, there is scope for the Commission to develop relevant guidance about compliance with the requirements of Regulations that takes a proportionate approach. We are encouraging the Commission to provide such flexibilities in developing guidance about compliance with the requirements of Regulations and to refer to activity specific guidance from expert bodies where appropriate.

5.24 In developing the registration requirement Regulations, we have also been very careful to ensure that they contain sufficient detail to give

clarity to the legal requirement and are enforceable, whilst at the same time allowing flexibility and not being unnecessarily detailed or prescriptive. The Regulations set clear parameters for the development of the Care Quality Commission's guidance about compliance with the requirements of Regulations. In view of the flexibilities we have built into the registration requirements, we are encouraging the Care Quality Commission to use its guidance about compliance with the requirements of Regulations and methodologies to assure the quality and consistency of inspectors' decisions.

We asked: Are the areas covered by the registration requirements the right ones to provide the assurance of the essential levels of safety and quality that we are aiming for? and

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

What we heard

5.25 Respondents were largely supportive of the topics proposed for registration requirements, and did not consider any of the proposed topics inappropriate. Financial position and public health promotion were suggested by some as additional topics.

5.26 Queries were raised about the potential for duplication between the Care Quality Commission's role and those of other bodies and legislation, with some respondents seeking assurance that the Care Quality Commission would not impose unnecessary burdens on providers. There was broad support for the Care Quality Commission's proposed role in minimising the overall burden of regulation on health and adult social care organisations.

5.27 Many responses felt that Requirements 15, 16, and 17 covered similar areas in that they all involved workers and could be consolidated into one Requirement about workers.

Our response

5.28 We welcome confirmation that the topics we have chosen for registration requirements are the right ones.

5.29 We agree with the comments made about the financial position of providers. Therefore, we now propose to make a Regulation under Section 20 of the Health and Social Care Act 2008 to create a requirement in relation to providers' financial positions. This will not apply to all providers of health and adult social care, as it needs to

reflect other mechanisms that assure the financial position of publicly accountable services. It will not therefore be part of the universal safety and quality set of registration requirements, but will be one of the other Regulations that underpin the new regulatory system. Chapter 6 has further information on proposals for this Regulation.

5.30 We also acknowledge the vital importance of the role of NHS commissioners and providers in protecting and promoting public health and securing our aim of better health and wellbeing for all. Registration can play an important part in this, ensuring that providers protect the health and wellbeing of individuals who use their services. Requirements also require providers to co-ordinate their response to emergencies to ensure that they are prepared to protect a wider community of service users when called upon to do so. Registration will not cover broader population based health promotion measures such as healthy eating campaigns as they are different in nature to the essential standards of safety and quality that registration is designed to assure.

5.31 In developing the registration requirement Regulations, our aim has been to avoid repeating and thus duplicating the requirements of any other legal enactment. The 2008 Act already enables the Care Quality Commission to take account of compliance with any other relevant enactment in its decisions on registration. The 2008 Act also gives the Commission duties to cooperate with other regulators and to act proportionately. The Commission will therefore be required to work closely with other regulators to minimise overall inspection burdens on registered providers.

We asked: Does the wording of the registration requirements provide appropriate coverage of these areas?

What we heard

5.32 Respondents felt that the proposed wording of requirements was broadly right. Over 30 suggestions were made to build upon the proposed wording to strengthen areas already covered by the proposed requirements. Many of these responses concerned providers' engagement with people using adult social care with respondents feeling that the wording of the requirements should place more emphasis on supporting people to determine their own care and treatment. Several respondents considered that the use of the language such as "involved in decisions about their receipt of care" was insufficiently strong.

5.33 Several areas were identified as requiring more emphasis, including people's rights, equality and diversity and the needs of children and young people. Some respondents thought that too little emphasis was placed on the specific needs of people who use mental health services and deprivation of liberty safeguards, and the provision of information to people who use services.

5.34 Some adult social care providers and independent healthcare providers suggested that the term 'staff' is not comprehensive enough, and that 'workers' should be used instead. Other respondents felt that the stated objective that people should have a good experience of care was lost in the wording of the requirements, with others requesting a greater emphasis on the quality of care.

Our response

5.35 As discussed previously, developing a coherent set of requirements that apply across health and adult social care makes it inevitable that different priorities for engagement with patients and people who use services in different circumstances are not fully explicit in these Regulations. The Regulations will allow the Care Quality Commission to develop flexible guidance about compliance with the requirements of Regulations that, where needed, reflect these differences and refer to activity specific guidance from expert bodies where relevant.

5.36 We have combined our previously proposed requirements to respect and involve people who use health and adult social care services to ensure a more coherent approach to engagement. This will work along with the provisions of the Mental Capacity Act to ensure that people have a strong voice in decisions that affect their care.

5.37 The specific needs of: people detained under the Mental Health Act; children; those receiving care at home; and those that receive accommodation together with their care, etc can, where needed, be emphasised through the guidance about compliance with the requirements of Regulations and the information to support implementation. We are encouraging the Commission to do so, making links to relevant activity specific guidance from expert bodies where appropriate.

5.38 We believe that greater legal clarity can be achieved by keeping separate the very different aspects of the requirements relating to workers, ie pre-employment checks, ensuring services have sufficient numbers of appropriately qualified staff and ensuring staff have appropriate ongoing support and development, rather than combining them into a single requirement.

Conclusion

5.39 The final list of registration requirements we have decided on is as follows:

Registration Requirements	Explanation
Care and welfare of service users	This requires providers to assess each user of service's needs, to identify and deliver safe and suitable treatment and care to meet those needs. This requires providers to have a sound evidential basis for the care and treatment they provide or put in place appropriate risk management for innovative procedures. It will work alongside equalities legislation and requirement 9 to ensure each individual's diverse needs are taken into account and that people are not unlawfully discriminated against in the provision of health and adult social care services.
Assessing and monitoring the quality of provision	This requires providers to assign management responsibilities and to operate systems that assess and are accountable for the overall safety and essential quality of care and treatment provided. This requires providers to learn from the views of users of services, including complaints, from incidents and near misses and sources of expert advice.
Safeguarding vulnerable service users	This requires providers to protect users of services against abuse. This requires providers to act proportionately and in the best interests of the user of services when using any form of restraint or other technique to address disturbed behaviour.
Cleanliness and infection control	This requires providers to protect people against the risks of acquiring a healthcare associated infection, using compliance guidance set out in the code of practice for the NHS on the prevention and control of healthcare associated infections.
Management of medicines and medical devices	This requires providers to ensure medicines and medical devices are appropriate for the purpose used and are handled and used safely.
Meeting nutritional needs	This requires providers to guard against malnutrition and dehydration where meeting users of services' nutritional and hydration needs are integral to the service provided (e.g. in residential care or for inpatients). This requires providers to provide sufficient quantities of nutritious food and assist users of services to eat and drink where needed.
Safety and suitability of premises	This requires providers to use premises that are suitable for the purpose used and maintained to provide a safe environment for users of services.

Registration Requirements	Explanation
Safety, availability and suitability of equipment	This requires providers to ensure equipment is appropriate for the purpose used, handled, and used safely. It requires providers to have sufficient equipment to ensure the safety and essential quality of care and treatment offered. In residential services, it requires the provision of a homely environment.
Respecting and involving service users	This requires providers to treat service users with respect and to protect their dignity, privacy and independence. It requires providers to treat all users of services equally and have regard for their diverse needs. It requires providers to inform users of services about their treatment and care and involve them in decision making. It will work alongside equalities legislation to ensure people are not unlawfully discriminated against in the provision of health and adult social care services.
Consent to care and treatment	This requires providers to ensure they obtain informed consent for the care and treatment they provide.
Complaints	This requires providers to operate an effective complaints process. It requires the complaints process to be accessible for service users. It requires providers to investigate complaints and, where possible, resolve them to the satisfaction of the complainant.
Records	This requires providers to keep records relevant to the carrying on of the regulated activity and specifically the care and treatment they provide to service users and to maintain the confidentiality of the information they contain.
Competence and suitability (in Regulations called 'fitness') of workers	This requires providers to operate effective recruitment procedures that ensure workers are competent and suitable for the roles they perform. It will work alongside equalities legislation to ensure that recruitment is free from unlawful discrimination.
Staffing	This requires providers to have sufficient numbers of competent staff in place at all times to ensure the safety and welfare of service users.
Effective management of workers (in Regulations called 'supporting staff')	This requires providers to operate effective people management to support workers in fulfilling their roles, ensure they operate within their competency and undergo necessary training and development. It will work alongside legislation to ensure that workers have equal opportunities and are free from unlawful discrimination.

Registration Requirements	Explanation
Cooperating with other providers	This requires providers to work together to ensure that service users are safe as they move between services. This requires providers to work together where they share responsibility for a service user's overall care and treatment. This requires providers to work together in developing their response to emergencies. This requires providers to support service users to access other services they need.

5.40 Registered service providers and 'registered managers' who contravene Regulations on safety and quality will be guilty of an offence, punishable on summary conviction by a fine not exceeding £50,000.

5.41 Annex C sets out our analysis of comments on our proposals on individual registration requirements, and our response. Annex D sets out the draft Regulations that will set these in legislation. The original proposals can be found in Annex A of the original consultation document.

What are we consulting on?

Q5.1: Do the draft Regulations set out at Annex D accurately reflect the policy set out in this Chapter and Annex C?

Q5.2: If not, what changes are needed to the draft Regulations to ensure they reflect the policy set out in this Chapter and Annex C?

6. Other Regulations to support the registration framework – consultation on policy content

Other Regulations supporting the registration framework

6.1 For the Care Quality Commission to operate the registration system, the Department of Health must make Regulations to underpin the framework for registration and enforcement set out in the Health and Social Care Act 2008. The policy and proposed content of some of these Regulations has been set out in the preceding chapters. We also need to make other Regulations covering the registration process and enforcement. Our proposals for the policy approach to these are set out below, and cover the following topics:

Other registration requirement Regulations

- fitness of registered persons;
- provision of information;
- financial position; and
- Regulations relating to termination of pregnancy.

Registration process

- the keeping of a register;
- the making of applications for registration;
- appointment of liquidators;
- death of a registered person; and
- power to require explanation.

Enforcement

- issue of penalty notices;
- publication of information relating to enforcement action;
- cancellation of registration; and
- notification to other bodies of certain matters.

6.2 Regulations on some of the registration process and enforcement topics have already been made to support the 2009/10 HCAI registration system for the NHS (Statutory Instrument 2009/660)[25] and require little change to make them applicable to a wider range of providers of regulated activities. Other Regulations are similar to those made under the CSA.

6.3 To implement the full 2008 Act registration system, we will revoke the Regulations that apply for 2009/10 and put in place a new set of Regulations that will apply from April 2010. We are now seeking views on the proposed policy approach that will be put in place through these Regulations.

Other registration requirement Regulations

Fitness of registered persons

6.4 The Secretary of State is responsible for making Regulations that will set out the fitness requirements for those wishing to carry on or manage a regulated activity. We therefore propose that the Secretary of State will make Regulations setting out the different types of legal entities that are required to register and stipulating that individuals or partners who are registered providers, persons responsible for supervising the management of provider organisations and 'registered managers' must:

- be of integrity and good character;
- be physically and mentally fit to perform their roles (with reasonable adjustments made in accordance with equalities legislation where relevant); and
- have relevant qualifications, skills and experience to perform their roles and have had the relevant checks carried out.

6.5 We do not propose to specify in detail in Regulations the qualifications, skills and experience that registered providers and managers must have. Instead, we propose that the Care Quality Commission describes this level of detail in its guidance about compliance, drawing on expert advice from relevant bodies such as professional regulators and sector skills bodies.

6.6 Registered service providers and 'registered managers' who contravene Regulations on the fitness of registered persons will be guilty of an offence, punishable on summary conviction by a fine not exceeding £50,000.

25 Regulation 5 of the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009 (Statutory Instrument 2009/660), available at www.opsi.gov.uk/si/si2009/uksi_20090660_en_1

Provision of information

6.7 We propose to make Regulations requiring the provision of two types of information:

- information that a registered provider must notify to the Care Quality Commission; and
- information that a registered provider must provide to people using their services and more widely.

Information to be notified to the Care Quality Commission

6.8 The Commission will need information to:

- allow it to target its resources wisely and proportionately;
- establish baselines for inspection of compliance with registration requirements and identify providers who lie outside expected parameters;
- be alert to critical events affecting the safety and wellbeing of people using regulated services and respond appropriately depending on how they are being managed;
- be assured that services continue to be appropriately carried on and managed and meet registration requirements; and
- keep up to date with changes in the carrying on and management of services.

6.9 The Commission will need varying types of information within certain categories. It will also need notification in formats that allow it to process information efficiently and it will need to have information within appropriate timescales. We do not propose to specify the precise detail of content, format and timescale of notification in Regulations. Instead, we propose to set out the categories of information that providers will need to supply and allow the Commission to provide further detail within its guidance about compliance with the Regulations.

6.10 The Commission will take a proportionate, risk-based approach to its regulatory role. To support this approach, it is essential it is notified of incidents that may be an indication of a risk to ongoing compliance with registration requirements. We have identified notification of the following categories as essential to support a risk-based approach:

- any death of a person that uses services that suggests that there may have been a failure in compliance with registration requirements that may have caused or contributed to the death;
- any death of a person who uses services who is liable to be detained under the Mental Health Act 1983;

- deprivation of liberty of a person who uses services in accordance with the safeguards in the Mental Capacity Act 2005;
- outbreaks of an infectious disease;
- injury to a person who uses services that suggests that there may have been a failure in compliance with registration requirements that may have caused or contributed to the injury;
- illness contracted by a person who uses services that suggests that there may have been a failure in compliance with registration requirements that may have caused or contributed to the illness;
- healthcare associated infection contracted by a person who uses services that suggests that there may have been a failure in compliance with registration requirements that may have caused or contributed to the contraction of the infection;
- events which adversely affect the registered provider's ability to comply with registration requirements (eg a fire which seriously damages the safety of the premises where a regulated activity is carried on);
- an allegation that a person who uses services has been abused;
- an incident which is reported to, or investigated by, the police and involves the health and well-being of people who use services;
- an allegation of misconduct in relation to registration requirements against a registered person or a person working for the purpose of carrying on the regulated activity; and
- an unauthorised absence of a person who uses services who is detained in hospital under the Mental Health Act 1983.

6.11 The Care Quality Commission will also need to be notified of information about the manner in which regulated activities are being carried on and any changes in leadership and management that indicate a potential risk to compliance with registration requirements and to ensure there is ongoing accountability for the essential safety and quality of the service provided.

6.12 We have identified the following information as likely to be essential for this purpose:

- to enable the Care Quality Commission to consider any conditions that may need to apply to the registration, a statement of purpose setting out:
  - the aims and objectives of the registered provider in carrying out the regulated activity;
  - the name and address of the registered provider and any 'registered manager' along with their business address;
  - the kinds of services provided for the purposes of the

  regulated activity and the range of needs of people who use services, which those services are intended to meet;
  - the locations at which the regulated activity is carried on;
- a report setting out the provider's self-assessment of their compliance with registration requirements and any improvements planned to ensure compliance;
- the absence of a registered provider or 'registered manager' from carrying on or managing the regulated activity and interim measures put in place to lead and manage the activity;
- the intention of a person other than the registered person to carry on or manage the regulated activity;
- when a registered person ceases or intends to cease to carry on or manage the regulated activity;
- a change in registered provider (for example where a privately owned service is sold);
- details of any 'registered manager' appointed by the registered provider;
- any change to the name or address of the principal office of the registered provider;
- where the service provider is a partnership, any change in the membership of the partnership;
- where the service provider is an organisation, any change to the name, address or senior management;
- when a trustee in bankruptcy is appointed or sequestration has been awarded in respect of the registered provider's estate;
- when a receiver, manager, liquidator, or provisional liquidator is appointed;
- where the service provider has made a composition or significant arrangement with, or granted a trust deed for, creditors and not been discharged in respect of it;
- if the registered provider makes changes to the statement of purpose;
- where the premises or localities in which the regulated activity is carried on are changing; and
- where planning permission is granted in relation to premises in which the regulated activity is carried on.

6.13 The Care Quality Commission intends to develop guidance about compliance that provides further detail about the circumstances in which the above types of information must be notified. Any notification of the above information must be given within a timescale and in a manner as specified by the Care Quality Commission in its guidance about compliance.

6.14 We recognise that there are existing national reporting arrangements in place for some of the above information in certain sectors. We know that this is particularly true in the case of organisations providing care under the NHS. For example, the NHS has existing mechanisms for notifying serious incidents to the National Patient Safety Agency. We do not wish to place additional reporting burdens by requiring duplicate reporting to the Care Quality Commission. We will therefore work with the Care Quality Commission and the National Patient Safety Agency and others to identify how they can best work together to collect and share information and avoid duplication. We may need to make Regulations to ensure that information is collected through the most appropriate body.

Information to be made available to people who use services and more widely

6.15 The draft registration requirement Regulations discussed in Chapter 5 above, and set out in Annex D, require registered providers to provide people who use services with appropriate information in relation to the regulated activity. The Care Quality Commission will set out the information it considers appropriate in judging compliance with this requirement in guidance about compliance. We do not therefore propose to make Regulations on these matters except where essential to ensure there are no barriers to cross-border trade in services between EU member states for future compliance with the European Services Directive.

6.16 However, we recognise that where people who use services are responsible for paying all or part of the costs of their care or treatment, that it is vital that they are provided with information about:

- the terms and conditions that apply to the services provided and where appropriate the form of contract that applies; and
- the amount and method of payment of fees.

6.17 We therefore propose to make Regulations to this effect.

6.18 Registered service providers and 'registered managers' who contravene Regulations on the provision of information will be guilty of an offence, punishable on summary conviction by a fine not exceeding level 4 on the standard scale (£2,500).

Financial position

6.19 Responses to the consultation identified providers' financial position as a gap in our proposed topics for registration requirements. We recognise that a sound financial position is important to ensure the continuity of safe and effective services that people rely on to meet their essential health and adult social care needs. We therefore propose to make a Regulation requiring that providers maintain a financial position that allows them to deliver the regulated activity in a way that meets registration requirements. This will enable the Care Quality Commission to refuse registration where an applicant does not have adequate financial plans to support their application. It will also enable the Care Quality Commission to ensure that providers act where they lack adequate resources to ensure ongoing compliance with registration requirements. The Care Quality Commission will develop guidance about compliance with this Regulation, but we do not expect this to involve detailed consideration of providers' financial accounts.

6.20 Whilst the need for sound finances applies to all sector providers, we recognise that mechanisms are already in place to assure the financial position of publicly accountable services. For example, Monitor already provides assurance of the financial position of NHS foundation trusts. For other NHS trusts, Strategic Health Authorities and the Department of Health provide appropriate assurance. For local authority provided services, the Audit Commission provides assurance through the Comprehensive Area Assessment linked to the Care Quality Commission's review of commissioning authorities. We do not want to duplicate those mechanisms through a regulation on providers' financial position. NHS trusts, NHS foundation trusts and local authority provided services will therefore be exempted from this Regulation.

6.21 Registered service providers and 'registered managers' who contravene Regulations on financial position will be guilty of an offence, punishable on summary conviction by a fine not exceeding level 4 on the standard scale (£2,500).

Regulations relating to termination of pregnancy

6.22 Currently, the Private and Voluntary Healthcare Regulations place additional requirements on providers who perform termination of pregnancy services. These requirements need to be carried forward into the new regulatory framework. A failure to comply with Regulation 41 in the Private and Voluntary Healthcare Regulations is an offence. We are making provision to maintain these requirements.

6.23 Registered service providers and 'registered managers' who contravene Regulations on termination of pregnancy will be guilty of an offence, punishable on summary conviction by a fine not exceeding level 4 on the standard scale (£2,500).

Registration process

The keeping of a register (Section 16)

6.24 The 2008 Act allows for Regulations to be made that require the Care Quality Commission to keep a register.

6.25 Under Section 38 of the 2008 Act, the register will be available for inspection by members of the public. Its purpose will be to keep the public informed about the identity of persons registered as service providers, and the details of which regulated activities they are registered to provide.

6.26 The form, type and content of the information may vary for different types of providers (eg individual providers, partnerships, organisations), and over time. We intend to carry forward the Regulation that we are putting in place for the registration of NHS providers in 2009/10. This sets out that the Care Quality Commission must establish and maintain a register containing such information as appears to the Commission to be necessary to keep the public informed about the identity of persons registered as service providers and their carrying on of regulated activities. The actual content of the register will be determined by the Care Quality Commission in accordance with this general purpose.

The making of applications for registration (Section 16)

6.27 The registration process operated by the Care Quality Commission will need to comply with the UK's obligations under the European Services Directive, which must be implemented by the end of December 2009. This Directive aims to break down barriers to cross border trade in services between EU member states, making it easier for service providers, particularly small and medium sized enterprises, to:

- set up business and offer services in other member states; and
- provide services temporarily and/or at a distance in other member states.

6.28 Once the legislation implementing the European Services Directive is in place we will consider what, if any, further provision is required in

Regulations relating to the Care Quality Commission to cover issues such as formalities and timescales for dealing with applications.

Appointment of liquidators (Section 41)

6.29 This Regulation-making power covers the appointment of liquidators, receivers and trustees if a registered provider goes into receivership, liquidation or becomes bankrupt. We propose to make Regulations that will require the liquidator, receiver or trustee to notify the Care Quality Commission of their appointment as soon as possible, and to appoint a manager to take full-time day-to-day charge of providing the regulated activity in any case where there is no 'registered manager'. The Regulations will also require the liquidators to inform the Commission of their intentions for the future operation of the regulated activity within 28 days of their appointment.

Death of a registered person (Section 42)

6.30 This Regulation-making power covers the circumstances when a registered provider dies. It is proposed to replicate the Regulation that currently applies in relation to the CSA. This sets out that, when a sole registered provider dies, or all registered providers die within a short period, their personal representatives must notify the Care Quality Commission of the death without delay. The personal representatives will also be required to notify the Care Quality Commission of their intentions about the future running of the service within 28 days.

6.31 The Regulation will enable the personal representatives of the deceased registered provider to continue to deliver the regulated activity without being registered for an initial period of up to 28 days. The Care Quality Commission will be able to extend this for further periods up to a total of a year. The proposed Regulation will enable the activity to be provided, minimising disruption and inconvenience to those using the service whilst alternative arrangements are put in place.

Power to require explanation (Section 65)

6.32 Sections 62 to 64 of the 2008 Act give the Care Quality Commission powers to enter and inspect premises and to require information and documents. The 2008 Act gives the Commission the power to require an explanation of any documents, records, information or other items inspected, copied or provided under Sections 62 to 64, and any other documents, records, other items or information provided to the

Commission for the purposes of its regulatory functions. We intend to amend the Regulation that we are putting place for the registration of NHS providers in 2009/10 in order to reflect the broader range of providers who will be registered in 2010/11. Regulations will prescribe the persons who are required to provide an explanation. Regulations will also enable the Care Quality Commission to determine where and when such explanations must be provided.

6.33 We propose that Regulations will prescribe that the following persons are required to provide an explanation:

- a person carrying on a regulated activity;
- a chair, director or employee of a person carrying on a regulated activity;
- a member of an English NHS body other than an NHS foundation trust;
- a member of a committee or sub-committee of an English NHS body other than an NHS foundation trust;
- a member of a committee or sub-committee of the board of directors of an NHS foundation trust;
- a local authority;
- a member of a local authority;
- an elected mayor of a local authority within the meaning of Section 39(1) of the Local Government Act 2000;
- a member of a committee or sub-committee of a local authority, or a member of a joint committee of two or more local authorities;
- an officer of a local authority;
- a person (other than the above) who is assisting a person carrying on a regulated activity in the provision of that activity;
- a person providing equipment or premises to a person carrying on a regulated activity;
- a chair, director or employee of a person providing equipment or premises to a person carrying on a regulated activity; and
- a person (other than the above) who is assisting a person providing equipment or premises to a person carrying on a regulated activity.

Enforcement

6.34 The Care Quality Commission will have a broader range of enforcement powers under the Health and Social Care Act 2008 than are available under current legislation. When service providers are registered under the 2008 Act, the Care Quality Commission will be able to consider the following statutory enforcement action:

- issuing a warning notice;
- imposing, varying and removing conditions of registration;
- issuing a monetary penalty notice for prescribed offences;
- suspending registration;
- cancelling registration; and
- prosecuting for offences.

6.35 The following section summarises these enforcement powers and discusses where Regulations are proposed.

Issue a warning notice (Section 29)

6.36 The notice will provide details of the breach and, if it is ongoing, set out a timescale within which the provider must rectify it. The notice will state that further action may be taken if the breach is not rectified in time. At the end of the period specified in the notice, the Care Quality Commission may take any follow-up action it deems necessary. These powers are set out in the 2008 Act and require no additional Regulations.

Impose, vary or remove conditions (Sections 12 and 31)

6.37 The Care Quality Commission may, at any time, impose additional conditions or vary/remove conditions in place on a provider's registration. There is a normal and an urgent process by which the Care Quality Commission can do this, and there is a right of appeal. These powers are set out in the 2008 Act and require no additional Regulations.

Issue a monetary penalty notice (Section 86)

6.38 The Care Quality Commission can offer a provider a monetary penalty notice in lieu of prosecution for a fixed penalty offence and will be able to do this in response to offences that will be set out in Regulations. A provider can choose to refuse to pay the penalty, in which case the Care Quality Commission will consider what other enforcement powers to use, for example whether to bring a prosecution.

6.39 In setting the value of the penalty, the intention is to provide an incentive to comply with Regulations rather than to damage the service provider or to remove large amounts of money from the care system. The 2008 Act states that the value of the penalty cannot exceed one half of the maximum amount of the fine liable on summary conviction for the relevant offence.

6.40 For 2010/11, it is proposed, in the case of service providers to continue the same value of penalty notices that will apply to the registration of NHS organisations in 2009/10. In 2010/11, 'registered managers' provisions in the 2008 Act will be commenced. In addition, some of the offences, such as obstructing an inspector, could be committed by an individual other than a 'registered manager'. It is recognised that the penalty notices are likely to impose a greater financial burden on individuals than on organisations. It is therefore proposed that the value of penalty notices as they apply to 'registered managers' and other individuals who are not service providers will be one half of the amount that applies to organisations.

6.41 The table below summarises offences that have been established either in the 2008 Act or will be established by Regulations, together with the maximum penalty on conviction and the proposed value of penalty notices.

Offences and proposed penalty notice values

Offence	Maximum court penalty set in the Health and Social Care Act 2008	Maximum court fine proposed to be set by Regulations	Proposed penalty notice value – registered service providers	Proposed penalty notice value for offences committed by individuals who are not a service provider (including 'registered managers')
Failure to be registered	12 months imprisonment and an unlimited fine[26]	n/a	£4,000	Not relevant
Failure to comply with conditions in relation to registration	£50,000	n/a	£4,000	£2,000
Failure to comply with suspension or cancellation	£50,000	n/a	£4,000	£2,000

26 This penalty relates to conviction on indictment. The maximum penalty on summary conviction is a fine not exceeding £50,000 and/or imprisonment for a term not exceeding 12 months.

Offence	Maximum court penalty set in the Health and Social Care Act 2008	Maximum court fine proposed to be set by Regulations	Proposed penalty notice value – registered service providers	Proposed penalty notice value for offences committed by individuals who are not a service provider (including 'registered managers')
Failure to comply with registration requirements whose contravention is an offence under Section 20 of the 2008 Act and which carry a maximum fine of £50,000 (registration requirements in Chapter 5 and fitness of persons)	n/a	£50,000	£4,000	£2,000
Failure to comply with the general registration requirements whose contravention is an offence under Section 20 of the 2008 Act and carry a maximum fine of level 4 on the standard scale (termination of pregnancy, financial position, provision of information)	n/a	£2,500	£1,250	£625
False description of concerns	£5,000	n/a	n/a	n/a
False statements in applications	£2,500	n/a	n/a	n/a
Obstructing an inspector	£2,500	n/a	£1,250	£625
Failure to provide documents or information	£2,500	n/a	£1,250	£625
Failure to provide an explanation of any relevant matter	£2,500	n/a	£1,250	£625

6.42 It is also proposed to make Regulations on two other aspects of penalty notices. These will provide:

- that the time by which the penalty is to be paid is 28 days from the date of the notice; and
- that if a registered service provider does not pay a penalty proceedings for the offence to which the notice relates may not be instituted before 28 days have elapsed from the date of the notice.

6.43 The Regulations will also set out details of: what the penalty notice will include; the methods for payment of the notice; and arrangements for withdrawing penalty notices.

Suspend registration (Sections 18 and 31)

6.44 The Care Quality Commission can suspend the registration of a provider for a specified period of time. This will give the provider an opportunity to rectify the issue, and then resume service provision. There is a normal and an urgent process by which the Care Quality Commission can do this, and there is a right of appeal. These powers are set out in the 2008 Act and require no additional Regulations.

Cancel registration (Sections 17 and 30)

6.45 The Care Quality Commission has the power to cancel registration without undertaking any other enforcement action. There is a normal and an urgent process by which the Care Quality Commission can do this and there is a right of appeal.

6.46 The 2008 Act sets out a number of grounds upon which the Care Quality Commission can cancel the registration of a service provider. These are:

- on the ground that the person registered as a service provider or manager has been convicted of, or admitted, a relevant offence;
- on the ground that any other person has been convicted of any relevant offence in relation to the regulated activity;
- on the ground that the regulated activity is being or has at any time been, carried on in contravention of the requirements imposed by or under Chapter 2 of the 2008 Act or of any other enactment that appears relevant to the Commission; and
- on the ground that the person registered as a service provider or 'registered manager' has failed to comply with a requirement imposed by Chapter 6 of the 2008 Act.

6.47 The Commission can also apply to a justice of the peace for an order to cancel the registration of a service provider or manager where there is a serious risk to person's life, health or well-being.

6.48 In addition, the Commission must cancel the registration of a 'registered manager' in respect of a regulated activity if:

- no-one is registered as service provider for the activity; and
- the registration of the service provider ceases to be subject to a 'registered manager' condition.

6.49 The 2008 Act also includes powers for Regulations to set further grounds for the cancellation of registration. It is proposed that Regulations set out the following further grounds for cancelling registration:

- failure to pay fees in the time prescribed by the Care Quality Commission;
- making false or misleading statements on applications.

Prosecute for specified offences

6.50 There are a number of offences for which providers can be prosecuted. On successful prosecution, the courts will ultimately decide on the fine imposed, which for some offences under the 2008 Act can be up to £50,000 (see table above). The courts will be able to issue a separate fine in relation to each and every offence that is successfully prosecuted.

Publication of enforcement action (Section 89)

6.51 Publication by the Care Quality Commission of information relating to enforcement action is also governed by Regulations. It is proposed that these Regulations will require and authorise the Care Quality Commission to publish information as shown in the table below.

Publication of enforcement action – proposals

Action	Information to be published	Deadline for publication
Issue of warning notice (Section 29)	Information that the Commission may publish: • Name of person registered as the service provider; • Where the action relates to a 'registered manager', the name of the 'registered manager'; • Address at which the regulated activity is being provided or such other address as the Commission considers relevant; • Description of the regulated activity to which the action relates; • Description of the conduct which appears to the Commission to constitute a failure to comply with the relevant requirements: and where relevant; and • The timescale given for the situation to be rectified. Before publishing information relating to a warning notice, the Care Quality Commission must first give the person to whom the notice was given an opportunity to make representations about the matters covered by the notice.	The Commission **may** publish information about the issuing of a warning notice at such times as it determines.

Action	Information to be published	Deadline for publication
Urgent imposition, variation or removal of conditions (Section 31) Non-urgent imposition, variation or removal of conditions (Sections 12(5) and 15(5))	• Name of person registered as the service provider; • Where the action relates to a 'registered manager', the name of the 'registered manager'; • Address at which the regulated activity is being provided or such other address as the Commission considers relevant; • Description of the regulated activity to which the action relates; and • Description of what action was taken and why, including a description of the condition which is being varied, removed or added. In relation to non-urgent imposition, variation or removal of conditions under Section 12(5) or 15(5), the information above must be published only where it appears to the Commission that this has a material impact on the services provided.	If no appeal is brought under Section 32, the information must be published between expiry of the time prescribed in Section 32(2) for appeals (28 days) and four months after the service on the person of the Commission's decision. If an appeal is brought under Section 32, and the first-tier tribunal has confirmed the Commission's decision or the appeal has been withdrawn, the information must be published within three months of the date of the first-tier tribunal's decision or withdrawal of the appeal. The information must not be published where the first-tier tribunal has directed that the decision is to cease to have effect or not to have effect.

Action	Information to be published	Deadline for publication
Issue of a penalty notice that has been paid (Section 86)	In the case of penalty notices with a value of £4,000 paid by registered service providers and £2,000 paid by 'registered managers': • Description of the fixed penalty offence; • Description of the regulated activity that the person given the penalty notice was carrying on or involved in carrying on; • Name of person registered as the service provider; • Where the penalty notice is given to a 'registered manager', the name of the 'registered manager'; and • Address at which the service was being provided or such other address as the Commission considers relevant. In the case of penalty notices with a value of £1,250 paid by registered service providers and £625 paid by 'registered managers', the Commission will be authorised to publish the above information	The information must be published within three months of the date of payment.

Action	Information to be published	Deadline for publication
Cancellation or suspension of registration, excluding voluntary suspension/ cancellation under Section 19 (Sections 17, 18, 30 or 31)	• Name of person registered as the service provider; • Where the cancellation or suspension relates to a 'registered manager', the name of the 'registered manager', except where the cancellation has been brought under Section 17(2) of the 2008 Act; • Address at which the service was being provided or such other address as the Commission considers relevant; • Description of the regulated activity to which the action relates; and • Explanation of why the registration has been cancelled or suspended.	If no appeal is brought under Section 32, the information must be published between i) expiry of the time prescribed in Section 32(2) for appeals (28 days) and ii) four months after the service on the person of the Commission's decision or the order made by a justice of the peace. If an appeal is brought under Section 32, and the first-tier tribunal has confirmed the Commission's decision or the appeal has been withdrawn, the information must be published within three months of the date of the first-tier tribunal's decision or withdrawal of the appeal. The information must not be published where the first-tier tribunal has directed that the decision is to cease to have effect or not to have effect.

Action	Information to be published	Deadline for publication
Prosecution (except under Section 76)	• Description of the offence committed; • Description of the regulated activity that the person so convicted was providing or involved in providing and the address at which the service was being provided or such other address as the Commission considers relevant; • Name of the person registered as a service provider of that regulated activity; and • Where the offence is committed by a 'registered manager', the name of the 'registered manager'. Information that the Commission may publish: • Where a person who is not a registered service provider or 'registered manager' is convicted of an offence, the prescribed information is the name and such other details the Commission considers relevant about the individual convicted of the offence; and • The fine imposed following conviction.	If no appeal is brought against conviction, the information must be published between i) 28 days after the date of the conviction and ii) four months after the date of conviction. Where an appeal is brought against a conviction the information must be published within three months of the determination or abandonment of the appeal. The information must not be published where an appeal is brought against a conviction and the conviction is quashed. The Commission **may** publish information about the fine imposed following conviction at such times as it determines.

Notification of enforcement action (Section 39)

6.52 The 2008 Act requires the Care Quality Commission to give a copy of a notice of proposals, a notice of decisions, a warning notice and a notice for an urgent procedure for suspension of registration or imposition of, variation of conditions under Section 31 to certain relevant bodies (including Monitor when it is an NHS foundation trust).

6.53 It is recognised that when all providers of regulated activities are brought into registration under the 2008 Act there will be a large increase in the number of notifications that the Commission may be required to issue. In order to ensure that PCTs, SHAs and local authorities do not receive a very large number of such notices, we intend to make the following arrangements in Regulations.

6.54 The Commission will be required to give copies of such notices to:

- the relevant PCT(s) where they relate to healthcare;
- the relevant SHA where they relate to a PCT or an NHS trust;
- the relevant local authority where they relate to adult social care; and
- Monitor where they relate to an NHS foundation trust.

6.55 The relevant PCT, SHA and local authority will be the body covering the geographical area to which the enforcement action relates. In some instances the enforcement action will relate to more systemic failures of service provision and the Care Quality Commission may feel that it is appropriate to notify bodies beyond the immediate geographical area to which the enforcement action relates. The Commission has the power to do this under the terms of the 2008 Act.

6.56 In recognition of the administrative burden of notification, the Commission will not be required to notify these bodies of some notices relating to applications for registration, and conditions of registration and warning notices that do not have a material impact on service provision.

6.57 These are notices of:

- proposals and decisions to grant applications for registration subject to conditions issued under Section 26(2) and Section 28(3);
- proposals and decisions to refuse applications for registration issued under Section 26(3) and Section 28(3);
- proposals and decisions to refuse an application by a service provider for changes to registration status issued under Section 26(5) and Section 28(3);
- decisions to grant registration unconditionally or subject only to conditions each of which is agreed in writing between the Commission and the provider applicant and which have been issued under Section 28(1);
- proposals and decisions to impose, vary and remove conditions of registration under Sections 26(4)(c) and (d) and Section 28(3) where they do not have a material impact on service provision; and
- warning notices under Section 29 where they do not have a material impact on service provision.

What are we consulting on?

Q6.1: Do the proposals set out in this Chapter create a practical framework for registration?

Q6.2: If not, what do we need to change?

7. Overview of timetable and process going forward

7.1 Chapters 3, 4 and 5 above set out the Government's response and our decisions following the previous consultation on the scope of registration and registration requirements. Alongside this publication, we have published a consultation impact assessment, including an equalities impact assessment, reflecting the decisions we have made. This can be found on the Department's website.

7.2 In the previous consultation we made a commitment to consult on the draft Regulations that will set the scope of registration and the registration requirements in legislation. Through this consultation we are seeking views on:

- the wording of the draft Regulations in Annexes B and D; and
- our proposals, set out in Chapter 6, for the policies that we need to put in place to support the registration system and enforcement.

7.3 Following this consultation, we will publish a consultation response and revised draft Regulations covering: the scope of registration; the registration requirements. Draft Regulations on the supporting policies will be laid in Parliament in time to allow the new Commission to start implementing the new registration framework from 1 April 2010.

7.4 In the meantime, the Care Quality Commission is developing and will be consulting on the principles of its methodology and guidance about compliance with the registration requirements. The Department will work with the Commission to help health and adult social care providers understand the new system and their responsibilities.

Timetable for implementation

7.5 The Health and Social Care Act 2008, which provides for the establishment of the Care Quality Commission and the new registration framework, was given Royal Assent on 21 July 2008. The Care Quality Commission was established on 1 October 2008 and will formally take over regulation of health and adult social care from the current Commissions on 1 April 2009.

7.6 During 2009/10, the new Commission will continue to operate the systems it inherits from the Healthcare Commission and the Commission for Social Care Inspection under the CSA. It will also implement the 2008 Act registration system for NHS organisations in relation to HCAI. This will allow the new Commission time to develop, consult on and test the principles of its new methodology and guidance for monitoring compliance with registration requirements.

7.7 The section on primary care services in Chapter 4 covers the arrangements we are putting in place for primary care services. The table below shows the proposed timetable for phasing in registration of primary care and other services.

April 2009	**April – October 2010**	**April 2011 – onwards**
Care Quality Commission takes over regulation of adult social care and private and voluntary healthcare providers under CSA. NHS bodies register with Care Quality Commission in relation to HCAI Regulations.	New registration framework starts to be introduced with single set of registration requirements for all providers of regulated activities. NHS providers will be registered under the new framework from 1 April. Providers of adult social care and private and voluntary healthcare currently registered under the CSA will become subject to the new registration system on 1 October 2010.	Primary dental care and primary medical care and activities that have not been regulated before, for example private ambulance services, come into registration.
During 2009	**During 2010**	
Department of Health makes Regulations setting out scope of registration, registration requirements and requirements supporting registration. Care Quality Commission develops and consults on the principles of its methodology and guidance about compliance with the registration requirements.	Care Quality Commission registers existing providers under the new system. Department of Health makes Regulations to bring other regulated activities into registration framework. Department of Health and Care Quality Commission prepare for registration of previously unregistered providers, including primary care.	

How will the new registration system be introduced for existing providers?

7.8 We want to make the transition for existing providers to registration under the Health and Social Care Act 2008 as straightforward as possible. In 2009/10, providers of adult social care services and private and voluntary healthcare services will continue to be registered under the CSA and will need to continue to comply with relevant Regulations and with National Minimum Standards. NHS organisations will be

registered under the Health and Social Care Act 2008, and be required to meet the registration requirement relating to healthcare associated infections.

7.9 Providers of regulated activities registered under these two systems will become subject to the new registration system under the 2008 Act during 2010/11. NHS organisations will be brought into the full registration system on 1 April 2010. Providers currently registered under the CSA will become subject to the new registration system on 1 October 2010.

7.10 NHS providers will be invited to submit an application against the full set of registration requirements in advance of April 2010. The content of these applications will be set out in due course. Providers that are currently registered under the CSA will be invited to submit applications to the new Commission from April 2010. Again the content of these applications will be set out in due course.

7.11 The new Commission will notify providers of the outcome of the registration decisions, and providers will have 28 days following the decision in which to make representations to the new Commission. There will also be a right of appeal to the First-Tier Tribunal in cases where the provider disputes the new Commission's decision.

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

7.12 These providers will be able to register under the new registration system, but the Care Quality Commission will consider the progress that service providers have made in resolving the issues for which the regulatory action was commenced. This will be a key component in the Commission's assessment of the registration status of these providers. It may be the case that the Commission will attach conditions to the registration of providers that are subject to ongoing regulatory action under the CSA.

Providers already under action to cancel registration

7.13 Providers whose registration under the CSA is currently being cancelled will not be able to register under the new registration system. The process of cancelling registration will continue under the CSA until a decision has been made to confirm the cancellation or to allow the provider to continue to operate. If it is decided that the provider can continue to operate, it will need to make an application to register under the new system at that point. If a decision is taken to cancel

registration, the provider will not be registered and will be committing an offence if it continues to provide services.

How will new providers register during the transition period?

7.14 Providers that are setting up new services that fall within the scope of the current registration system under the CSA will need to apply for registration under that Act in the run-up to the new system being introduced.

Fees

7.15 All providers of regulated activities will be required to pay fees for registration with the Care Quality Commission. These fees will be used to cover the cost of registering providers and cannot be used by the Commission to generate extra income. The Commission will be responsible for setting the level of fees and will consult on these in due course. The fee structure proposed by the Commission will be subject to approval by the Secretary of State.

8. Responding to the consultation

8.1 This document launches a consultation on the draft Regulations that will set the scope of registration and the registration requirements in secondary legislation, and on the policy supporting the registration framework and the enforcement regime for the new Commission.

8.2 The consultation is being run in accordance with the Cabinet Office Code of Practice on Consultations (reproduced below). However, this is a limited eight-week consultation with Ministerial approval. The closing date for the consultation is 29 May.

8.3 In order to accommodate the Parliamentary processes associated with laying and making affirmative Regulations, and because we have already consulted on the background policy that the draft Regulations relate to, it will run for a period of eight weeks rather than twelve. This will allow us to make the Regulations in time for: the new Commission to develop and consult on the principles of its methodology and guidance on judging compliance with the registration requirements; and the new registration framework to be introduced from April 2010. The Minister of State for Health Services, Ben Bradshaw MP, is aware of the reason for the shortened consultation period and has approved it.

8.4 There is a full list of the questions we are asking in this consultation in Annex E and there is a questionnaire on the Department's website which can be printed and sent by post to:

Registration Consultation
Room 3E58
Quarry House
Quarry Hill
Leeds LS2 7UE

or, preferably, e-mailed to: registration.consultation@dh.gsi.gov.uk.

8.5 It will help us to analyse the responses if respondents fill in the questionnaire but responses that do not follow the structure of the questionnaire will be considered equally. It would also help if responses were sent in Word format, rather than pdf.

The consultation process

Criteria for consultation

8.6 This consultation follows the 'Government Code of Practice', in particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least twelve weeks with consideration given to longer timescales where feasible and sensible;
- be clear about the consultations process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

8.7 The full text of the code of practice is on the Better Regulation website at: www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html

Comments on the consultation process itself

8.8 If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact

Consultations Coordinator
Department of Health
3E48, Quarry House
Leeds LS2 7UE

e-mail consultations.coordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

8.9 We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter (www.dh.gov.uk/en/FreedomOfInformation/DH_088010).

8.10 Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

8.11 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.

8.12 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.

Summary of the consultation

8.13 A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website at: www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

Annex A: Detailed analysis of responses to the consultation on the scope of registration

A.1 The activity topics define which activities require providers to register with the Commission. Where necessary, the Care Quality Commission will restrict a provider's provision of a particular regulated activity by applying conditions. For example, a provider registered to carry out the regulated activity of *Surgical procedures* might have limitations put on what it can provide applied as conditions by the Commission – eg to limit it to providing only orthopaedics, or treating only adults. Conditions will vary depending on what the provider is able to provide.

A.2 We are keen to have views on whether the policy we describe and the accompanying draft Regulations are clear, unambiguous, and would be clear enough for providers to understand whether they need to register or not. The underlined headings in bold relate to the original list of activities in the consultation document.

Personal care

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.3 The responses covering this activity supported the proposal to have personal care as a regulated activity.

A.4 Respondents wanted reassurance that regulation by the Care Quality Commission and Ofsted would work effectively together, particularly around children's domiciliary care and the transition between children's and adult care. Some respondents highlighted that introducing a wider definition of personal care would unnecessarily bring low-risk services into the scope of registration. For example, including prompting could bring in anyone giving verbal prompts to people with learning disabilities or memory loss.

A.5 There were responses relating to the regulation of agencies. These are covered in Chapter 3.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.6 A number of responses felt that shared lives (adult placement) services should be included within the scope of registration.

A.7 There were also a few suggestions that the following services should be within the scope of registration:

- daycare (especially where personal care is involved);
- personal assistants;
- personal budgets; and
- direct payments to people who are particularly vulnerable or have learning disabilities.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.8 In response, we have revised the definition of personal care to make it clearer.

A.9 As there is no longer a separate palliative care activity (see below), we have also broadened the personal care definition to include personal care related to palliative care.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.10 Where provision of shared lives services includes regulated activities (such as personal care), they will require registration. However, we have decided that shared lives services should not be a regulated activity in itself, as it is a service model rather than an activity.

A.11 Where care purchased through a direct payment or personal budget is a regulated activity, for example personal care provided by a domiciliary care agency, the care provider will need to be registered with the Commission. The exception to this is where the provider is a friend or family member (see Regulation 19). We have not included direct payments and personal budgets as activities in themselves as they are the mechanism by which the provision of care is secured, not about the provision itself.

A.12 This approach will allow the person using the service to choose to purchase regulated activities if that is the route they wish to take, but does not take away the opportunity for them to choose to purchase other services or equipment if they decide it best suits their needs and lifestyle. To make it a requirement that all services provided under direct payment or personal budget arrangements must register with the Commission would be counter-productive to this objective. We also intend to take this approach with direct payments for healthcare, subject to the passage of the current Health Bill.

A.13 For similar reasons, we have decided that providing personal assistance should not be a regulated activity. This care is provided on a basis of direct employment of a personal assistant by the individual receiving care. An exemption has been put in place for this in the draft Regulations. This is the same as the current situation under the CSA.

A.14 We have considered daycare and concluded that people who use daycare services are likely to be less vulnerable than people living in care homes and therefore the risk is lower. We have not found evidence to justify including daycare at the moment.

What the Regulations will cover

Regulated activity: Personal care

A.15 The relevant draft Regulation is Regulation 4 in Annex B.

What will be within the scope of registration?

A.16 The definition covers services that provide physical help to people with their: eating and drinking; using the toilet; washing; dressing; oral care; or care of their skin, hair or nails where they cannot do it for themselves due to old age, illness or disability. It also includes services that do not provide physical help, but prompt or supervise people to undertake their own care, where they are unable to make decisions for themselves.

A.17 It covers services provided to people where they are living, whether this is their own home or another location. For example, care provided by a domiciliary care agency to a person who needs help with bathing at home, or personal care provided to an in-patient in a hospital. It will also cover personal care services for children, where these are not covered by Ofsted eg children's domiciliary care agencies.

What will be outside of the scope of registration?

A.18 Our policy is not to include:

- personal care in a daycare setting, for example in an older people's luncheon club;
- any agencies solely supplying care workers to other registered providers, where they are not directly providing regulated activities themselves;
- personal budgets and direct payment arrangements which do not specifically include regulated activities;
- services where an individual is directly employed by the person requiring the service, including personal assistant arrangements;
- help with bathing delivered to a person by a friend, neighbour, or individual who is assisting with such activities as part of a family or friendship arrangement and for no personal gain;
- child-minding and nannying services;
- a small number of currently registered shared lives (adult placement) schemes that do not provide personal care.

Will any activities outside the scope of registration be kept under review?

A.19 We are continuing to look at the potential benefit of regulating daycare with a personal care component, including consideration of the situation in Scotland, where daycare is regulated, and will keep our position under review.

A.20 We will keep the coverage of children's services under review and work with DCSF to ensure they are appropriately regulated.

Accommodation together with personal or nursing care

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.21 The responses covering this activity supported the proposal to have accommodation together with personal or nursing care as a regulated activity, separate from personal care.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.22 Respondents sought reassurance that the definition would not enable services functioning as care homes, particularly small providers, to evade registration by describing the care element as a separate service.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.23 As noted above, we have revised the definition of personal care, so that it now includes personal care related to palliative care.

A.24 Many different factors need to be taken into account to determine whether accommodation is being provided 'together with' personal or nursing care. In the same way as the CSCI supports providers now, these factors will be set out in guidance issued by the Care Quality Commission.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.25 The consultation responses and our analysis support the decision to include the activity in the scope of registration.

What the Regulations will cover

Regulated activity: Accommodation for persons who require nursing or personal care

A.26 The relevant draft Regulation is Regulation 5 in Annex B.

What will be within the scope of registration?

A.27 The policy is to include residential accommodation which is provided together with:

- personal care, as defined in the personal care activity above; or
- care provided by nurses.

What will be outside of the scope of registration?

A.28 The policy is to not include:

- a small number of currently registered shared lives (adult placement) schemes that do not provide personal or nursing care;
- residential services that are not provided together with personal or nursing care, eg sheltered housing for elderly people, where they are able to separately arrange any other care services themselves.

Will any activities outside the scope of registration be kept under review?

A.29 We do not anticipate specifically keeping any of these activities under review.

Accommodation together with intensive treatments

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.30 The responses supported the proposal to have this as a regulated activity. There were suggestions around what should be covered, and how it should be defined.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.31 Respondents felt that registration should cover accommodation where intensive treatment is a *condition* of the residence (even if it takes place elsewhere).

A.32 There were suggestions that registration should be wider to cover other significant risks, for example, intensive/specialist psychological therapies, neurological patients, or non-residential drug or alcohol services.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.33 Further work on the policy has led us to conclude that the consultation proposal was not the most appropriate approach to capturing the services we intended to capture. Apart from drug and alcohol misuse services, most of these services will now be covered by other activities such as *Personal care* or *Treatment for disease, disorder or injury.*

A.34 However, significant medical treatments that could pose a risk to patients, combined with the vulnerability of the situation (where patients may not have access to other people to give support if problems are arising) pose inherent risks not captured elsewhere in the activity definitions.

A.35 To cover these risks, we have refined the policy on this activity so that it will capture the treatment of drug and alcohol misuse in a residential setting that would otherwise be missing.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.36 We do not have sufficient evidence that bringing some other drug and alcohol misuse services (eg needle exchange services) into system regulation would provide enough benefit to justify the burden on both the providers and the regulator. There is also the risk that this may unnecessarily deprive people of access to some services, eg drop-in centres. However, although these services will not be subject to registration under the Care Quality Commission, they will continue to be overseen by the National Treatment Agency and PCTs as part of their commissioning responsibilities.

What the Regulations will cover

Regulated activity: Accommodation for persons who require treatment for drug and alcohol misuse

A.37 The relevant draft Regulation is Regulation 6 in Annex B.

What will be within the scope of registration?

A.38 The policy is to include drug and alcohol misuse services where treatment is provided together with accommodation. This includes residential drug and alcohol misuse services where the acceptance of the treatment is a condition of the residence, even if it takes place elsewhere.

What will be outside of the scope of registration?

A.39 The policy is to not include community-based drug and alcohol services. However, some of these will be captured under other Regulations, for example *Treatment for disease, disorder or injury*.

Will any activities outside the scope of registration be kept under review?

A.40 We are doing further work on refining definitions for community-based (non-residential) drug and alcohol services, where we have identified the risk and think that system regulation can address them, with a view to bringing them into regulation in the near future. These include structured care programmes for people who misuse drugs or alcohol.

Accommodation together with personal care and further education

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.41 Responses were quite evenly split between the suggestion that Ofsted or the Care Quality Commission should be responsible for regulating this activity. Most respondents specifically wanted reassurance that both regulators would work together.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.42 There were no suggestions about further inclusions for the scope of this regulated activity.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.43 The responses to the consultation were content with our proposed policy, which has been carried through into the drafting of Regulation 7.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.44 This activity already requires registration with the Commission for Social Care Inspection under the CSA (these services are currently registered as ‘care homes’). This needs to continue under the scope of registration under the Care Quality Commission pending further review and discussions with DCSF and Ofsted.

A.45 Paragraph 3.8 above sets out how we envisage the Care Quality Commission will work with Ofsted.

What the Regulations will cover

Regulated activity: Accommodation and nursing or personal care in the further education sector

A.46 The relevant draft Regulation is Regulation 7 in Annex B.

What will be within the scope of registration?

A.47 The policy is to include residential further education schools or colleges where the services provided to more than one in ten of the students who live in such institutions include personal care, or care provided by registered nurses.

What will be outside of the scope of registration?

A.48 As now, the policy is to exclude further education colleges that do not have at least one tenth of pupils who require personal care.

Will any activities outside the scope of registration be kept under review?

A.49 We are continuing to discuss whether it would be more appropriate for Ofsted to regulate this activity in future.

Palliative care

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.50 Generally, respondents agreed with the proposals in the consultation. Some responses suggested that a separate activity for palliative care was not necessary, because those palliative care services that should be within the scope of registration will be captured within other activities, such as *Specialist medical services*, *Accommodation for persons who require nursing or personal care*, or *Personal care*.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.51 There were suggestions that we reconsider our proposals and include counselling, befriending, bereavement support services, mentoring and advocacy services within the scope of registration.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.52 We agree that to ensure consistency, and to avoid unnecessary regulation of low-risk activities, palliative care does not need to be a separate activity. The services we want to include are effectively specialist palliative care (under medical supervision and/or carried out by healthcare professionals) rather than all forms of support for people at the end of life. This will be captured through the *Treatment of disease, disorder or injury* activity.

A.53 Children's hospices will be registered with the Care Quality Commission under the activity covering *Treatment for disease, disorder or injury* unless registered with Ofsted as children's homes (in which case, the new Commission will work with Ofsted to ensure effective regulation).

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.54 We have considered regulating befriending, mentoring and advocacy services. Our conclusion is that while there is a level of risk attached to each of those activities, any benefit attached to regulating them through the Care Quality Commission would be relatively small. This is because the checks that the Care Quality Commission would focus on for these services are already covered by other safety mechanisms that are in place for these providers, such as criminal records checks and protection for vulnerable adults.

A.55 Counselling and psychotherapy is a special case, and is covered under the *Mental health services* activity, below.

What the Regulations will cover

What will be within the scope of registration?

A.56 Palliative care services will now be covered under the following activities: *Personal care*; *Accommodation for persons who require nursing or personal care;* and *Treatment of disease, disorder or injury.*

A.57 The policy is to include hospice palliative care, and home palliative care where a regulated activity (such as personal care, nursing care or treatment for disease, disorder or injury) is part of the care.

What will be outside of the scope of registration?

A.58 The policy is to not include care that does not involve a regulated activity, such as befriending, bereavement services, mentoring or advocacy.

Will any activities outside the scope of registration be kept under review?

A.59 Other than counselling and psychotherapy (which is covered in the section on mental health services) we do not anticipate specifically keeping any of these activities under review.

Surgical services

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.60 The responses covering this activity supported the proposal to have surgical services as a regulated activity.

A.61 A number of responses made suggestions about how minor surgery could be defined to ensure the appropriate services were captured or excluded. These included decisions based on the kind of anaesthetic used, or the premises where the surgery was carried out.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.62 Some responses explicitly supported the proposals that would bring in all surgical treatment other than minor surgery. Other responses proposed including specific activities such as various beauty industry treatments, for example non-surgical cosmetic procedures, botulinum toxin injections, non-surgical laser treatment, tattoo parlours and tooth whitening. A small number of responses suggested we should consider whether religious or cultural circumcision should be within the scope of registration.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.63 In the light of the consultation responses, we have considered how best to ensure those services that are most risky are within the scope of registration without unnecessarily bringing in lower-risk activities. We concluded that it would not be possible to use a definition of minor surgery that would effectively exclude low-risk activities, so we have changed the policy to bring in any surgery carried out by a healthcare professional.

A.64 This activity now incorporates surgery carried out as part of *Primary medical services* and *Dental services*, which were previously listed as separate activities. These will, however, be excluded until they come into registration alongside other primary care activities.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.65 Non-surgical cosmetic procedures, such as ear and body piercing and tattooing are subject to regulation by Local Authorities. A self-regulatory system is being developed for botulinum toxin treatments and dermal fillers. As such, to avoid duplication, we have not included these services within the scope of registration under the Care Quality Commission. Our decisions on the future regulation of non-surgical lasers and intense pulsed lights are set out in Chapter 3.

A.66 Subsequent discussions with internal and external experts raised the issue of whether non-medical circumcision (ie for religious or cultural reasons) should be included in scope. Circumcision is a surgical procedure with significant risks. It is not covered under the current CSA registration system other than where it is undertaken for therapeutic or cosmetic reasons. However, there are also significant numbers of non-therapeutic circumcisions carried out, especially in areas with large Muslim or Jewish populations. We do not think that religious leaders should be required to register as healthcare providers where they perform circumcision for religious purposes, although we recognise that there is a need to promote consistent standards of safety in these cases. However, where healthcare professionals undertake non-therapeutic circumcision, our intention is that they should be held to account by the Care Quality Commission for ensuring the same standards of safety and quality of care as in any other surgical procedure.

A.67 Our analysis of the available information on this area found the procedure carried a risk, but we also concluded that system regulation was not necessarily the best way of addressing this risk, for several reasons. These include difficulties in identifying non-health professional practitioners (information on these services often passes on by word of mouth). It is possible that non-health professional practitioners would continue to operate without being registered, unknown and untraceable by the Commission. Registration would, therefore, offer little assurance of safety and quality, and therefore lack credibility. There is also the risk that requiring registration with the Commission could drive the service underground, thus preventing people from coming forward if a problem arises as a result of the procedure.

A.68 Therefore, we have decided to continue with our proposals as set out in the previous consultation document, and only include circumcision by healthcare professionals within the scope of registration.

What the Regulations will cover

Regulated activity: Surgical procedures

A.69 The relevant draft Regulation is Regulation 10 in Annex B.

What will be within the scope of registration?

A.70 The policy is to include any surgery carried out by a healthcare professional, including cosmetic surgery and minor surgery. This will include non-medical led services, walk-in centres, and minor injuries units.

What will be outside of the scope of registration?

A.71 The policy is to not include:

- circumcision other than by healthcare professionals;
- surgical procedures not done for the purpose of treatment of disease, disorder, injury or cosmetic purposes;
- non-surgical cosmetic procedures, such as tattooing or botulinum toxin injections;
- provision of non-surgical lasers and intense pulsed lights services (see Chapter 3).

Will any activities outside the scope of registration be kept under review?

A.72 Surgical services carried out as part of NHS primary medical and dental care have a global exclusion from all regulated activities. These will be brought into regulation during 2011/12, alongside other primary care services.

Dental services

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.73 The majority of those who commented supported dental care being included within the scope of registration. The responses were concentrated on primary dental care. Chapter 4 sets out our intention with regard to these services.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.74 A large number of respondents suggested that tooth whitening should be brought into the scope of registration. Some respondents wanted reassurance that services provided by dental hygienists, dental therapists, dental nurses and dental technicians, as well as those provided by dentists and clinical dental technicians would be within the scope of registration.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.75 As we have developed the policy on other activities, it has become clear that dental services will be captured under other registered activities, such as *Treatment of disease, disorder or injury*, or *Surgical procedures*. These activities capture care provided by or under the direction of a range of dental professionals. Therefore, there is no longer a separate activity for dental services.

A.76 The General Dental Council considers the provision of tooth whitening to be the practice of dentistry. All dental practices and hospitals providing dental services will be registered, including those providing tooth whitening. We are currently waiting for an EU decision on the safety of tooth whitening products. We will consider the implications of this and the risks to patients identified as part of the EU decision making process once that decision has been made.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.77 The consultation responses and our analysis support the decision to include the activity in the scope of registration.

What the Regulations will cover

What will be within the scope of registration?

A.78 Because of the development of policy on the other activities, dentistry is now covered within the *Treatment of disease, disorder or injury, Surgical procedures* and *Diagnostic procedures* activities.

A.79 The definition of the *Treatment of disease, disorder or injury* activity covers care carried out under the direction of: dentists, dental hygienists, dental therapists, dental nurses, dental technicians, clinical dental technicians, or orthodontic therapists. In addition, any kind of surgery carried out by a healthcare professional, including cosmetic surgery, will be within scope under the *Surgical procedures* activity. Diagnostic procedures involving radiation or x-rays will be within the scope of registration under the *Diagnostic procedures* activity.

What will be outside of the scope of registration?

A.80 The policy is to have no specific exclusions to this activity.

Will any activities outside the scope of registration be kept under review?

A.81 Primary dental care providers have a global exclusion from all regulated activities. These will be brought into the scope of registration alongside other primary care service providers during 2011/12. Hospital dental services will however be within the scope of registration from 2010.

Diagnostic procedures

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.82 The responses covering this activity supported the proposal to have diagnostic procedures within the scope of registration. A number of responses agreed with the specific proposals in the consultation document, in particular that low-risk or non-invasive diagnostic procedures should not be within the scope of registration.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.83 A number of responses were related to the detail of specific services, such as procedures that involve radiation or x-rays. Some responses suggested that national screening programmes should be within the scope of registration.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.84 In deciding which diagnostic procedures to include within the scope of registration, we considered both the risk inherent in the procedure (for example taking an x-ray) and the risk inherent in the diagnosis (for example, misdiagnosis leading to inappropriate treatment).

A.85 There is a broad spectrum of diagnostic procedures and services. At one end, these can be done at home as self-diagnosis (such as a person with diabetes checking their own sugar levels). At the other end, diagnostic tests can involve sophisticated equipment which can only be performed by specialists. We have considered services at both ends of this spectrum, taking into account further analysis and feedback from the consultation and have refined the scope of registration in this area.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.86 Providers of some national screening programmes will need to register with the new Commission because they involve activities that are within the scope of registration (for example diagnostic activities). At this stage, we have not identified a need to specifically make other national screening programmes into regulated activities as there are already robust and bespoke arrangements for quality management in place for these programmes.

A.87 Non-diagnostic ultrasound services (eg taking photographs of babies in the womb for non-clinical purposes) were flagged as having a perceived risk. However, there is insufficient evidence on adverse incidents arising from these procedures for us to be able to justify regulation in this area at this time. We will review this coverage if further evidence indicates this is necessary in future. Ultrasound used for diagnostic procedures will be within the scope of registration, due to the risk of misdiagnosis.

What the Regulations will cover

Regulated activity: Diagnostic procedures

A.88 The relevant draft Regulation is Regulation 11 in Annex B.

What will be within the scope of registration?

A.89 The policy is to include:

- pathology and cytology;
- x-rays, other kinds of radiation used for diagnostic imaging, ultrasound or magnetic resonance imaging;
- cameras or other equipment that is used to look inside the body, or to take samples eg of blood or for biopsy;
- other equipment used to measure or monitor the physiological functioning of the major organ systems, for example lung function equipment or cardiopulmonary exercise testing equipment;
- analysis and interpretation of results of all of the above.

A.90 A small number of private providers will be brought into registration for the first time as a result of this definition. Others are already included under other activities, but will need to register for this activity where appropriate. Many of these will be brought into registration under the CSA from April 2009 as a result of changes in service delivery.

What will be outside of the scope of registration?

A.91 The policy is to not include:

- non-diagnostic ultrasound services;
- pin-prick blood tests for simple and routine monitoring purposes only, that do not require laboratory analysis (eg blood glucose monitoring in diabetes).

Will any activities outside the scope of registration be kept under review?

A.92 At this time, we have decided that pin-prick blood tests or any test that does not require the sending of samples to a laboratory should not be included. However, we understand that these tests are increasing in sophistication so will keep this field under review and consider whether to bring other tests into regulation in the future.

A.93 Diagnostic services carried out as part of primary care services have a global exclusion from all regulated activities. These will be brought into regulation alongside other primary care services during 2011/12.

Specialist medical services

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.94 There was widespread support for including this activity. A number of responses explicitly agreed with the proposals in the consultation document to include all medical treatment provided under the direction of a consultant or other similar treatment by healthcare professionals.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.95 There were a number of respondents who felt that the definition should be widened to include activities such as complementary medicine, and the review, assessment and diagnosis as well as the actual care and treatment.

A.96 A number of more specific points were made in reference to clarifying coverage for treatment for different groups, such as deaf or blind people, or neurological conditions.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.97 After consideration of how this activity fits together with the whole registration framework, we decided to broaden the definition and rename it as *Treatment of disease, disorder or injury* to reflect the fact that it will cover *Palliative care*, *Specialist mental health services*, *Specialist medical services*, *Primary medical services* and *Dental services*, which we previously proposed as separate activities. This will ensure that it also includes support services, such as critical care.

A.98 To ensure services provided in slimming clinics are still captured, we have decided that a separate activity is needed specifically for this activity. This is covered below.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.99 We do not want to duplicate the professional regulation systems already in place for healthcare professionals. Our analysis of the available information showed that the risks posed by the services provided were more appropriately mitigated by the professional regulation already in place than by system regulation, when those services were provided as standalone from other services. Therefore, the services provided by certain specified healthcare professionals only fall within scope where they are provided as part of a care package delivered by multidisciplinary teams with certain other healthcare professionals. The professions involved are listed below.

A.100 This approach applies to this regulated activity only. If these professionals are providers of other regulated activities, for example *Diagnostic procedures* or *Surgical procedures* the provider will have to register.

What the Regulations will cover

Regulated activities: Treatment of disease, disorder or injury and Services in slimming clinics

A.101 The relevant draft Regulation is Regulation 8 in Annex B.

What will be within the scope of registration?

A.102 The policy is to include:

- any healthcare which is provided for the treatment or assessment of disease, disorder or injury provided by, or under the direction of, one of the healthcare professionals listed below;
- emergency care, end of life care, mental health care;
- counselling services for treatment of disease or disorder, where they are provided by healthcare professionals in the following list (usually as part of mental health services). Counselling and psychotherapy is covered in more detail below, under *Mental health services*.

A.103 The provision of care or treatment provided by, or in multidisciplinary teams including, the following healthcare professionals will be within the registration framework:

- doctors;
- dentists (including special care dentists);
- dental hygienists;
- dental therapists;
- dental nurses;
- dental technicians;
- clinical dental technicians;
- orthodontic therapists;
- nurses;
- midwives;
- specialist community public health nurses;
- biomedical scientists;
- clinical scientists;
- operating department practitioners;
- paramedics;
- radiographers.

What will be outside of the scope of registration?

A.104 The policy is to not include healthcare provided by the following professionals, except as part of a care package delivered by multidisciplinary teams including others from the list above:

- osteopaths;
- chiropractors;
- arts therapists;
- chiropodists;
- podiatrists;
- dieticians;
- occupational therapists;
- orthoptists;
- physiotherapists;
- prosthetists and orthotists;
- speech and language therapists.

A.105 First aid, alternative or complementary medicine, treatment carried out at sports facilities, work places etc is also excluded.

Will any activities outside the scope of registration be kept under review?

A.106 Services carried out in primary care have a global exclusion from all regulated activities. The arrangements for primary care are covered in Chapter 4.

Emergency and urgent care

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.107 The responses covering this activity supported the proposal to have emergency and urgent care in the scope of registration. Responses relating to the regulation of Patient Transport Services (PTS) are covered earlier in Chapter 3 because we asked a specific question about these services in the original consultation.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.108 A small number of responses suggested that voluntary first aid should be registered, and that walk-in centres and out-of-hours GP services should be covered under primary care.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.109 This activity covers those emergency and urgent care services not already covered under the *Treatment of disease, disorder or injury* activity, such as triage or the transport aspect of ambulances. Emergency adult social care, where appropriate, will be captured under the *Personal care* activity, and the *Accommodation with personal or nursing care* activities. The treatment received by a person while in an emergency vehicle will be covered by *Treatment for disease, disorder or injury*, if no treatment is provided during the journey, the provider will not have to register under that category.

A.110 As set out in the section on PTS earlier in this chapter, we have decided to define the scope of registration as transport services provided by means of a vehicle which is designed for the primary purpose of carrying persons for the purposes of treatment, and have set that definition in the draft Regulations. This will ensure that all vehicles used for this purpose are covered, with the exception of taxis, hospital cars and other similar services.

A.111 For remote urgent health advice and triage services, we have found that the greatest risk is from misdiagnosis. This is most likely to be due to the diagnosis algorithm used, and the standard of training in its use. As NHS Direct services are relied upon by millions of people every year, we will continue the level of public accountability that is currently provided by the Healthcare Commission's Annual Health Check, by including this service in registration. However, we will keep the inclusion of this service under review, to ensure that this approach is the best way of assuring safety in this area. The Regulation will also bring into registration equivalent non-NHS provided telehealth services that are not currently within the scope of the CSA.

A.112 We agree that most walk-in centres, urgent care for minor injuries and out-of-hours care should not be captured by this activity. These services will now be captured by the activity covering *Treatment for disease, disorder or injury*. However, depending on the kind of contract in place, many of these providers will be excluded from registration alongside other primary care services.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.113 We considered the regulation of first aid, but we have concluded that the potential benefits of system regulation would be outweighed by the burden. Voluntary organisations, such as St John's Ambulance service, will need to be registered with the new Commission if they provide services that exceed first aid and extend into regulated activities.

What the Regulations will cover

Regulated activity: Transport services, triage and medical advice provided remotely

A.114 The relevant draft Regulation is Regulation 13 in Annex B.

What will be within the scope of registration?

A.115 The policy includes:

- transport services, including private ambulance services and helicopter ambulances, and other transport in a vehicle which is designed for the primary purpose of carrying people for treatment;
- emergency triage, for example, the process of categorising calls in ambulance call centres or the process of deciding referrals by NHS Direct;
- urgent medical advice provided over the phone, or by e-mail etc by a body established for that purpose (ie NHS Direct and similar services).

What will be outside of the scope of registration?

A.116 The policy is to not include transport which is not designed for the primary purpose of carrying people for treatment (eg taxi services).

A.117 The current policy specifically excludes private ambulance services. We will bring these into registration later, for the reasons set out below.

Will any activities outside the scope of registration be kept under review?

A.118 We recognise that there is still further work to be done on refining the definition of transport services for the Regulation, and will continue to work with stakeholders to develop the definition further.

A.119 The definition of transport services will include private ambulances. However, following discussions with stakeholders, we have concluded that further development work is needed in order to bring the sector into registration in an effective manner, so that they are able to provide appropriate evidence of compliance with registration requirements. We intend to bring private ambulance service providers into regulation from April 2011.

Maternity services – obstetrics and gynaecology

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.120 The responses covering this activity supported the proposal to have maternity services within the scope of registration.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.121 A number of responses suggested extending coverage to include services such as family planning and sexual health services. Some respondents queried how services supporting home births would be covered.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.122 Because we have refined our policy on this and other activities, obstetrics and gynaecology services will be brought into regulation through the *Treatment for disease, disorder or injury* activity.

A.123 We want maternity and midwifery services, including pre- and post-pregnancy services, to be within the scope of registration. As regulation will be based on activities rather than locations, this will capture maternity and midwifery services provided to mothers having home births, but not those independent midwifery services currently exempt from the CSA at this stage for the reasons set out below.

A.124 We have considered family planning services and agree that some family planning services should fall within the scope of registration, for example the fitting of intra-uterine devices and contraceptive caps. These will, however, be captured within the *Nursing care* activity, or as services ancillary to maternity services. Where these are provided in primary care, these will come within registration alongside other primary care providers.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.125 We have not found evidence that bringing antenatal classes, advisory services, parent craft classes, doulas, or other lay providers of support into the scope of registration would bring further assurance of the quality and safety of the services provided.

What the Regulations will cover

Regulated activity: Maternity and midwifery services

A.126 The relevant draft Regulation is Regulation 14 in Annex B.

What will be within the scope of registration?

A.127 The policy is to include maternity and midwifery services, including pre- and post-pregnancy services, for example pre- and post-pregnancy health.

What will be outside of the scope of registration?

A.128 The policy is to not include:

- antenatal classes;
- lay pregnancy advisory services;
- parentcraft classes by lay providers;
- doulas or any other lay providers of support.

Will any activities outside the scope of registration be kept under review?

A.129 Under the current system, some independent midwifery services are registered as providers under the CSA (ie midwife-led maternity services – obstetrics & gynaecology is a listed service), whereas others are specifically exempt from registration as they are providing services in people's homes (usually as a direct arrangement with the mother).

A.130 The latter services are inherently risky and primarily provided by single-handed providers. The Department of Health is developing policy to support these providers in operating as part of third sector organisations, which will give them a corporate 'umbrella' under which to work. These organisations will provide systems of contracting and corporate governance that will support independent midwives in their provision. However, as this system is not yet functioning, and the sector is not otherwise sufficiently prepared for system regulation, we are excluding these services from registration in 2010, with a view to bringing them into registration from 2011/12.

A.131 There is a global exemption for NHS primary care maternity services. These will come into regulation alongside other primary care services.

Termination of pregnancy

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.132 The responses covering this activity supported the proposal to have termination of pregnancy within the scope of registration.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.133 Some responses suggested we should also register lay voluntary groups providing advice to women in relation to termination of pregnancy.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.134 We have not changed the policy. Organisations only offering advice to women will not be required to register as they are not directly providing care.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.135 The consultation responses and our analysis support the decision to include the activity in the scope of registration.

What the Regulations will cover

Regulated activity: Termination of pregnancy

A.136 The relevant draft Regulation is Regulation 15 in Annex B.

What will be within the scope of registration?

A.137 The policy is to include medical and surgical termination of pregnancy services.

What will be outside of the scope of registration?

A.138 The policy is to have no specific exclusions to this activity.

Will any activities outside the scope of registration be kept under review?

A.139 We do not anticipate specifically keeping any of these activities under review.

Specialist mental health services

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.140 The responses covering this activity supported the proposal to have mental health services within the scope of registration. Many responses were concerned about the wording used in the consultation document, which they felt did not reflect current best practice.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.141 The main cause of concern was the suggestion that regulation should be restricted to care under the supervision of psychiatrists. Several responses suggested it would be better if the Regulation referred to care under the supervision of a clinical supervisor or responsible clinician. Some respondents felt that the description of regulated services should be consistent with *New ways of working*[27], and the way services are commissioned. There were also concerns that counselling and psychotherapy services should be included.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.142 After consideration of how this activity fits together with the whole registration framework, mental health services will now be covered under the activity *Treatment of disease, disorder or injury*.

A.143 We agree with the comments that the activities we want to include in scope are wider than we set out in the consultation document. Therefore we have widened the definition to cover care or treatment for a mental disorder by, or in a multidisciplinary team containing, healthcare professionals as set out in paragraph A.103.

27 New ways of working for psychiatrists: Enhancing effective, person-centred services through new ways of working in multidisciplinary and multiagency contexts (Published jointly by Royal College of Psychiatrists and National Institute for Mental Health in England, October 2005), available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4122342

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.144 The consultation responses and our analysis support the decision to include the activity in the scope of registration.

What the Regulations will cover

Regulated activity: Treatment of disease, disorder or injury

A.145 The relevant draft Regulation is Regulation 8 in Annex B.

What will be within the scope of registration?

A.146 Because of the development of the policy on this and other activities, specialist mental health services are now covered within the *Treatment of disease, disorder or injury* activity. The definition covers care or treatment for a mental disorder, by or in a multidisciplinary team containing any of the healthcare professionals listed in paragraph A.103. This includes counselling and psychotherapy services, where carried out by those professionals. The term 'mental disorder' is defined to mean any disorder or disability of the mind, including dependence on alcohol or drugs.

What will be outside of the scope of registration?

A.147 The policy is to not include services that are not carried out by or in a multidisciplinary team containing healthcare professionals as set out in paragraph A.103. This excludes some counselling and psychotherapy services, and social worker or psychologist services that are not provided within multidisciplinary teams.

Will any activities outside the scope of registration be kept under review?

A.148 There are a wide range of services described as counselling and psychotherapy. Our analysis of these services supported the view that some areas are relatively risky and should be within the scope of registration, but some services described as counselling and psychotherapy were found to have less inherent risk, with little to be gained from system regulation. A lack of clarity around the definition of these services made it difficult to distinguish between the range of counselling and psychotherapy services.

A.149 However, proposed changes to professional regulation in this area over the next year or so are expected to bring more clarity to the definition of counselling and psychotherapy services provided by people who are not currently in one of the registered healthcare professions. Therefore, we will keep counselling and psychotherapy services under review.

A.150 We will also keep under review other mental health services delivered by teams that do not contain the healthcare professionals listed, particularly specialist mental health services provided by social workers and psychotherapists, with a view to bringing some services into the scope of registration either within these regulations, or at a later date.

Detention or deprivation of liberty for care or treatment

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.151 The responses covering this activity supported the proposal to have detention or deprivation of liberty for care or treatment within the scope of registration, but there were conflicting views about whether the activity would be captured under other activities.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.152 It was suggested that we should include detention for assessment as well as detention for care or treatment.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.153 We agree that deprivation of liberty for care or treatment is closely related to some other regulated activities (for example *Treatment for disease, disorder or injury*), and in many cases this activity will fall within them. In particular, we think that care and treatment for people deprived of their liberty under the new deprivation of liberty safeguards in the Mental Capacity Act 2005 will invariably fall within one of the other regulated activities.

A.154 However, the Mental Health Act 1983 contains its own unique definition of medical treatment and it is therefore possible that someone could be detained under that Act but not fall within any other regulated activity. Therefore, we have included a separate Regulation in relation to detention under the Mental Health Act 1983.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.155 The consultation responses and our analysis support the decision to include the activity in the scope of registration.

What the Regulations will cover

Regulated activity: Assessment or medical treatment for persons detained under the Mental Health Act 1983

A.156 The relevant draft Regulation is Regulation 9 in Annex B.

What will be within the scope of registration?

A.157 This regulated activity will cover the assessment or medical treatment of a person who is detained under the Mental Health Act 1983 (or its equivalent) in the hospital in which they are detained. This includes people on supervised community treatment who have been recalled to hospital. It means that, apart from the exceptions below, any service provider which runs a hospital in which patients are detained (however infrequently) will need to be registered for this activity.

What will be outside of the scope of registration?

A.158 This regulated activity will not include:

- Assessment or treatment in a hospital where the hospital is only being used as a ‘place of safety’ under Section 135 or 136 of the Mental Health Act;
- Assessment or treatment of a detained patient anywhere other than the hospital in which they are detained (including cases where they are being kept in custody at another hospital as a condition of leave of absence, eg for treatment of a physical health problem).

Will any activities outside the scope of registration be kept under review?

A.159 We do not anticipate specifically keeping any of these activities under review.

Nursing care

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.160 The responses covering this activity supported the proposal that nursing care should be within the scope of registration. There was also some support for the suggestion that services that are sufficiently overseen by other regulatory systems should be outside the scope of registration.

A.161 Responses relating to the regulation of agencies are covered in Chapter 3.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.162 Some responses suggested a broader definition of nurse services should be within registration, including health visitor services, school nurse services, and agencies providing nursing staff to other providers.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.163 We have broadened the definition of nursing care, so that it now includes family planning services (which was previously included in the *Maternity services, obstetrics and gynaecology* activity) and all nursing care that is not defined under other regulated activities (such as *Treatment for disease, disorder or injury*).

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.164 As set out earlier in Chapter 3, nurses agencies that do not directly provide care and solely supply staff to registered providers will not be covered by system regulation.

What the Regulations will cover

Regulated activity: Nursing care

A.165 The relevant draft Regulation is Regulation 17 in Annex B.

What will be within the scope of registration?

A.166 The policy is to include nursing care which is not provided as part of any other regulated activity, for example, district nursing services. This includes nursing care provided in a person's own home, subject to the exclusions below. This activity will also include some aspects of school nursing not covered by Ofsted. It is not our intention to cover low risk services, for example, supplying plasters. However, we do want to ensure that more complex tasks, such as the administration of vaccines is appropriately incorporated. We will work with DCSF to ensure that coverage is appropriate for these services.

What will be outside of the scope of registration?

A.167 The policy is to not include:

- nursing provided by a nurse directly employed by the person receiving the care;
- nurses agencies solely supplying staff to registered providers.

Will any activities outside the scope of registration be kept under review?

A.168 We do not anticipate specifically keeping any of these activities under review.

Primary medical services

A.169 As we have developed the policy on other activities, it has become clear that primary medical services will be captured under other registered activities, such as *Treatment of disease, disorder or injury* or *Surgical procedures*. These activities capture care provided by or under the direction of a range of primary medical practitioners. Therefore, there is no longer a separate activity for primary medical services.

A.170 The detail of the consultation responses and our proposals for primary medical services are covered in Chapter 4.

Prescribing, administration, sale and supply of medicines (as an activity in its own right)

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.171 There was general support for the proposal that these services should not be regulated except where they form part of a regulated activity. Some responses suggested we should review the situation in future as independent prescribing increases.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.172 There were no suggestions about further inclusions for the scope of this regulated activity.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.173 We have found no evidence to suggest that we should make prescribing, administration, or the sale and supply of medicines regulated activities in their own right because this area is already highly regulated by other measures.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.174 The consultation responses and our analysis support the decision not to specifically include the activity in the scope of registration.

What the Regulations will cover

What will be within the scope of registration?

A.175 Where these activities are part of a regulated activity (eg *Treatment of disease, disorder or injury*), providers will be accountable for them under the relevant registration requirement. Providers of these services who also provide a regulated activity will need to register with the Care Quality Commission in respect of that activity.

What will be outside of the scope of registration?

A.176 The policy is to not include high street pharmacies.

Will any activities outside the scope of registration be kept under review?

A.177 We will keep this activity under review as services develop.

Therapies (as an activity in its own right)

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.178 There was general support for the proposal that therapy services should not be within the scope of registration, but should only be included where they form part of another regulated activity.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.179 A number of responses suggested services that should be included within the scope of registration, for example, alternative and complementary therapies and psychotherapy, or asked how these services would be monitored.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.180 The responses to the consultation were content with our proposals for this activity.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.181 We considered several different service types under this activity: services provided by allied health professionals, such as physiotherapists; counselling and psychotherapy and similar services, which may or may not be delivered by healthcare professionals; and alternative and complementary medicine.

A.182 Our analysis of stand-alone therapies, except counselling and psychotherapy, found that the risks to patients were relatively low (both in terms of likelihood and severity of hazards) and that professional regulation, through the Health Professions Council, was the best way to address these risks. As set out in paragraphs A.148 to A.150, we will keep counselling and psychotherapy services under review.

A.183 Complementary therapies are now covered by independent, voluntary regulation – the Complementary and Natural Healthcare Council (CNHC) started a register of practitioners of a range of complementary healthcare services on 19 January 2009.

What the Regulations will cover

What will be within the scope of registration?

A.184 Therapy services will be included when they are provided as part of another regulated activity, for example, physiotherapy services in an orthopaedic unit. Providers of these services who also provide other regulated activities will need to register with the Care Quality Commission in relation to those services.

What will be outside of the scope of registration?

A.185 The policy is to exclude stand-alone therapy services, for example high street physiotherapy, chiropractic or podiatry services.

A.186 Alternative and complementary therapies will not be included within the scope of registration.

Will any activities outside the scope of registration be kept under review?

A.187 Coverage of counselling and psychotherapy services is described under *Treatment for disease, disorder or injury*.

Telemedicine and telecare (as activities in their own right)

What we heard

Did the consultation responses support this activity being within the scope of registration?

A.188 Some responses covering this activity supported the proposal that telemedicine and telecare should not be within the scope of registration, but should be included where they form part of another regulated activity. There were concerns about proposals that we would be leaving some services outside the scope of registration that should be in, for example NHS Direct.

Did the consultation responses suggest other areas that might be brought within the scope of registration?

A.189 Some respondents sought reassurance about how these activities would be captured appropriately.

Our response

Do we think there is a clear case to change our definition of the scope of registration?

A.190 We agree that telephone services offering urgent medical advice, such as NHS Direct and similar telehealth services should be within the scope of registration. These services will be captured under the *Transport services, triage and medical advice provided remotely* activity.

A.191 Telemedicine, the electronic transfer of diagnostic or other information for remote assessment, will be regulated under the *Diagnostic procedures* activity, if it is provided as part of a regulated activity.

Do we think registration with the Care Quality Commission is the most effective way to assure people of the quality and safety of services?

A.192 Remote social care services, referred to as telecare, for example, personal care call systems, and remote healthcare services, referred to as telehealth, for example, self assessments relayed electronically to a remote clinician for surveillance, will not be set out as regulated activities in their own right. However, the health and social care provided to those patients and people who use services will be regulated if it falls within, or is ancillary to, other regulated activities. For example, if a programme of treatment for a particular disease requires the patient to send results to their doctor regularly, it will fall within the *Treatment for disease, disorder or injury* category.

What the Regulations will cover

What will be within the scope of registration?

A.193 Telemedicine (ie the remote analysis of diagnostic tests) and urgent telephone health advice lines will be covered under the *Diagnostic procedures* activity and the *Transport services, triage and medical advice provided remotely* activities, respectively.

What will be outside of the scope of registration?

A.194 The policy is to not specifically include telehealth and telecare. These will only be covered where they are part of or, ancillary to, another regulated activity.

Will any activities outside the scope of registration be kept under review?

A.195 We will keep these services under review as they develop and become more widespread.

Regulations carried forward from the current Regulations

Exclusions

A.196 We have carried forward exclusions covering healthcare activities which are provided in sports facilities, exclusively in places of work, or which are carried out in connection with insurance policies.

Management and supply of blood and blood derived products

A.197 Regulation 12 carries forward the policy content of the 2009/10 HCAI scope Regulations that come into force on 1 April 2009.

Services in slimming clinics

A.198 Regulation 16 covers the medical services provided in these clinics that are not covered elsewhere in the above regulated activities. It is a slight change from the CSA coverage, as non-medically led services will be included.

A.199 Services carried out in NHS primary care have a global exclusion from all regulated activities. The arrangements for primary care are covered in Chapter 4. However, the policy is to include services delivered by doctors who solely provide treatment to private patients.

Annex B: Draft scope Regulations

Draft Order laid before Parliament under section 162(3) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.

S T A T U T O R Y   I N S T R U M E N T S

2009 No. XXXX

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2009

Made - - - -	*****
Laid before Parliament	*2009*
Coming into force - -	*1st April 2010*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 8(1) and 161(3) and (4) of the Health and Social Care Act 2008(**a**).

A draft of these Regulations was laid before Parliament in accordance with section 162(3) of the Health and Social Care Act 2008 and approved by resolution of each House of Parliament.

Citation, commencement and application

1.—(1) These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009 and come into force on 1st April 2010.

(2) These Regulations apply in relation to England.

Interpretation

2. In these Regulations—

"the Act" means the Health and Social Care Act 2008;

"the 2006 Act" means the National Health Service Act 2006(**b**);

"employment agency" and "employment business" have the same meaning as in section 13(2) and (3) respectively of the Employment Agencies Act 1973(**c**);

(**a**) 2008 c. 14. "Prescribed" and "regulations" are defined in section 92(1) of the Act.
(**b**) 2006 c.41.
(**c**) 1973 c. 35. Section 13(2) was amended by the Employment Relations Act 1999 (c. 26), section 31, Schedule 7, paragraphs 1, 7.

"health care professional" means, subject to regulation 8(11)(e), a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(**a**) applies;

"medical practitioner" means a registered medical practitioner within the meaning of Schedule 1 to the Interpretation Act 1978(**b**);

"personal care" means—

(a) physical assistance given to a person in connection with—

(i) eating or drinking,

(ii) toileting (including in relation to the process of menstruation),

(iii) washing or bathing,

(iv) dressing,

(v) oral care, or

(vi) the care of skin, hair and nails; or

(b) the prompting and supervision of a person, in relation to the performance of any of the activities listed in sub-paragraph (a), where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision;

"service provider" means a person registered with the Commission under Part 1 of the Act as a service provider in respect of a regulated activity;

"treatment" includes—

(a) a diagnostic or other investigative procedure;

(b) nursing, personal and palliative care; and

(c) the giving of vaccinations and immunisations.

Prescribed activities

3.—(1) Subject to regulations 18 and 19, for the purposes of section 8(1) of the Act, the activities described in regulations 4 to 17 are prescribed as regulated activities.

(2) An activity which is ancillary to, or is carried out wholly or mainly in relation to, a regulated activity shall be treated as part of that activity.

Personal care

4.—(1) Subject to paragraph (2), the provision of personal care for persons who, by reason of old age, illness or disability are unable to provide it for themselves, and which is provided in a place where those persons are, for the time being, living.

(2) The following types of provision are excepted from paragraph (1)—

(a) the supply of carers to a service provider for the purposes of carrying on a regulated activity by an undertaking acting as an employment agency or employment business; and

(b) the services of a carer engaged and directed by an individual in order to meet that individual's own personal care requirements.

Accommodation for persons who require nursing or personal care

5. The provision of residential accommodation, together with nursing or personal care.

(**a**) 1999 c.8. Section 60(2) was amended by the Health and Social Care Act 2008, section 111, 166, Schedule 8, paragraphs 1(1), (3)(a), (b) and (c) and Schedule 15, Part 2. In addition, see: S.I. 2002/253, article 54(3), Schedule 5, paragraph 16(a) and S.I. 2002/254, article 48(3), Schedule 4, paragraph 8(a).

(**b**) 1978 c. 30.

Accommodation for persons who require treatment for substance misuse

6. The provision of residential accommodation for a person, together with treatment for drug or alcohol misuse, where acceptance by the person of such treatment is a condition of the provision of the accommodation.

Accommodation and nursing or personal care in the further education sector

7.—(1) Subject to paragraph (2), the provision of residential accommodation together with nursing or personal care for persons in an institution within the further education sector (within the meaning of section 91 of the Further and Higher Education Act 1992(**a**)).

(2) Paragraph (1) applies where the number of persons to whom nursing or personal care and accommodation is provided is more than one tenth of the number of students to whom both education and accommodation is provided.

Treatment of disease, disorder or injury

8.—(1) Subject to paragraphs (2) to (10), the provision of treatment for disease, disorder or injury by, or under the supervision of, a health care professional.

(2) This regulation does not apply where regulation 9 applies.

(3) The carrying on of the activities set out in paragraphs (4) to (10) are excepted from paragraph (1).

(4) The provision of treatment by means of surgical procedures;

(5) The practice of alternative and complementary medicine;

(6) The provision of first aid treatment by organisations established for that purpose, or persons trained to deliver such treatment;

(7) The provision of treatment in a sports ground or gymnasium where it is provided for the sole benefit of persons taking part in sporting activities and events;

(8) The provision of medical services in a surgery or consulting room (which is not part of a hospital) in which a medical practitioner provides such services only under arrangements made on behalf of service users by—

(a) their employer;

(b) a government department or any executive agency of a government department; or

(c) an insurance provider with whom the service users hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity;

(9) The provision of hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) through a mask to a person who is in a sealed chamber which is gradually pressurised with compressed air, where the primary use of that chamber is—

(a) pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997(**b**) or regulation 8 or 12 of the Work in Compressed Air Regulations 1996(**c**); or

(b) otherwise for the treatment of workers in connection with the work which they perform.

(10) The carrying out of any of the activities authorised by a licence granted by the Human Fertilisation and Embryology Authority under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990(**d**).

(11) In this regulation—

(**a**) 1992 c.13.
(**b**) S.I 1997/2776.
(**c**) S.I. 1996/1656.
(**d**) 1990 c. 37. Paragraph 1 of Schedule 2 was amended by the Human Fertilisation and Embryology Act 2008 (c. 22), section 11(2), Schedule 2, paragraphs 1 and 2 and section 66, Schedule 8, Part I and by S.I. 2007/1522.

(a) "disorder" means a physical or a mental disorder;

(b) "hospital" has the same meaning as in section 275 of the 2006 Act;

(c) "insurance provider" means—

(i) a person regulated by the Financial Services Authority who sells insurance, or underwrites the risk of such insurance; or

(ii) the agent of such a person;

(d) "mental disorder" means any disorder or disability of the mind, including dependence on alcohol or drugs; and

(e) references to a "health care professional" do not include a person ("P") carrying on a profession referred to in paragraph (12) unless—

(i) P is acting under the direction of another health care professional ("H"), and

(ii) H does not carry on a profession referred to in paragraph (12).

(12) For the purposes of paragraph (11)(e), the professions are—

(a) osteopath;

(b) chiropractor;

(c) arts therapist;

(d) chiropodist;

(e) podiatrist;

(f) dietician;

(g) occupational therapist;

(h) orthoptist;

(i) physiotherapist;

(j) prosthetist and orthotist; and

(k) speech and language therapist.

Assessment or medical treatment for persons detained under the 1983 Act

9.—(1) The assessment of, or medical treatment for, a mental disorder affecting a person in a hospital ("the hospital") where that person is—

(a) detained in the hospital pursuant to the provisions of the 1983 Act (with the exception of sections 135 or 136 of that Act);

(b) recalled to the hospital under section 17E of that Act; or

(c) detained pursuant to an order or direction made under another enactment, where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

(2) In this regulation—

(a) "the 1983 Act" means the Mental Health Act 1983(**a**);

(b) "assessment" should be construed in accordance with that Act;

(c) "hospital" means a hospital within the meaning of Part 2 of that Act;

(d) "medical treatment" has the same meaning as in section 145 of that Act; and

(e) "mental disorder" has the same meaning as in section 1 of that Act(**b**).

(**a**) 1983 c.20.

(**b**) Section 1 was substituted by section 1(2) of the Mental Health Act 2007 (c. 12).

Surgical procedures

10.—(1) Subject to paragraph (2), surgical procedures (including all pre-operative and post-operative care associated with such procedures) carried out by a health care professional for—

(a) the purpose of treating disease, injuries or disorders;

(b) cosmetic purposes, where the procedure involves the use of instruments and equipment which are inserted into the body; or

(c) the purpose of religious observance.

(2) The following cosmetic procedures are excepted from paragraph (1)(b)—

(a) ear and body piercing;

(b) tattooing;

(c) the subcutaneous injection of a substance or substances for the purpose of enhancing a person's appearance; and

(d) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.

Diagnostic procedures

11.—(1) Subject to paragraph (3), diagnostic procedures involving—

(a) the use of X-rays and other methods in order to examine the body through the use of radiation, ultrasound or magnetic resonance imaging;

(b) the use of instruments and equipment which are inserted into the body to—

(i) view its internal parts, or

(ii) gather physiological data; and

(c) the use of equipment in order to measure and monitor complex physiological characteristics in major organ systems of the body and to examine bodily tissues, fluids and cells for the purposes of obtaining information on—

(i) the causes and extent of disease, or

(ii) the response to a therapeutic intervention.

(2) The analysis and reporting of the results of the procedures referred to in paragraph (1)

(3) The taking and analysis of blood samples is excepted from paragraph (1) where—

(a) the procedure is carried out by means of a pin prick; or

(b) it is not necessary to send such samples to a specialist facility for analysis.

Management and supply of blood and blood derived products etc.

12. The management of—

(a) the supply of blood, blood components and blood derived products intended for transfusion;

(b) the supply of tissues and tissue derived products intended for transplant, grafting or use in a surgical procedure; and

(c) the matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion.

Transport services, triage and medical advice provided remotely

13.—(1) Transport services provided by an English NHS provider by means of a vehicle which is designed for the primary purpose of carrying patients.

(2) Triage.

(3) Urgent medical advice provided over the telephone or by electronic mail by a body established for that purpose.

(4) For the purposes of this regulation "vehicle" includes an air ambulance.

Maternity and midwifery services

14.—(1) Subject to paragraph (2), maternity and midwifery services carried out by, or under the supervision of, health care professionals.

(2) The following services are excepted from paragraph (1)—

(a) midwifery services, where the provision of those services is carried on by an individual—

(i) acting on their own behalf,

(ii) otherwise than in pursuance of the 2006 Act, and

(iii) who provides such services solely to service users in their own homes and to no-one else;

(b) information, advice and support provided by lay organisations in connection with—

(i) childbirth, or

(ii) the acquisition and exercise of parenting skills; and

(c) arrangements relating to the care of pregnant women and women who are breastfeeding pursuant to section 254 of, and Schedule 20 to, the 2006 Act (local social services authorities).

Termination of pregnancies

15. The termination of pregnancies.

Services in slimming clinics

16. Medical services provided in slimming clinics, including the prescribing of medicines for the purposes of weight reduction.

Nursing care

17.—(1) Subject to paragraph (2), the provision of nursing care which is not provided as part of any other regulated activity, including nursing care provided in a person's own home.

(2) The following types of provision are excepted from paragraph (1)—

(a) the supply of nurses to a service provider for the purposes of carrying on a regulated activity by an undertaking acting as an employment agency or employment business; and

(b) the services of a nurse engaged and directed by an individual in order to meet that individual's own nursing requirements.

General exceptions

18.—(1) The services referred to in paragraphs (2) to (8) are not regulated activities for the purpose of these Regulations.

(2) Primary medical services provided under arrangements made pursuant to the following sections of the 2006 Act—

(a) section 3 (Secretary of State's duty as to provision of certain services),

(b) section 83(2)(b) (primary medical services), or

(c) section 92 (arrangements by Strategic Health Authorities for the provision of primary medical services)

(3) Services provided under a contract entered into pursuant to section 84 of the 2006 Act (general medical services contracts: introductory).

(4) Dental services—

(a) provided as primary dental services in pursuance of Part 5 of the 2006 Act, except where those services are provided—

(i) by a Primary Care Trust under section 99(2) (primary dental services); or

(ii) by an NHS trust or NHS foundation trust;

(b) of a kind which, if provided in pursuance of that Act, would be provided as primary dental services under Part 5.

(5) In paragraph (4), "primary dental services" includes the provision of dental implants.

(6) Primary ophthalmic services provided under Part 6 of the 2006 Act and services of a kind which, if provided in pursuance of that Act, would be provided as primary ophthalmic services under that Part of that Act;

(7) Pharmaceutical services and local pharmaceutical services provided under Part 7 of the 2006 Act, and services of a kind which, if provided in pursuance of that Act, would be provided as pharmaceutical services and local pharmaceutical services under that Part of that Act.

(8) Defence Medical Services being—

(a) health care provided by the Armed Services;

(b) education and training provided by the Armed Services to service and other personnel in connection with the provision of health care, including the maintenance of the clinical skills of such personnel; and

(c) any service or facility falling within paragraph (a) or (b) provided on behalf of the Armed Services under any agreement or arrangement made with the Armed Services.

Family and personal relationships

19.—(1) Nothing in these Regulations will apply to any activity which is carried out—

(a) in the course of a family or personal relationship; and

(b) for no commercial consideration.

(2) A family relationship includes a relationship between two persons who—

(a) live in the same household; and

(b) treat each other as though they were members of the same family.

(3) A personal relationship is a relationship between or among friends.

(4) A friend of a person (A) includes a person who is a friend of a member of A's family.

Name
Parliamentary Under Secretary of State

Date

Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which are to come into force on 1st April 2010 are made under the Health and Social Care Act 2008 ("the Act") and prescribe the kinds of activities that will be regulated

activities for the purposes of Part 1 of the Act. The Regulations apply in relation to a regulated activity carried on in England (regulation 1). Part 1 of the Act establishes the Care Quality Commission and provides for the registration of persons carrying on a prescribed regulated activity. It also provides powers to make regulations imposing requirements in relation to the carrying on of those regulated activities.

Regulation 2 is an interpretation provision.

Regulations 3 to 17 set out the activities that are prescribed as regulated activities, together with certain specific exceptions where applicable.

Regulations 18 and 19 prescribe activities which are generally excepted from the scope of Regulations 3 to 17.

Annex C: Detailed analysis of responses to the consultation on registration requirements

C.1 Respondents strongly supported the proposed registration requirement topics. Many made additional comments and suggestions on the detail of individual registration requirements, which mostly relate to the implementation of the requirements in particular services and how the Care Quality Commission will judge compliance. These comments and suggestions are therefore particularly relevant to the Care Quality Commission's development of guidance about compliance with the requirements of Regulations and we are sharing a summary of them with the Care Quality Commission. The numbers and titles refer to those in the previous consultation.

Requirement 1: Making sure people get care and treatment that meets their needs safely and effectively

What we heard

C.2 Respondents supported the topic of this requirement, some seeing this as an overall aim of registration. Some responses questioned how the new Commission would judge whether treatment and care provided is 'effective' in securing people's health, safety and wellbeing. Some asked about how the Care Quality Commission will take into account specific types of National Institute for Health and Clinical Excellence (NICE) guidance and other sources of guidance in judging compliance.

C.3 Some responses suggested that we expand this requirement to require the involvement of patients and people using services, including the provision of choice, discussion about risk and regular reviews.

Our response

C.4 The Care Quality Commission will be able to address the issues raised about NICE and other guidance as it develops its guidance about compliance with the requirements of Regulations. The Commission will be able to work with other authoritative bodies to identify and secure relevant evidence of the effectiveness of different types of care. We would encourage and support the Commission in this respect.

C.5 We agree that the involvement of patients and people using services, including the provision of choice, discussion about risk and regular reviews are important issues. However, we have covered them in other registration requirements for respecting and involving people who use services, for consent and managing the quality of service provision. We have not, therefore, duplicated them in this particular requirement.

C.6 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 7.

Requirement 2: Safeguarding people when they are vulnerable

What we heard

C.7 Respondents said this was a vital topic for registration requirements. A small number of responses suggested that we expand a service provider's duty to safeguard individuals beyond vulnerable patients and people using their service to a general duty towards the public as a whole.

C.8 Some respondents suggested we should specify groups of vulnerable people to whom this requirement applies. Some wanted us to provide greater clarity about the types of abuse covered by the requirement. Some thought that arrangements to safeguard people from abuse when their liberty is restricted should explicitly cover non-physical as well as physical restraint.

C.9 Some people commented that the Care Quality Commission would need to give early thought to its role in multi-agency safeguarding arrangements.

Our response

C.10 We do not feel it would be reasonable, or legally enforceable in practice, to expect service providers to have such a wide-ranging responsibility beyond the boundaries of their service towards the public as a whole. It would also be impractical for a regulator to determine compliance in relation to the public as a whole. We have not therefore expanded the requirement as suggested.

C.11 We believe that vulnerability is caused by circumstances, rather than necessarily being an inherent feature of particular groups of people. The aim of this requirement is to get service providers to identify and address the circumstances that make any individual using their service particularly vulnerable. For example, a person who in other circumstances would be able to safeguard themselves, will be unable to do so when under general anaesthesia. A person with a learning disability may need additional support to assert their rights where circumstances mean the balance of power lies with their service provider. We have not therefore added a definition of vulnerable groups that would necessarily be lengthy and too unwieldy and may well draw adverse comments from the parliamentary committee overseeing secondary legislation. The important thing is to ensure that what we have drafted will encompass all the different types of vulnerability as they arise.

C.12 We have defined the enforceable coverage of abuse we wish to achieve in the Regulation. This is not a detailed list of all the types of abuse that fall within the definition but it is sufficient to cover physical, emotional, psychological, sexual and financial abuse and abuse of a discriminatory nature and neglect. It covers both child and elder abuse and abuse of adults. It also covers the use of restraint by physical and non-physical means.

C.13 We agree that the Care Quality Commission will need to consider how it will implement its role in safeguarding and work with its partners in doing so. We have been reassured that the Commission is addressing safeguarding issues as a matter of priority.

C.14 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 9.

Requirement 3: Managing cleanliness and infection control

What we heard

C.15 Respondents supported the inclusion of a requirement on this topic. Some respondents thought this requirement should include reference to staff training.

Our response

C.16 From April 2009, we are introducing registration for NHS bodies (but not including primary medical and primary dental care) with a single enforceable requirement on healthcare associated infection. Application of the requirement for NHS bodies will extend to other registered providers of regulated activities as they are brought into registration from 2010 onwards. Guidance about compliance with this requirement in NHS bodies is contained in the Code of Practice for the prevention and control of healthcare associated infections. This guidance was published under powers in Section 21 of the Health and Social Care Act 2008. We will shortly consult upon and then publish a revised version of the Code of Practice that will contain guidance about compliance in NHS bodies and all the activities that will be registered from 2010. A further Code of Practice will be produced when primary medical and primary dental care are brought into registration.

C.17 We agree that effective training is important across all aspects of care delivery, so we have included requirements specifically focused on workers' competency rather than duplicating these issues in each of the other requirements. The requirements set out in Regulations are supported by guidance about compliance. In the case of this particular requirement, the guidance is set out in the Code of Practice for the prevention and control of healthcare associated infections (see above). This Code includes guidance covering the suitable education of staff in the prevention and control of infection.

C.18 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 10.

Requirement 4: Managing medicines safely

What we heard

C.19 Respondents felt that this was a suitable topic for registration requirements. Some respondents thought this requirement should include safe and effective prescribing, voicing particular concerns about the prescribing of anti-psychotic drugs for people with dementia.

C.20 Some respondents felt this requirement needed to be underpinned by standards for appropriate self-medication.

Our response

C.21 We recognise the essential role of pharmacists working alongside colleagues to deliver a regulated activity in promoting appropriate prescribing practice. Prescribing is an activity covered by the Medicines Act 1968 (and associated NHS Regulations). The prescribing practice of clinicians is a matter for professional regulation. Where there is inappropriate, systemic prescribing of anti-psychotic or other drugs within a provider organisation, there is scope for the Commission to address this through Requirement 1 on safe and effective care that meets people's needs. Where there is inappropriate administration of anti-psychotic or other drugs, this would be covered by this requirement on the management of medicines.

C.22 It will be for the Care Quality Commission to develop guidance about how it will judge compliance with this requirement. We would encourage the Commission to refer to other relevant enactments and guidance issued by relevant expert bodies as it does this.

C.23 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 11.

Requirement 5: Making sure people get the nourishment they need

What we heard

C.24 Respondents strongly welcomed the inclusion of nutrition and hydration in registration requirements. Some respondents felt that this requirement should be set at a higher level, promoting health through good nutrition and ensuring enjoyable meals and mealtimes rather than focussing on malnutrition. They also felt that the requirement should apply a general duty to safeguard people's nutrition to all services, not only those where the service has a clear responsibility to provide meals.

Our response

C.25 The requirement is set at the level of safety and essential quality, as non-compliance is linked to the Care Quality Commission's enforcement powers. However, we accept that a clinical definition of malnutrition is too low for this level and have raised it to inadequate nutrition and hydration. Other parts of the system for managing quality in health and adult social care, along with public health developments, will build upon this bedrock of essential practice to secure further improvement in the quality of meals and mealtimes.

C.26 We do not wish to be prescriptive about the activities to which the requirement applies, because different kinds of service will have different levels of responsibility for the nutrition and hydration of people who use their services. We believe that the Care Quality Commission's guidance about compliance can further clarify how this requirement will be applied to different activities.

C.27 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 12.

Requirement 6: Making sure people get care and treatment in safe, suitable places which support their independence, privacy and personal dignity

What we heard

C.28 Respondents agreed with the inclusion of this topic in registration requirements. Some respondents were concerned that this requirement might be used to close small local facilities, such as local outreach premises, in favour of large purpose built and centralised sites.

C.29 Some respondents were concerned that the Care Quality Commission might prioritise safety over the need to promote independence, particularly in adult social care services.

Our response

C.30 This requirement is necessary to ensure that any premises in which care is delivered are safe and appropriate to meet the needs of people using them and the regulated activities provided there. It can be applied flexibly to meet a wide range of models for the delivery of local services and does not favour any particular type of facility or organisational model. We recognise the importance of services reaching out to those who might otherwise find them hard to access. We have asked the Care Quality Commission to keep this in mind as it develops its guidance about compliance with the requirements of Regulations.

C.31 We have provided the Commission with a summary of the points that respondents made in relation to the practical implications of balancing safety and independence and have asked it to bear these in mind as it develops its approach to the appropriate management of risk and guidance about compliance for this requirement.

C.32 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 13.

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

What we heard

C.33 Respondents agreed with the inclusion of this topic in registration requirements. Some respondents were concerned that the Care Quality Commission might prioritise the safety aspects of furnishings and equipment for day-to-day living over the homeliness and the independence, dignity and comfort they afford in judging compliance with this requirement in adult social care settings.

Our response

C.34 We recognise the importance people place on their dignity, independence and comfort and that this requirement for safe and suitable equipment will, in some cases, be applied where people live or stay long-term. We understand that people want to be fully involved in choices and decisions about their surroundings and the management of risks inherent in particular choices. We have asked the Commission to bear this in mind as it develops guidance about compliance with the requirements of Regulations.

C.35 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 14.

Requirement 8: Involving people in making informed decisions about their care and treatment

What we heard

C.36 Respondents supported the inclusion of this topic in registration requirements. Some respondents felt this requirement did not adequately reflect the development of user-led services in adult social care. They wanted references to service-user involvement and consent strengthened.

Our response

C.37 Decision making between care providers and people using their services needs to be personalised to individual circumstances. We recognise that different types of decision in relation to different regulated activities will call for different types of approach. However, this is something that should be addressed in guidance about compliance rather than the Regulations. We have asked the Care Quality Commission to consider activity specific guidance issued by expert bodies about how decision processes can be individualised, as it develops guidance about compliance for this requirement.

C.38 Taking account of all the comments we have received on this requirement, we have combined it with requirements 11 and 12, see below.

Requirement 9: Getting people's ongoing agreement to care and treatment

What we heard

C.39 Respondents agreed with the inclusion of this topic in registration requirements. Some respondents felt this requirement should contain more detail about the action expected when a person lacks capacity to consent to treatment or where the person to be treated is a child.

C.40 A small number of respondents felt that consent should be excluded from registration requirements as failure to secure appropriate consent is a matter only for criminal action against the individual professional involved.

Our response

C.41 The 2008 Act enables the Care Quality Commission to take into account any other relevant enactment in judging compliance with registration requirements. We have asked the Care Quality Commission to pay particular regard to the Mental Capacity Act and the legislation relating to children as it develops its guidance about compliance with this requirement.

C.42 The registration requirement recognises the individual's obligations under law and professional regulation and requires care providers' systems to support these obligations.

C.43 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 15.

Requirement 10: Responding to people's comments and complaints

What we heard

C.44 Respondents recognised the importance of comments and complaints and welcomed their inclusion in registration requirements. Some respondents commented that this should include a requirement upon providers to supply advocacy support to encourage people to voice their complaints.

C.45 Some respondents felt there should be encouragement of learning from complaints.

C.46 Some respondents felt there should be a specific requirement to disclose information to complainants.

Our response

C.47 The availability of appropriate advocacy support is a matter for commissioning practice rather than registration requirements for safe and effective care.

C.48 We agree that it is essential providers learn from complaints and have covered this in Requirement 13 which requires providers to identify and learn from a wide range of information.

C.49 We have asked the Care Quality Commission to consider the issue of disclosing information in relation to effective systems for the handling of complaints, taking account of other relevant enactments and particularly data protection legislation, as it develops guidance about compliance for Requirement 14, which covers the keeping of, and access, to records.

C.50 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 17.

Requirement 11: Supporting people to be independent

What we heard

C.51 Respondents from the adult social care community strongly supported the inclusion of this topic in registration requirements. There were polarised views about how this requirement should be applied to a range of different health and adult social care activities. Many people emphasised the need for personal autonomy in all care and treatment circumstances. Others held that this requirement had no relevance for many aspects of healthcare, other than where people have long-term health conditions. These respondents thought that an emphasis on independence would be a perverse incentive for leaving people in vulnerable situations.

Our response

C.52 We recognise that different views of how this requirement should be implemented arise from the different approach appropriate in different services. We have therefore asked the Care Quality Commission to consider this issue carefully in developing guidance about compliance with this Regulation, and to strike an appropriate balance for particular activities.

C.53 Taking account of all the comments we have received on this requirement, we have combined it with requirements 8 and 12, see below.

Requirement 12: Respecting people and their families and carers

What we heard

C.54 Respondents welcomed a registration requirement on dignity and respect. Some respondents thought that compliance with this requirement would be difficult to assess, involving subjective views about the degree to which people felt respected. Respondents felt guidance about compliance would need to provide examples of the specific ways in which this respect could be demonstrated.

Our response

C.55 We and others have done a great deal of work to help us understand what people mean when they say they want to be treated with dignity and respect. Some of the key learning from this work is reflected in our Dignity in Care Campaign[1]. We have asked the Care Quality Commission to consider how these important aspects of dignity might be reflected when developing its guidance about compliance with this requirement.

C.56 Taking account of all the comments we have received on this requirement, and combining with requirements 8 and 11, the draft Regulation for these requirements is in Annex D, at Regulation 15.

Requirement 13: Having arrangements for risk management, quality assurance and clinical governance

What we heard

C.57 Respondents thought that inclusion of this topic in registration requirements supported an essential infrastructure in services, enabling them to achieve the other registration requirements. Some respondents felt that this requirement should specifically cover the detail of existing arrangements for investigation and reporting of incidents in healthcare services. They also wanted it to stress the need to learn from incidents and near misses and to prescribe the features of required clinical governance systems.

C.58 Some respondents asked for recognition that some types of service need to use innovative methods to capture 'true' views of people who use services.

Our response

C.59 We agree that these are important issues. However, we do not wish to be prescriptive about the use of particular systems that do not recognise what works best in different sectors and which may not provide the flexibility local managers need. We feel that the guidance about compliance with this requirement could usefully expand upon the features of effective systems. We have therefore asked the Care Quality Commission to consider these issues as it develops its guidance about compliance.

1 www.dh.gov.uk/en/SocialCare/Socialcarereform/Dignityincare/index.htm

C.60 Appropriate methods to capture the widest possible views will vary according to the type of activity involved. We have suggested that the Care Quality Commission considers this level of detail as it develops its guidance about compliance with this registration requirement.

C.61 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 8.

Requirement 14: Keeping records of the provision of care and treatment

What we heard

C.62 Respondents agreed that this should be a subject for registration requirements. Some respondents thought the Regulation should specify in detail, which records are to be kept, and that this should include the keeping of records to facilitate research.

C.63 Some respondents thought this requirement should set out the detail of good practice in records management.

Our response

C.64 The records that need to be kept in relation to any particular activity may differ, and a flexible approach will be needed that reflects different types of provider. We feel that good practice in records management at this level of detail is more appropriate to guidance about compliance than in legislation for registration requirements.

C.65 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 18.

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

What we heard

C.66 Respondents saw this as a key topic for registration requirements. Some respondents felt that this requirement should recognise the role of professional regulators.

C.67 Some respondents felt that this requirement should be strengthened and include Criminal Records Bureau (CRB) checks in relation to work with children and vulnerable adults to be taken on all workers employed by a provider organisation (whether or not involved in the provision of the regulated activity).

C.68 Some respondents felt that this requirement should ensure that providers take a pro-active approach to checking to protect people from unsuitable workers.

Our response

C.69 The Regulation for this requirement will include a requirement to employ professionally registered staff where it is relevant to specific roles and to perform pre-employment checks on workers.

C.70 We can only require Criminal Records Bureau checks to the extent permitted by the Rehabilitation of Offenders Exceptions Order made under the Police Act 1997. Therefore, we have required that providers must carry out such checks where the certificate relates to a purpose relating to the relevant provisions of the Police Act 1997. This reflects the position in the CSA Regulations. In addition, monitoring checks under the Safeguarding Vulnerable Groups Act 2006 will also be required where the worker concerned is carrying out regulated activity under that Act in relation to either a vulnerable adult or a child. If that Act is not fully in force by the time these Regulations come into force, we will also have to provide for Protection of Vulnerable Adults and Protection of Children Agency checks where appropriate in the interim.

C.71 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 19.

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

What we heard

C.72 Respondents had polarised views about the means of applying this requirement. Some people called for authoritative national staffing ratios (including restrictions on the use of agency staff) to ensure safety. Others were adamant that this must be left flexible and local managers allowed to make staffing decisions in the light of local circumstances.

Our response

C.73 Providers are responsible for designing and resourcing their services so that they are safe and provide essential quality. The best way to do this will vary in light of the nature of the service and local circumstances. Therefore, we do not believe it is appropriate to have nationally prescribed staffing configurations. We suggest that this issue be explored further by the Commission as it develops its guidance about compliance with this registration requirement and determines how registered providers might demonstrate that they have taken into account key information and that their resulting staffing arrangements are delivering safe and effective care that meets people's needs.

C.74 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 20.

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

What we heard

C.75 Respondents thought this was a key topic for registration requirements. Some respondents felt that this requirement should include a requirement for providers to protect workers from violence. Some felt that there should be specific provisions relating to arrangements for volunteers and students. Others felt that the requirement should recognise and underpin obligations imposed on both individual professionals and employers by professional regulation and Codes of Practice.

Our response

C.76 This requirement covers the key issues related to safe and appropriate care. Health and safety at work legislation already covers issues of worker safety and employment legislation covers issues of employment. We suggest that the Care Quality Commission considers the relevance of these other enactments as it develops its guidance about compliance and methodologies for how it will work with other regulators.

C.77 The registration requirement recognises the individual's obligations under law and professional regulation and requires care providers' systems to support these obligations.

C.78 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 21.

Requirement 18: Working effectively with other services

What we heard

C.79 Respondents supported the inclusion of this topic in registration requirements. Some respondents suggested this requirement should include wider aspects of services working together, encompassing the widest possible range of other services. Some suggested that the Care Quality Commission should have a role in looking at how well teams work together across care pathways.

Our response

C.80 We recognise the importance of providers working together, cooperating to deliver integrated services that are organised around the needs of the people who use them. The way in which services work together are primarily influenced by strategic commissioning and will be covered by other parts of the overall system for managing quality across care pathways. Registration will hold individual providers to account for their own actions in ensuring service user safety through cooperation across services and in preparing for and responding to emergencies.

C.81 The Care Quality Commission has other functions in addition to its registration function. It will consider the effectiveness of care pathways when reviewing and reporting on the overall experience of people using health and adult social care services.

C.82 Taking account of all the comments we have received on this requirement, the draft Regulation for this requirement is in Annex D, at Regulation 22.

Offences

C.83 Registered service providers and ‘registered managers’ who contravene these provisions will be guilty of an offence, punishable on summary conviction by a fine not exceeding £50,000.

Annex D: Draft registration requirement Regulations

Draft Regulations laid before Parliament under section 162(3) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.

STATUTORY INSTRUMENTS

2009 No. XXXX

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

The Health and Social Care Act 2008 (Registration Requirements) Regulations 2009

Made - - - -	*2009*
Laid before Parliament	*2009*
Coming into force - -	*2010*

The Secretary of State makes the following Regulations, in exercise of the powers conferred by sections 13, 20(1) to (5), 35, and 161(3) and (4) of the Health and Social Care Act 2008(**a**).

In accordance with section 20(8) of the Act, the Secretary of State has consulted such persons as he considers appropriate.

A draft of these Regulations was laid before Parliament in accordance with section 162(3) of the Health and Social Care Act 2008 and approved by resolution of each House of Parliament.

PART 1

GENERAL

Citation, commencement and application

1.—(1) These Regulations may be cited as the Health and Social Care Act 2008 (Registration Requirements) Regulations 2009 and come into force on 1st April 2010.

(2) These Regulations apply in relation to regulated activity carried on in England.

(**a**) 2008 c 14. “Prescribed” and “regulations” are defined in section 97(1) of the Act.

Interpretation

2. In these Regulations—

"the Act" means the Health and Social Care Act 2008;

"employment" means—

(a) employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract; and

(b) consulting or practising privileges granted to registered medical practitioners,

and "employed" and "employee" should be construed accordingly;

"health care professional" means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(**a**) applies;

"practising privileges" in relation to a registered medical practitioner refers to the grant to a person of permission to practise in relation to the carrying on of a regulated activity;

"premises" means—

(a) any building or other structure; or

(b) a vehicle,

owned or used by the registered person for the purposes of carrying on the regulated activity;

"registered manager" means a person registered with the Commission under Part 1 of the Act as a manager in respect of a regulated activity, and "manage" should be construed accordingly;

"registered person" in respect of a regulated activity, means any person who is the service provider or registered manager;

"responsible individual" must be construed in accordance with regulation 3(2)(c)(i);

"service provider" means a person registered with the Commission under Part 1 of the Act as a service provider in respect of a regulated activity;

"service user" means a person who receives services provided in the carrying on of a regulated activity;

"statement of purpose" means the statement referred to in regulation 25 and Schedule 2;

"treatment" includes—

(a) a diagnostic or other investigative procedure;

(b) nursing, personal and palliative care; and

(c) the giving of vaccinations and immunisations;

"vulnerable adult" has the same meaning as in the Safeguarding Vulnerable Groups Act 2006(**b**).

(**a**) 1999 c.8. Section 60(2) was amended by the Health and Social Care Act 2008, section 111, 166, Schedule 8, paragraphs 1(1), (3)(a), (b) and (c) and Schedule 15, Part 2. In addition, see: S.I. 2002/253, article 54(3), Schedule 5, paragraph 16(a) and S.I. 2002/254, article 48(3), Schedule 4, paragraph 8(a).

(**b**) 2006 c.47. See section 59 of that Act for the meaning of "vulnerable adult".

PART 2

REQUIREMENTS RELATING TO PERSONS CARRYING ON OR MANAGING A REGULATED ACTIVITY

Fitness of service provider

3. [to be drafted after consultation has ended]

Registered manager condition

4.—(1) Subject to paragraph (2), for the purposes of section 13 of the Act, the registration of a service provider in respect of a regulated activity must be subject to a registered manager condition where the service provider—

(a) is an organisation or a partnership;

(b) does not meet the requirements set out in regulation 5; or

(c) is not, or does not intend to be, in full-time day to day charge of carrying on the regulated activity.

(2) Paragraph (1) does not apply where the service provider is an English NHS provider carrying on an activity which involves, or is connected with, the provision of health care.

Fitness of registered manager

5. (1) A person (M) shall not manage the carrying on of a regulated activity as a registered manager unless M is fit to do so.

(2) M is not fit to be a registered manager in respect of a regulated activity unless M is—

(a) of integrity and good character;

(b) physically and mentally fit and has the necessary qualifications, skills and experience to manage the carrying on of a regulated activity; and

(c) able to supply, or arrange for the availability of, full and satisfactory information relating to M in respect of each of the matters specified in Schedule 1.

Registered person: general requirements and training

6. [to be drafted after consultation has ended]

PART 3

QUALITY AND SAFETY OF SERVICE PROVISION IN RELATION TO REGULATED ACTIVITY

Care and welfare of service users

7. The registered person must take proper steps to ensure that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe, by means of—

(a) the carrying out of an assessment of the needs of the service user by a suitably qualified or suitably trained person; and

(b) the planning and delivery of care and, where appropriate, treatment in such a way as to—

(i) meet the service user's individual needs,

(ii) ensure the welfare and safety of the service user, and

(iii) where appropriate, reflect published research evidence and guidance issued by the appropriate professional and expert bodies as to good practice in relation to such care and treatment.

Assessing and monitoring the quality of service provision

8.—(1) The registered person must protect service users against the risks of inappropriate or unsafe care and treatment by means of the effective operation of systems designed to enable the registered person to—

(a) regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirements set out in this Part of these Regulations; and

(b) identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.

(2) For the purposes of paragraph (1), the registered person must—

(a) where appropriate, obtain relevant professional advice;

(b) have regard to—

(i) the complaints and views expressed by service users, and those acting on their behalf, pursuant to regulation 17,

(ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the regulated activity,

(iii) the information contained in the records referred to in regulation 18,

(iv) relevant professional, and expert advice (including any advice obtained pursuant to sub-paragraph (a)),

(v) reports prepared by the Commission from time to time relating to the registered person's compliance with the provisions of these Regulations, and

(vi) periodic reviews and special reviews and investigations carried out by the Commission in relation to the provision of health or social care, where such reviews or investigations are relevant to the regulated activity carried on by the service provider;

(c) embody, in the treatment or care provided, knowledge relating to protecting service users from unsafe or inappropriate care obtained as a result of—

(i) the analysis of incidents that resulted in, or had the potential to result in, harm to a service user, and

(ii) the conclusions of local and national service reviews and clinical audits by relevant expert bodies;

(d) establish mechanisms for—

(i) the appropriate delegation of the power to make decisions in relation to care or treatment for service users, and

(ii) ensuring proper accountability for such decisions; and

(e) regularly seek the views of service users, persons acting on their behalf and persons who are employed for the purposes of the carrying on of the regulated activity, to enable the registered person to come to an informed opinion of the standard of care and treatment provided to service users.

Safeguarding vulnerable service users

9.—(1) The registered person must make suitable arrangements to ensure that service users are protected against the risk of abuse by means of—

(a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and

(b) responding appropriately to any allegation of abuse made by a service user or a person acting on behalf of a service user.

(2) This paragraph applies where any form of—

(a) restraint; or

(b) management of disturbed behaviour,

is used in the carrying on of a regulated activity.

(3) Where paragraph (2) applies, the registered person must ensure that the restraint, or management of disturbed behaviour employed, is no more than is reasonable, proportionate and justifiable for—

(a) minimising risks to the health and safety of the service user; and

(b) where applicable, protecting any other person who may be at risk from the service user's behaviour.

(4) The registered person must have regard to any guidance issued by the Secretary of State or appropriate expert body, in relation to the protection of children and vulnerable adults.

(5) For the purposes of paragraph (1), "abuse", in relation to a service user, means—

(a) sexual abuse;

(b) physical or psychological ill-treatment;

(c) theft, misuse or misappropriation of money or property; or

(d) neglect and acts of omission which cause harm or place at risk of harm.

Cleanliness and infection control

10.—(1) The registered person must, so far as reasonably practicable, ensure that—

(a) service users;

(b) persons employed for the purpose of the carrying on of the regulated activity; and

(c) others who may be at risk of exposure to a health care associated infection arising from the carrying on of the regulated activity,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

(2) The means referred to in paragraph (1) are—

(a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;

(b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and

(c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—

(i) premises occupied for the purpose of carrying on of the regulated activity,

(ii) equipment and reusable medical devices used in such premises, and

(iii) materials to be used in the treatment of service users, where such materials are at risk of being contaminated with a health care associated infection.

Management of medicines and medical devices

11.—(1) The registered person must protect service users against the risks associated with the unsafe use and management of medicines and medical devices, by means of—

(a) the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, safe administration and disposal of medicines and medical devices used for the purposes of the regulated activity; and

(b) having regard to any guidance issued by the Secretary of State or appropriate expert body in relation to the safe handling and use of medicines and medical devices.

(2) For the purposes of this regulation, “medical device” has the same meaning as in the Medical Devices Regulations 2002(**a**).

Meeting nutritional needs

12.—(1) Where food and hydration are provided to service users as a component of the carrying on of the regulated activity, the registered person must ensure that service users are protected from the risks of inadequate nutrition and dehydration, by means of the provision of—

(a) a choice of suitable, wholesome and nutritious food and hydration, in sufficient quantities to meet their needs;

(b) food and hydration that meets any requirements arising from a service user’s religious or moral persuasion or cultural background; and

(c) support, where necessary, for the purposes of enabling them to eat and drink sufficient amounts for their needs.

(2) For the purposes of this regulation, “food and hydration” includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.

Safety and suitability of premises

13.—(1) The registered person must ensure that service users, employees and others having access to premises where the regulated activity is carried on are protected against the risks associated with unsafe or unsuitable premises, by means of—

(a) suitable design and layout; and

(b) adequate maintenance of—

(i) the premises, and

(ii) any surrounding grounds, which are owned or occupied by the registered person in connection with the carrying on of the regulated activity.

(2) For the purposes of paragraph (1), the registered person must have regard to any relevant design, technical and operational standards relating to the premises.

(3) In paragraph (1), the term “premises where the regulated activity is carried on” does not include a service user’s own home.

Safety, availability and suitability of equipment

14.—(1) The registered person must make suitable arrangements to protect service users, employees and others who may be at risk from the use of unsafe equipment by ensuring that equipment provided for the purposes of the carrying on of the regulated activity is—

(a) properly maintained and suitable for its purpose; and

(b) utilised correctly in accordance with the technical specifications and guidance issued by the manufacturer, the Secretary of State or relevant expert bodies.

(2) The registered person must ensure that equipment is available in sufficient quantities in order to ensure the safety of service users and meet their assessed needs.

(3) Where equipment is provided to support service users in their day to day living, the registered person must ensure that, as far as practicable, such equipment promotes the independence and comfort of service users.

(**a**) S.I. 2002/618.

Respecting and involving service users

15.—(1) The registered person must, so far as reasonably practicable, make suitable arrangements to ensure—

(a) the dignity, privacy and independence of service users; and

(b) that service users are enabled to make, or participate in making, decisions relating to their care or treatment.

(2) For the purposes of paragraph (1), the registered person must—

(a) treat service users at all times with consideration and respect;

(b) provide service users with appropriate information and support in relation to their care or treatment;

(c) encourage service users, or those acting on their behalf, to—

(i) understand the care or treatment choices available to them, and discuss with an appropriate health care professional, or other appropriate person, the balance of risks and benefits involved in any particular course of care or treatment, and

(ii) express their views as to what is important to them in relation to the care or treatment;

(d) where necessary, assist service users, or those acting on their behalf, to express the views referred to in paragraph (c)(ii) and, so far as appropriate and reasonably practicable, accommodate those views;

(e) where appropriate, provide opportunities for service users to manage their own care or treatment;

(f) where appropriate, involve service users in decisions relating to the way in which the regulated activity is carried on;

(g) provide appropriate opportunities, encouragement and support to service users in relation to promoting their independence, community involvement and the way in which they wish to live their lives; and

(h) take care to ensure that care and treatment is provided to service users with due regard to their age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

Consent to care and treatment

16. The registered person must have—

(a) suitable arrangements in place for obtaining, and acting in accordance with, the consent of service users in relation to the care and treatment provided for them; and

(b) regard to any guidance issued by the Secretary of State or other expert body in relation to the matters referred to in paragraph (a).

Complaints

17.—(1) For the purposes of preventing or reducing the incidence of unsafe or inappropriate care or treatment, the registered person must have an effective system in place (referred to in this regulation as "the complaints system") for identifying, receiving, handling and responding appropriately to complaints and comments made by service users, or persons acting on their behalf, in relation to the carrying on of the regulated activity.

(2) In particular, the registered person must—

(a) bring the complaints system to the attention of service users and persons acting on their behalf in a suitable manner and format;

(b) provide service users and those acting on their behalf with support to bring a complaint or make a comment, where such assistance is necessary; and

(c) ensure that any complaint made is fully investigated and, where possible, resolved to the satisfaction of the service user, or the person acting on the service user's behalf.

Records

18.—(1) The registered person must ensure that service users are protected against the risks of unsafe or inappropriate care and treatment arising from a lack of proper information about them by means of the maintenance of—

(a) an accurate record in respect of each service user which shall include appropriate information and documents in relation to the care and treatment provided to each service user; and

(b) such other records as are appropriate in relation to the carrying on of the regulated activity.

(2) The registered person must ensure that the records referred to in paragraph (1) (which may be in paper or electronic form) are—

(a) kept securely and can be located promptly when required;

(b) retained for an appropriate period of time; and

(c) subject to sub-paragraph (b), securely destroyed when it is appropriate to do so.

(3) In deciding what records are appropriate for the purposes of paragraph (1)(b), and for how long such records should be retained for the purposes of paragraph (2)(b), the registered person must have regard to guidance issued by the Commission.

Fitness of workers

19. The registered person must—

(a) have effective recruitment procedures in place in order to ensure that no person is employed for the purposes of carrying on a regulated activity unless that person—

(i) is of integrity and good character,

(ii) has the qualifications, skills and experience which are necessary for the work to be performed, and

(iii) is physically and mentally fit for that work;

(b) ensure that full and satisfactory information is available in respect of a person employed for the purposes of carrying on a regulated activity in relation to each of the matters specified in Schedule 1, and such other matters as are appropriate, having regard to guidance issued by the Commission;

(c) ensure that a person employed for the purposes of carrying on a regulated activity is registered with the relevant professional body where such registration is a requirement for the work that the person is to perform;

(d) take appropriate steps in relation to a person who is no longer fit to work for the purposes of carrying on a regulated activity including—

(i) where the person is a health care professional, informing the body responsible for regulation of the health care profession in question, or

(ii) where the person is a social care worker registered with the General Social Care Council, informing the Council(**a**).

Staffing

20. In order to safeguard the health, safety and welfare of service users, the registered person must take appropriate steps to ensure that, at all times, there are sufficient numbers of suitably

(**a**) The General Social Care Council is established under Part 5 of the Care Standards Act 2000 (c.14). *See* section 55 of that Act for the definition of "social care worker", and S.I. 2004/561.

qualified, skilled and experienced persons employed for the purposes of carrying on the regulated activity.

Supporting staff

21. The registered person must have suitable arrangements in place in order to ensure that persons employed for the purposes of carrying on the regulated activity are appropriately supported in relation to their responsibilities, to enable them to deliver care and treatment to service users safely and to an appropriate standard, including by—

(a) receiving appropriate training, professional development, supervision and appraisal; and

(b) being enabled to—

(i) from time to time, obtain further qualifications appropriate to the work they perform, and

(ii) where relevant, meet the requirements of their professional regulatory body.

Cooperating with other providers

22.—(1) The registered person must make suitable arrangements to protect the health, welfare and safety of service users in circumstances where responsibility for the care and treatment of service users is shared with, or transferred to, others, by means of—

(a) so far as reasonably practicable, working in cooperation with others to ensure that appropriate care planning takes place;

(b) subject to paragraph (2), the sharing of appropriate information in relation to—

(i) the admission, discharge and transfer of service users, and

(ii) the co-ordination of emergency procedures; and

(c) supporting service users, or persons acting on their behalf, to obtain appropriate health and social care support, having regard to guidance issued by the Commission.

(2) Nothing in this regulation shall require or permit any disclosure or use of information which is prohibited by or under any enactment, or by court order.

PART 4

PROVISIONS RELATING TO TERMINATION OF PREGNANCIES

Requirements relating to termination of pregnancies

23. [to be drafted after consultation has ended]

PART 5

FINANCIAL POSITION

Financial position

24. [to be drafted after consultation has ended]

PART 6

REQUIREMENTS AS TO THE PROVISION OF INFORMATION

INFORMATION TO BE GIVEN TO THE COMMISSION

Statement of purpose

25. [to be drafted after consultation has ended]

Notice of absence

26. [to be drafted after consultation has ended].

Notice of changes

27. [to be drafted after consultation has ended]

Notification of incidents

28. [to be drafted after consultation has ended]

Miscellaneous

29.[to be drafted after consultation has ended]

INFORMATION TO BE GIVEN TO SERVICE USERS AND PROSPECTIVE SERVICE USERS

Fees etc.

30. [to be drafted after consultation has ended]

PART 7

COMPLIANCE AND OFFENCES

Compliance with regulations

31. Where there is more than one registered person in respect of a regulated activity, or in respect of that activity as carried on at or from particular premises, anything which is required under these Regulations to be done by the registered person shall, if done by one of the registered persons, not be required to be done by any of the other registered persons.

Offences

32.—(1) A registered person who contravenes, or fails to comply with, the provisions of regulations 7 to 22 of these Regulations is guilty of an offence.

(2) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine not exceeding £50,000.

Signatory text

Name
Parliamentary Under Secretary of State
Date Department of Health

SCHEDULE 1

Regulations 3(3)(c), 5(2)(c) and 19(b)

INFORMATION REQUIRED IN RESPECT OF PERSONS SEEKING TO CARRY ON, MANAGE OR WORK FOR THE PURPOSES OF CARRYING ON, A REGULATED ACTIVITY

1. Proof of identity including a recent photograph.

2. Either—

(a) where the certificate is required for a purpose relating to section 113B of the Police Act 1997(**a**), an enhanced criminal record certificate issued under section 113B of that Act; or

(b) in any other case, a criminal record certificate issued under section 113A of that Act,

together with, where applicable, confirmation that the person is subject to monitoring in accordance with section 24 of the Safeguarding Vulnerable Groups Act 2006(**b**).

3. Satisfactory evidence of conduct in previous employment where such employment was concerned with the provision of services relating to—

(a) health or social care; or

(b) children or vulnerable adults.

4. Where a person has previously worked in a position whose duties involved work with vulnerable adults or children, verification, so far as reasonably practicable, of the reason why the position ended.

5. Documentary evidence of any relevant qualification.

6. A full employment history, together with a satisfactory written explanation of any gaps in employment.

7. Information about any physical or mental health conditions which are relevant to the person's ability to carry on, manage or work for the purposes of, the regulated activity.

(**a**) 1997 c. 50. Sections 113A and B were inserted by the Serious Organised Crime and Police Act 2005 (c. 15), section 163(2), and amended by the Safeguarding Vulnerable Groups Act 2006 (c.47), Schedule 9, Part 2, paragraphs 14(1), (2) and (3).
(**b**) 2006 c.47.

SCHEDULE 2

Regulation 25

INFORMATION TO BE INCLUDED IN THE STATEMENT OF PURPOSE

[to be drafted after consultation has ended]

EXPLANATORY NOTE

(This note is not part of the Regulations)

[to be drafted after consultation has ended]

Annex E: Draft Regulations and supporting policy content: summary of consultation questions

Chapters 3, 4 and 5 and Annexes A and C set out the decisions we have made as a result of the previous consultation on scope and registration requirements. We now want views on whether the draft Regulations attached in Annexes B and D reflect the policy we have set out.

Chapter 3 – Who will have to register?

Q3.1: Do the draft Regulations set out at Annex B accurately reflect the policy set out in Chapter 3 and Annex A?

Q3.2: If not, what changes are needed to the draft Regulations to ensure they reflect the policy set out in Chapter 3 and Annex A?

Chapter 5 – What requirements will registered bodies have to meet?

Q5.1: Do the draft Regulations set out at Annex D accurately reflect the policy set out in Chapter 5 and Annex C?

Q5.2: If not, what changes are needed to the draft Regulations to ensure they reflect the policy set out in Chapter 5 and Annex C?

Chapter 6 – Other regulations to support the registration framework?

Q6.1: Do the proposals set out in Chapter 6 create a practical framework for registration?

Q6.2: If not, what do we need to change?

Please send responses to:

Registration Consultation
Room 3E58
Quarry House
Quarry Hill
Leeds LS2 7UE

or, preferably, by e-mail to: registration.consultation@dh.gsi.gov.uk.

Annex F: Glossary

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.
Better regulation	The Better Regulation Executive (BRE) is part of the Department for Business, Enterprise and Regulatory Reform and leads the regulatory reform agenda across government. Its aims are: • to work with Departments to improve the design of new Regulations and how they are communicated; • to work with Departments and regulators to simplify and modernise existing Regulations; and • to work with regulators to change attitudes and approaches to regulation to become more risk-based. A key part of the BRE's work has been to determine five key principles of regulation, which are now a cornerstone of better regulation strategy and implementation. These state that any regulation should be: • transparent • accountable • proportionate • consistent • targeted – only at cases where action is needed
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.
Care Standards Act 2000 (CSA)	Legislation reforming the regulatory system for care services, private and voluntary healthcare in England and Wales.

European Services Directive	The Directive aims to open up the EU's internal market to cross-border trade in services by making it easier for service providers to set up business or offer their services in other EU countries.
Fair playing field	An approach to ensure that different providers (independent sector, public providers of health or adult social care) are treated in a consistent, transparent and non-discriminatory way.
First-Tier Tribunal (Care Standards)	Part of the Tribunals Service (an executive agency of the Ministry of Justice) who currently consider appeals against the Commission for Social Care Inspection and the Healthcare Commission.
Foundation trusts	A type of NHS trust in England that has been created to devolve decision-making from central government control to local organisations and communities so they are more responsive to the needs and wishes of their local people. NHS foundation trusts provide and develop healthcare according to core NHS principles – free care, based on need and not ability to pay.
General Social Care Council (GSCC)	A non-departmental public body established by the CSA. The GSCC is responsible for setting standards of conduct and practice for social care workers and their employers, for regulating the workforce, and for regulating social work education and training.
Guidance about compliance with the requirements of Regulations	Guidance setting out how the Care Quality Commission will assess a provider's adherence to the registration requirements. The Commission will usually develop and consult on the guidance itself (see Section 23 of the Health and Social Care Act 2008: 'Guidance as to compliance with requirements'). Exceptionally, in the case of registration requirements relating to the prevention or control of healthcare associated infections, the guidance about compliance will be set by the Secretary of State in a code of practice under Section 21 of the 2008 Act.
Health and Social Care Act 2008 ('The 2008 Act')	The legislation that establishes the Care Quality Commission and lays out the framework for its powers and responsibilities.
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, or made more susceptible, in circumstances where health or social care is being (or has been) provided. This is where the individual's (or another individual's) risk of exposure to the infection, is directly or indirectly attributable to the provision of that care.

High quality care for all	See 'NHS Next Stage Review'
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 determining whether 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 the authority deems to be relevant to the inspection. It may involve a visit to the organisation in question. The Care Quality Commission will establish its inspection policy and consult on this in due course.
Mental Capacity Act 2005	The Mental Capacity Act allows, among other things, the deprivation of liberty of people who lack the capacity (defined in the 2008 Act) to consent to arrangements proposed for their care in care homes and hospitals.
Mental Health Act 1983	The Mental Health Act 1983 makes provision, among other things, for the compulsory detention and treatment in hospital of those with a mental disorder that means they are at risk of harm to themselves or others. The 2008 Act includes safeguards to make sure people's rights are maintained in such circumstances.
Monitor	The independent regulator responsible for authorising, monitoring and regulating NHS foundation trusts. Monitor's functions and powers are detailed in the NHS Act 2006.
National Institute for Health and Clinical Excellence (NICE)	An independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.
New Ways of Working	An initiative aimed at developing new, enhanced and changed roles for mental health staff, and redesigning systems and processes to support staff in delivering effective, person-centred care in a way that is personally, financially and organisationally sustainable.
NHS Next Stage Review	A review led by Lord Darzi. This was primarily a locally led process, with clinical visions published by each region of the NHS in May 2008 and a national enabling report, *High quality care for all*, published in July 2008. Building on engagement with thousands of front-line clinicians, *High quality care for all* set out that quality, defined as safety, effectiveness and patient experience, should be at the heart of everything the NHS does.

NHS provider	Means: a PCT; an NHS trust where all or most of its hospitals, establishments and facilities are situated in England; or an NHS foundation trust.
Nurse-led services	Services that are organised and run by a nurse or nurse practitioner, including those traditionally provided by another profession, for example GPs.
Ofsted	The Office for Standards in Education, Children's Services and Skills is a non-ministerial government department. Amongst other functions, Ofsted are responsible for regulating children's social care.
Performance assessment	A process that uses a range of measures and indicators to judge how well organisations are performing.
Primary care	Health services primarily based in the local community, including GPs, pharmacists, dentists and opticians. These are usually the first point of contact for people accessing health services.
Proportionate approach to regulation	The method for applying regulation in proportion to the risk posed by the activity being carried out. This directs regulatory activity to where it is most needed.
Providers	See 'Registered provider'
Quality and Outcomes Framework (QOF)	A voluntary incentive scheme that rewards GP practices for implementing systematic improvements in quality of care for patients.
Registered manager	An individual who is registered with the Care Quality Commission to provide a regulated activity at particular premises where the registered provider is not in day-to-day control (see Section 13 of the Health and Social Care Act 2008).
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 (see Section 10 of the Health and Social Care Act 2008).
Registration	Providers of regulated activities (services) must be registered with the Care Quality Commission in order to operate (see Section 13 of the Health and Social Care Act 2008). 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. We have set out draft Regulations for the registration requirements (in particular see Section 20 of the Health and Social Care Act 2008) in this consultation.
Regulated activities	Broad service areas or types of care that will be set out in Regulations under Section 8 of the Health and Social Care Act 2008. These are the health and adult social care services, which an organisation needs to register with the Care Quality Commission in order to provide care or treatment in England. These activities are set out in the proposed secondary legislation in this consultation.
Regulation	The control of a particular market or industry through a system of rule making and adjudication. This is often carried out by an independent organisation (regulator) within a framework set by the Government, interpreted into clear rules by the regulator. Its role is to assure the public that services providers 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.
Risk/risk based regulation	An approach to regulation that takes into account the likelihood of adverse outcomes to patients or people who use services. Under this approach, generally, the smaller the risk is assessed to be, the lighter the regulation. The larger the risk, the more comprehensive the regulation.
Scope of registration	The Health and Social Care Act 2008 contains a definition of the wider scope of health and adult social care, so that all providers can be covered. The 'regulated activities' that need to be covered by registration in the proposed secondary legislation under Section 8 of the Health and Social Care Act 2008 are set out in this consultation.
Secondary legislation	The Parliamentary procedure that is used to flesh out an Act in 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.
Shared lives	Shared lives, formerly the adult placement scheme, is a service provided by individuals and families in local communities, supporting adults who require care or support.

Standards for Better Health	Requirements that should be met by all organisations in the NHS. The Government published 24 standards for the NHS. These cover all aspects of health and healthcare, including safety, clinical effectiveness, cost effectiveness and public health. These will be replaced by the Care Quality Commission's guidance about compliance in April 2010.
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.
Third sector	The third sector covers 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.