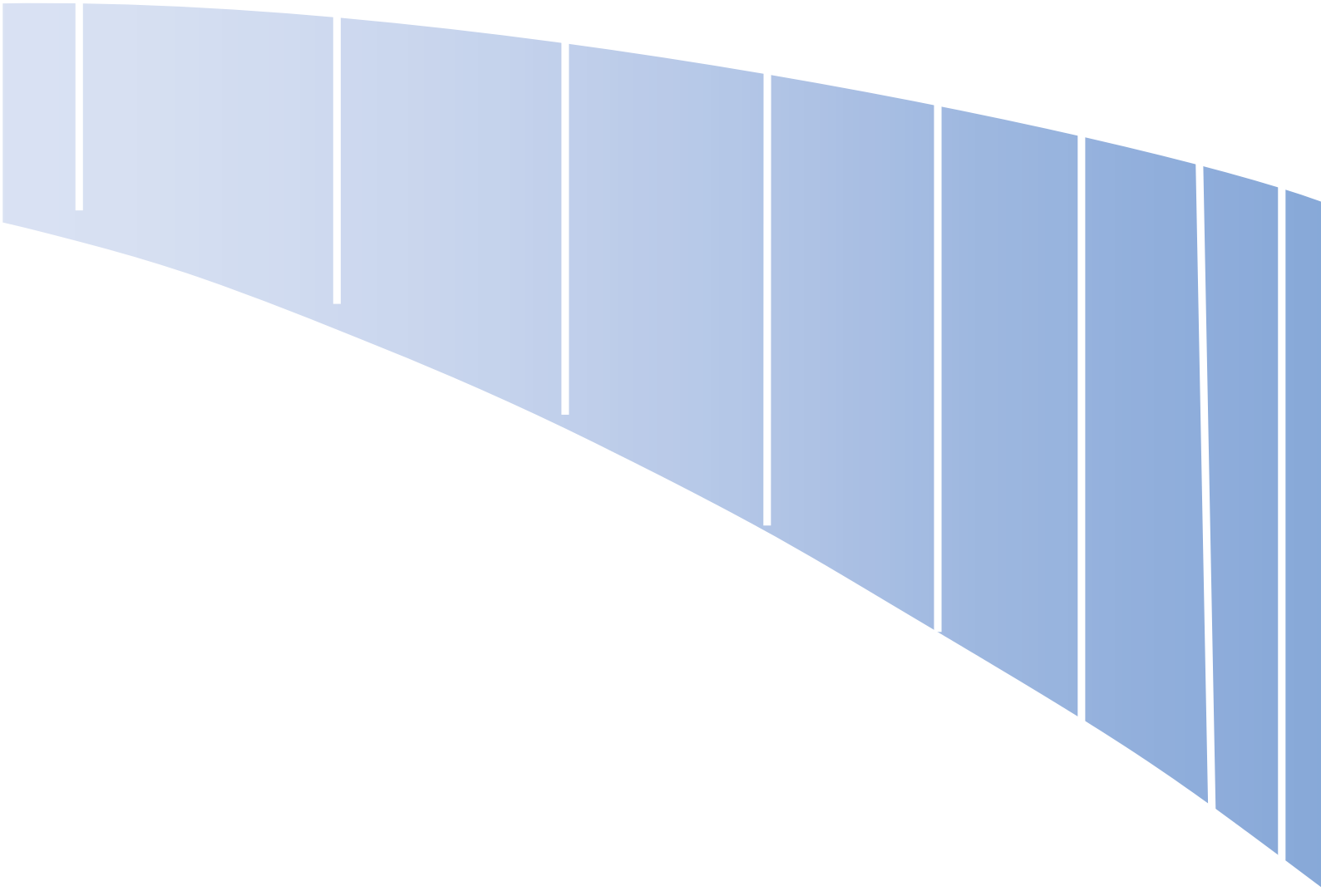
Response to the consultation on draft Regulations for the framework for the registration of health and adult social care providers



The future regulation of health and adult social care in England

Health and social care working together in partnership

DH INFORMATION READER BOX

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Contents

Executive summary

1. This document provides the response to the consultation on draft Regulations launched in the *Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations*.[1]

2. The new registration system is a key component of the Government's new regulatory framework for health and adult social care. It will be run by the Care Quality Commission, the new integrated regulator of health and adult social care. For the first time, it will create a common framework for providers from all sectors (public, private, third sector) and across healthcare and adult social care. For people who use services it will provide greater assurance of the safety and quality of services, and offer them better information on which to make their choice of service provider.

3. A set of draft Regulations has been laid before Parliament under powers in the Health and Social Care Act 2008 and will be subject to debate by both Houses of Parliament. These draft Regulations:

   - list the 'regulated activities' that will define the scope of registration by the Care Quality Commission;
   - set out the safety and quality requirements that providers of these regulated activities must meet to become and remain registered; and
   - enable the Care Quality Commission to use enforcement powers established in the Health and Social Care Act 2008.

4. We intend to lay further sets of draft Regulations later this year that will be subject to the negative parliamentary procedure. These Regulations will also be made under powers in the Health and Social Care Act 2008, and will cover other aspects of the registration system, such as registration of managers and the provision of information.

5. Subject to parliamentary approval, these Regulations will come into force from 1 April 2010, enabling the Care Quality Commission to start registering providers of health and adult social care under the new system from that date. The draft Regulations set out the start dates for different categories of provider.

1 *Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations*, Department of Health, March 2009 (www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991).

6. This consultation response covers all the Regulations we intend to make for the system that will run from 2010/11. We have previously consulted extensively on the overall framework for the new registration system and adapted it to respond to feedback. In this particular consultation we were consulting specifically on the wording of the draft regulated activities and registration requirements Regulations and the supporting policy framework. The consultation ran from 30 March to 29 May 2009. We received 72 responses from a wide range of organisations and individuals across the health and adult social care sectors. These are summarised in Chapter 2.

7. The document considers each of the draft Regulations in turn, clarifies the policy position, and explains the drafting changes that resulted from the consultation.

8. Chapter 3 focuses on the draft regulated activity Regulations and describes what we heard and our response. We asked whether the draft Regulations accurately reflected the policy and if not, what changes could be made. As a result, we have made a number of changes to the wording of the draft Regulations. The start dates for different categories of provider are also confirmed:

    - NHS providers must be registered by 1 April 2010;
    - all other health and social care providers of regulated activities (including those currently registered under the Care Standards Act 2000) must be registered under the new system by 1 October 2010;
    - providers of primary dental care services and private ambulance services must be registered by 1 April 2011; and
    - providers of primary medical care services must be registered by 1 April 2012.

9. To obtain registration, and continue to hold registration, providers must demonstrate compliance with safety and quality requirements, set in Regulations. Non-compliance will be an offence, subject to a maximum court fine of £50,000. Having previously consulted on the overall policy for these registration requirements, we consulted on whether the draft registration requirement Regulations accurately reflected the policy and if not, what changes could be made. Chapter 4 describes what we heard, and our response. Again, we have made changes to the drafting of the Regulations in response to comments received, but retained the same safety and quality topics agreed through the previous consultation.

10. The policy behind other registration and enforcement Regulations was also set out in the consultation document. We asked whether our proposals would create a practical framework for registration and if not, what changes could be made. Chapter 5 describes what we heard and our response. The responses were broadly supportive, but some amendments have been made, for example to the penalty notice rates for certain offences.

11. The constructive responses to this consultation and the earlier consultation on the overall registration framework have influenced and improved both the policy and the legal drafting of the Regulations introduced to Parliament.

1. Introduction

1.1 The Care Quality Commission is the new regulator of health and adult social care in England. On 1 April 2009, it replaced the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission.

1.2 From April 2010, a new registration framework will be introduced under the Health and Social Care Act 2008 ('the 2008 Act'). Under this system, health and adult social care providers (including the NHS) will be required to register with the Care Quality Commission under a coherent framework that aligns the regulation of health and adult social care, across public and independent sectors. It will replace the current registration system for adult social care and private and voluntary healthcare under the Care Standards Act 2000 (CSA) and extend the registration beyond the single requirement relating to healthcare associated infections (HCAI), which was introduced for NHS providers on 1 April 2009.

1.3 In our consultation during spring 2008,[2] we proposed to change the scope of registration by defining services in terms of 'regulated activities' – what was being provided (for example personal care or surgical procedures), rather than where, or by who, it was being provided (care homes, hospitals or agencies). We also proposed to bring NHS providers into the registration system for the first time. We received 230 responses to that consultation.

1.4 To become and remain registered, providers of regulated activities must comply with registration requirements and these were also subject to consultation. We have developed a single coherent set of requirements focused on essential levels of safety and quality of care and treatment for all providers. These outcome-based requirements have been built around the main risks in providing health and adult social care services. These include topics from the current Regulations and standards (including the Standards for Better Health that currently apply to the NHS, and National Minimum Standards and Regulations under the CSA).

1.5 If providers breach these registration requirements, the Care Quality Commission can take proportionate enforcement action.

2 *A consultation on the framework for the registration of health and adult social care providers*, Department of Health, March 2008 (www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625).

1.6 We launched a further consultation in March 2009.[3] This document explained our policy on the detailed content of the registration process and enforcement Regulations needed to support the registration system set out in the 2008 Act. It included the draft regulated activities and registration requirements Regulations and asked for comments. The document also contained the response to our spring 2008 consultation on the new registration framework.[4] For each of the three parts of the framework (scope, registration requirements and supporting policy) there were two questions. There were, therefore, six questions in all.

1.7 The consultation ran from 30 March to 29 May 2009 and we received 72 responses. This document is the formal response to that consultation.

1.8 The Care Quality Commission will issue guidance about compliance, which will explain in more detail how providers can comply with the new registration requirements Regulations. The only exception is compliance with the 'Cleanliness and infection control' requirement, for which the Secretary of State sets the code of practice on the prevention and control of infections. The guidance about compliance will not itself be enforceable, but providers must have regard to it in complying with the registration requirements Regulations, and it must be taken into account when any decision about registration is taken.

1.9 The Care Quality Commission has carried out a twelve-week formal consultation, which closed on 24 August 2009.[5] The Commission is currently analysing the responses and refining the guidance. The Commission will also publish guidance about who needs to register.

1.10 The Department of Health is currently consulting on the code of practice for compliance with the 'Cleanliness and infection control' registration requirement in the draft Regulations.[6] The consultation closes on Friday 6 November 2009.

3 *Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations*, Department of Health, March 2009 (www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991).
4 *A consultation on the framework for the registration of health and adult social care providers*, Department of Health, March 2008 (www.dh.gov.uk/en/Consultations/Closedconsultations/DH_083625)
5 See: www.cqc.org.uk/getinvolved/consultations/pastconsultations.cfm#4
6 *Consultation on the Health and Social Care Act 2008 Code of Practice for health and social care on the prevention and control of infections and related guidance*, Department of Health, August 2009 (www.dh.gov.uk/en/Consultations/Liveconsultations/DH_104114).

1.11 During and since the March consultation, we have held discussions with a number of key stakeholders, contacted consultation respondents in order to clarify their position or draw on their expertise and continued discussions with the Care Quality Commission.

1.12 In this document, we will explain what we have changed in the light of consultation responses and our continuing discussions with stakeholders. We also describe what we have not changed and why.

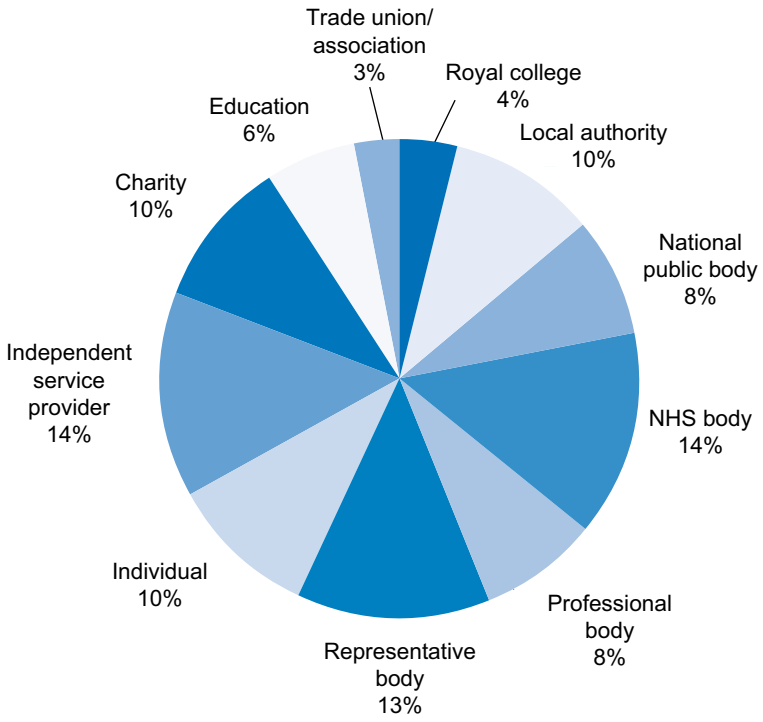
1.13 We have laid the updated set of draft Regulations before Parliament for approval. These set out:

- the regulated activities, defining the scope of registration;
- the registration requirements, with which providers of those activities must comply; and
- penalty notice amounts in lieu of prosecution for various offences under the 2008 Act.

1.14 We intend to lay a second set of draft Regulations before Parliament later in autumn, covering the registered manager condition, financial position, provision of information and further enforcement provisions.

2. Overview of responses

2.1 We received 72 responses to the consultation.



2.2 A number of respondents took the time to point out that previous comments they had made had been incorporated during the consultation process, suggesting that the process had been effective.

2.3 One commented, “what is apparent is that both sets of Regulations put the ‘patient experience’ at the heart of regulation, focusing on the quality of service and care for patients in a variety of health and social care settings.” Two more welcomed the interface between professional and system regulation.

2.4 Chapters 3, 4 and 5 set out what we heard in more detail and our response. Chapters 3 and 4 do this on a Regulation-by-Regulation basis. Chapter 5 is set out policy-by-policy.

2.5 The draft *Health and Social Care Act 2008 (Regulated Activities) Regulations 2009* that have been laid before Parliament are available on the Office for Public Sector Information website.[7]

7 See: www.opsi.gov.uk/si/dsis2009

Reaction to impact assessment

2.6 A number of respondents commented on the impact assessment. One welcomed the acknowledgement in the impact assessment of the importance of considering the impact on small providers. Another stressed the need for the costs of regulation to be proportionate. The revised impact assessment and equalities impact assessment have been published separately alongside the Regulations.

2.7 In addition to the main impact assessment, we have published a second impact assessment, focusing on the effect of bringing primary care into registration.

3. Who will have to register?

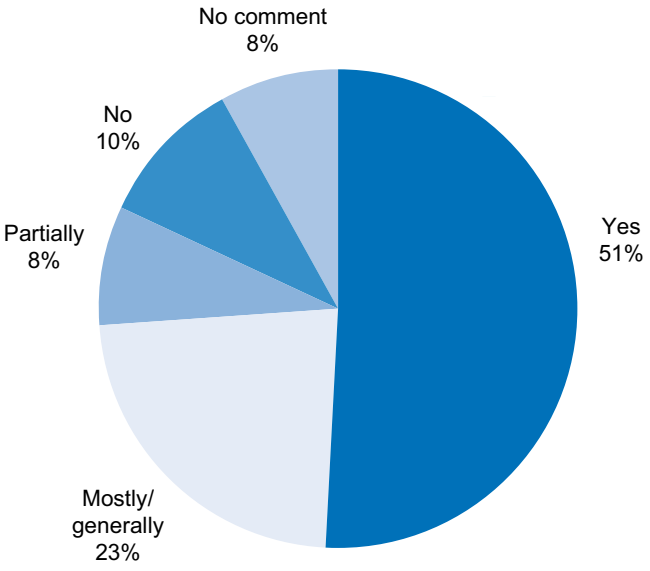
What we asked

3.1 ***Q3.1 Do the draft regulated activity Regulations set out at Annex B accurately reflect the policy set out in Chapter 3 and Annex A?***

3.2 ***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?***

What we heard in answer to Q3.1

3.3 Of the 72 respondents, 39 responded directly to question 3.1. Of those, 51% thought that the Regulations do reflect the policy, 23% stated that they mostly or generally do, 8% thought they partially do, 10% said they do not and 8% had no comment.



What we heard in answer to Q3.2

3.4 The two activities that received the most comment were 'Personal care' and 'Treatment of disease, disorder and injury'. This reflects the number of providers that will need to register with the Commission to carry out these activities.

3.5 The more detailed comments, and our response, are given below in the rest of this chapter.

Citation, commencement and application

3.6 This Regulation is now titled 'Citation and commencement'. As we are combining the two sets of draft Regulations we consulted on, this Regulation now covers both. The reference to England has been moved to the 'Prescribed activities' Regulation for technical drafting reasons.

Interpretation

3.7 As we are combining the two sets of draft Regulations we consulted on, this Regulation now covers both.

3.8 A number of respondents commented on the definition of 'personal care' in the Regulations – in particular, on the way we had described prompting and supervision and how this could have unintentionally brought a number of activities into regulation. We have now amended the wording around prompting to make it clear that the definition is intended to cover prompting *together with* supervision, where the person needs to be supervised in relation to performing the activity. This definition of personal care will now capture the care of people whose circumstances make them particularly vulnerable; situations where the person providing care supervises activities, without necessarily having physical contact with the person receiving care.

3.9 We have also excluded the care of skin, hair and nails provided by a chiropodist or podiatrist from the definition of personal care, to ensure they are not accidentally captured under this definition.

3.10 We have clarified our definition of employment, to make it clear that agencies providing carers to individuals will need to register, where they have continuing involvement in the care of that individual, whether or not under a formal employment contract.

3.11 We have also added definitions of 'adult placement schemes' and 'adult placement carers', to make it clear that individual carers providing adult placements will not need to register with the Commission. However, adult placement schemes, which arrange placements that involve personal care, will need to register.

3.12 We have made other additions to the definitions in the interpretation section. For example, we have clarified 'treatment', which includes continuing assessment, confirmed that references to a 'nurse' mean a registered nurse, and set out a definition of nursing care.

Prescribed activities

3.13 We have added drafting to ensure that regulated activities only apply to England. Where English NHS bodies provide regulated activities, these will be brought within the scope of registration under the new framework on 1 April 2010. However, any NHS providers currently registered under the CSA will not be required to bring these services into the new framework until 1 October 2010.

3.14 The draft Regulations setting out the regulated activities have been moved to Schedules 1 and 2.

Ancillary services

3.15 Our intention is that if a non-registerable service supports the provision of a regulated activity, the registered provider will be accountable for it. The provider of the ancillary service will not need to register separately in relation to the ancillary service.

3.16 The purpose of the draft Regulation is to allow the Commission to inspect and enforce against the provider of the regulated activity in relation to support activities, for example laundry, decontamination, or catering services in a hospital, and care or treatment that has a direct impact on users of the regulated activity, where they would not otherwise be included.

Personal care

3.17 We have made some changes to this draft Regulation. A number of respondents had concerns about the clarity of the policy on employment agencies and employment businesses. We have amended the draft Regulations to make the position clearer. We have not changed our policy that:

- agencies that only provide personal care staff to registered providers will not need to register with the Care Quality Commission; and
- agencies that only introduce personal care staff to an individual, who then directly engages them to meet their own personal care needs, and where the agency has no further involvement with the care of that person, will not need to register.

3.18 As set out in the consultation document, and in line with the principles of better regulation, agencies that do not carry out regulated activities under the 2008 Act will not be required to register. In cases where

registration with the Care Quality Commission is not required, the Safeguarding Vulnerable Groups Act 2006 still requires the agency to ensure staff are registered with the Vetting and Barring Scheme where appropriate, and that staff who are barred by the Independent Safeguarding Authority do not work with children or vulnerable adults. In addition, where the care is funded using public money, the local authority will have oversight.

3.19 However, we have re-drafted to make it clear that agencies that directly provide personal care (for example domiciliary care agencies), or those that have a continuing role in the personal care of an individual (for example, introduction agencies who might monitor carers' performance, respond to complaints, or develop care plans) will need to register with the Care Quality Commission.

3.20 Providers of regulated activities to people held within prisons and immigration detention centres will need to register with the Care Quality Commission. However, there are some innovative models of provision of personal care developing within prisons and other custodial establishments, where the care is provided by fellow inmates or other individuals working under a direct arrangement with the prison. We do not want registration with the Care Quality Commission to unnecessarily stifle these arrangements and we need more time to consider how registration would apply in practice. Therefore, we have temporarily added an exemption in relation to personal care provided directly by prisons (and similar establishments). This will ensure that organisations such as primary care trusts or independent providers providing personal care to prisoners and detainees will remain within regulation, but that personal care provided by those directed by the establishment will be exempt for the time being. We intend to keep this exemption under review.

3.21 It was suggested that further analysis was needed to identify whether there should be a hierarchy of activities and exemptions. Where there were possible overlaps in the draft Regulations published in March 2008, we have made a number of amendments. For example, we have made it clear that the 'Personal care' Regulation does not apply where either 'Accommodation together with nursing or personal care' or 'Accommodation and nursing or personal care in the further education sector' applies. This should make it clearer for which activity a provider will have to register.

3.22 System regulation of children's domiciliary care will remain the responsibility of the Care Quality Commission. Section 8 of the 2008 Act makes it clear that the Care Quality Commission will regulate any

prescribed health and social care activities carried out in England that are not regulated by Ofsted. Domiciliary care services for children that include providing regulated activities (ie personal care as defined) will, therefore, be required to register with the Care Quality Commission.

Shared Lives (adult placement schemes)

3.23 A number of responses drew attention to the need to ensure Shared Lives services were properly captured within the Regulations. Adult placement schemes that oversee provision of personal care will need to register with the Care Quality Commission. This is consistent with our position on agencies that provide care staff to individuals. Most adult placement schemes will have some placements that involve personal care, and therefore we believe that the majority of schemes will need to register.

3.24 Under these arrangements, the Commission will register the schemes (not the individual placements). Under the CSA, all adult placement schemes were required to register, irrespective of the activities carried on in the placements. As a result of the changes we are introducing, there may be a small number of Shared Lives schemes that will now be outside the scope of registration because they do not offer placements with personal care.

Accommodation for persons who require nursing or personal care

3.25 We have made some changes to this draft Regulation. We have added an exclusion to make it clear that individual adult placement carers, schools and further education colleges are not included under this Regulation.

3.26 Further to the consultation, we were advised that the 'Accommodation and nursing or personal care in the further education sector' Regulation would not bring independent specialist colleges into the scope of registration, where they are not within the definition of further education. They will, however, be captured under this Regulation.

Accommodation for persons who require treatment for substance misuse

3.27 We have made no changes to this Regulation, but the 'Treatment of disease, disorder or injury' Regulation now includes treatment for a mental disorder provided by a social worker, or by a team including

a social worker (see paragraph 3.31 below). This might bring some additional drug and alcohol misuse services into the scope of registration, where they take place in a non-residential setting. We are working to gain a better understanding of non-residential community drug and alcohol services, such as structured care programmes for people who misuse drugs or alcohol. If we identify that registration with the Care Quality Commission may be able to address those services' particular risks effectively, we will consider amending the Regulations.

Accommodation and nursing or personal care in the further education sector

3.28 We are continuing to have discussions with the Department for Children, Schools and Families, Ofsted and the Care Quality Commission about where responsibility for inspection of these services best lies. In the meantime, where the Commission currently regulates an activity in this sector under the CSA, it will continue to do so under the 2008 Act.

Treatment of disease, disorder or injury

3.29 We have undertaken significant further work on this Regulation. Some respondents suggested that we should change the wording that defines this Regulation's scope as treatment 'by, or under the supervision of, a healthcare professional', to include treatment carried out by a multidisciplinary team that includes a healthcare professional. They made the point that it should not matter who was leading the team. We have changed the wording accordingly.

3.30 A number of consultation responses raised similar concerns about defining the scope of this activity by who carries it out, ie by a list of healthcare professionals as defined by the Health Act 1999, with some specific exclusions. We have changed the wording of this Regulation substantially, so it is no longer at risk of unintended extension when changes are made to the professions listed in that Act. It now specifically lists and defines each of the professionals whose involvement will trigger the requirement to register.

3.31 This Regulation covers both mental and physical healthcare services. Respondents noted that relatively high-risk mental health services are often provided by teams that do not include one of the healthcare professionals that would trigger registration. Some respondents suggested that adding social workers to this Regulation would improve mental health service coverage. We have considered this suggestion

and agreed that those services that require the involvement of a social worker are indeed likely to carry sufficient risk to require registration. We have, therefore, revised the wording of the draft Regulation so that where a social worker, or a team that includes a social worker, provides treatment for a mental disorder, it will be a regulated activity. We will be keeping this activity under review.

3.32 We have amended the exclusion for alternative and complementary medicine, to clarify our position that this does not apply to osteopathy or chiropractic.

3.33 Some respondents suggested that the exclusion for treatment in a sports ground or gymnasium was too narrow. We agree and have extended coverage of this exclusion so that it now excludes 'associated premises', and covers treatment provided for persons taking part in, *or attending*, sporting events.

3.34 A few respondents suggested that there should be an exclusion for services set up specifically for the Olympic Games. We agree that it would not be practical for the Commission to register such a short-lived service provider. We have extended that principle with an exemption to cover any temporary arrangements for sporting or cultural events.

Psychologists

3.35 Since the publication of the consultation on the Regulations, psychologists have been added to the list of professions that must be registered with the Health Professions Council.

3.36 As a result of the redrafting explained above in paragraph 3.35, psychologists will not automatically come within the list of healthcare professionals that trigger registration with the Care Quality Commission.

3.37 We considered whether to add psychologists to that list. We concluded that many large practices employing psychologists are likely to be registered anyway, because they will employ other healthcare professionals, such as nurses and psychiatrists, that will require the practice to be registered. For smaller, single-discipline practices, we felt that the financial and other burdens would be great and the benefits of registration, in terms of addressing risk over and above that addressed by professional registration, would be low. This led us to conclude that we should not add psychologists to the list at this time.

3.38 Treatment provided by psychotherapists and counsellors will not be a regulated activity, unless provided as part of a multidisciplinary team including a healthcare professional or social worker as described in paragraphs 3.29–3.31 above. We have already made a commitment to keep such services under review. The Regulations will be amended in future, if necessary.

Assessment or medical treatment for persons detained under the 1983 Act

3.39 We have made a small amendment to this Regulation to clarify that it does not include surgical procedures. Providers who are registered to provide the 'Assessment or medical treatment for persons detained under the 1983 Act' regulated activity, and who wish to undertake surgery will also need to be registered in respect of the 'Surgical procedures' activity.

Surgical procedures

3.40 We have made some changes to this draft Regulation. While it was always our intention to continue to exclude high street chiropodists or podiatrists (as under the CSA), the Regulations, as drafted in the consultation document, did not reflect this. We have therefore added exclusions for high street chiropodists or podiatrists where they perform simple surgery on nails, verrucae etc, not involving anaesthetic (other than local anaesthetic). We have made similar provision for medical practitioners who undertake minor surgical procedures, again as under the previous framework.

Diagnostic procedures

3.41 We have made some changes to this draft Regulation, which is now titled 'Diagnostic and screening procedures'.

3.42 Some respondents sought clarification over whether we intended to include screening services within this Regulation. We have added the word 'screening' to the description of what comes under this activity to make it clear that this was indeed our intention. This also confirms that providers of screening procedures (where they involve, for example, x-rays, ultrasound, endoscopy and pathology) for asymptomatic people fall within the scope of the Regulation.

3.43 However, we have specifically excluded procedures carried out in the course of national cancer screening programmes, because there

is already sufficient independent oversight and quality assurance of these services. Regional Directors of Public Health are responsible for the quality assurance of these services, ensuring independence from front-line services and NHS management structures.

3.44 We have added wording to ensure that the removal of tissue for the purposes of discovering the presence, cause or extent of disease is included within the scope of registration.

3.45 We were asked to clarify the position on genetic testing. Our intention is to ensure healthcare-related genetic testing is within the scope of registration where it is part of a regulated activity, such as 'Treatment of disease, disorder or injury'. We have therefore included an exemption for genetic testing other than where it is part of the planning and delivery of care or treatment. However, we accept that this is a fast-developing area, and we are keeping the sector under review.

3.46 We have added an exclusion to avoid bringing fitness assessment carried out in a gymnasium into regulation.

3.47 We have also added exclusions for:

- x-rays, when carried out by chiropractors, because we know that their professional body (the General Chiropractic Council) oversees their training in, and use of, x-rays, and they are subject to regulation under Ionising Radiation (Medical Exposure) Regulations;
- ultrasound, when carried out by physiotherapists, as they will have a direct face-to-face relationship with their client during the procedure. We think they are therefore much less likely to, for example, scan the wrong body part or record the results against the wrong patient. Bringing in physiotherapists who use ultrasound would bring in a large number of high street practitioners who would not otherwise be included; and
- the use of an auroscope, so that we do not inadvertently bring in high street providers of (low-risk) hearing aid services.

3.48 Some respondents suggested we should specifically exclude 'simple' electrocardiography (where it is used, for example, in gymnasia to monitor heart rate during exercise) and treadmill stress tests. We have considered these suggestions, but decided not to include these exemptions. The use of electrocardiograms and treadmill tests in gymnasia will already be excluded. However, where treadmill or other tests are carried out as a diagnostic test intended to measure or

monitor the physiological effects of exercise in order to plan or deliver treatment, they will be within the scope of regulation.

Management and supply of blood and blood derived products etc.

3.49 This draft Regulation is now titled 'Management of supply of blood and blood derived products etc', but that is the only change.

Transport services, triage and medical advice provided remotely

3.50 We have made some changes to this draft Regulation. We have amended it so that it explains more clearly what we mean by 'triage'. We have also made it clear that the Regulation is intended to cover water ambulances as well as ground and air ambulances.

3.51 A number of respondents were concerned that the Regulation appeared only to include NHS ambulance service providers. Our intention is to bring non-NHS providers into regulation in April 2011. The phasing (which we announced in the consultation response[8]) is to allow the Commission and the providers time to prepare. We have now added a provision into the Regulations that will require non-NHS providers to register with the Commission from 1 April 2011, so that we will not need to change the Regulations to bring them in.

3.52 Some respondents commented on the description of the kind of transport that will be within scope. In particular, that we should reword the Regulation to ensure that vehicles that are 'modified or equipped to be ambulances' fall within the scope of registration. We have considered these comments, but concluded that these vehicles will be included under the definition, on the grounds that using the words 'designed for the primary purpose of carrying a person who requires medical treatment or personal care' does not limit the definition to vehicles originally designed for that purpose.

3.53 There was concern that community first responders would not be included. It is our intention that providing a community first response service will be included, because it provides care or treatment under the direction of a healthcare professional, for example a doctor or paramedic. In any case, where they are working for an ambulance service provider, the service will be within the scope of registration.

8 *Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations*, Department of Health, March 2009 (www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991).

Repatriation services

3.54 Repatriation services, where an insurance provider arranges them, will be excluded under the general exemption in Schedule 2 8(c). For example, an ambulance provider solely providing a transport service under arrangements made by an insurance company would not need to register. The exclusion for care arranged by an insurance company does not cover hospital care. Therefore, any care delivered in hospital will be included, even where it is provided under arrangements made by an insurance company.

Maternity and midwifery services

3.55 We have made some changes to this Regulation. We have made it clear that the exclusion for information, advice and support provided by 'lay' organisations refers to organisations not providing other medical services.

3.56 A suggestion was made that there should be a clear date for the inclusion of independent midwives. We have considered this, but are not currently in a position to set a date in the Regulations. As we explained in the consultation response, we are expecting systems of contracting and corporate governance to develop, and so we will keep the position under review and return to it in the future.

Termination of pregnancies

3.57 This Regulation has not changed from the consultation position.

Services in slimming clinics

3.58 This Regulation has not changed from the consultation position.

Nursing care

3.59 We have made some changes to this draft Regulation. As described above in paragraph 3.12, we have defined a nurse and nursing care in the 'Interpretation' Regulation. In addition, we have clarified the drafting for this activity to ensure that services that qualify for exemptions elsewhere in the Regulations are not automatically included when performed by a nurse.

3.60 We have also changed the exclusions relating to nursing agencies, so that they reflect the same policy position as the Regulations relating to

care agencies providing care staff under the 'Personal care' Regulation. This reasoning is set out in some detail in paragraph 3.17.

Family planning

3.61 We have added this draft Regulation to bring some family planning services, ie the fitting of intra-uterine devices carried out by, or under the supervision of, a healthcare professional, into the scope of registration. It was always our intention for this to be within scope, but it would not otherwise have been captured, unless performed by a nurse, because it does not come under any of the other Regulations.

General exceptions

3.62 We have made a number of changes to the 'General exceptions' Regulation.

3.63 In accordance with Section 8 of the 2008 Act, we have included provision that will mean that an establishment or agency that is registered with Ofsted under the CSA will not be required to register with the Care Quality Commission, unless it is also carrying out a separate regulated activity, in which case it will need to register. We are continuing discussions with the two regulators and the Department for Children, Schools and Families, to ensure that people who use health and social care services registered with Ofsted have a consistent assurance of safety and quality, without placing an unnecessary burden on the providers or the regulators.

3.64 The draft Regulations we consulted on included exemptions for most primary medical care providers and all primary dental care providers, seeking to reflect the current position under the CSA. These have been amended to ensure that the policy expressed in the consultation document has been delivered. As a result, the provision of NHS primary medical services (under General Medical Services, Primary Medical Services and Alternative Provider Medical Services contracts) and the provision of all dental services outside hospitals will not need to be registered initially.

3.65 In light of the overwhelming support for registering primary medical and dental care providers from our previous consultations, we have looked at how best this can be achieved. To demonstrate our commitment and to allow the Commission and providers the maximum amount of time to prepare for implementation, the exclusions are now time-limited. The Regulations state that the exclusion for primary dental care providers

will expire on 1 April 2011 and the exclusion for primary medical care providers will expire on 1 April 2012.

3.66 In the consultation document (paragraph 3.54)[9], we explained our intention to maintain the current exemptions from registration for independent clinics and independent medical agencies. For example, under the CSA, where an individual NHS doctor also undertakes some private clinic work, their independent clinic is exempted from registration. This exemption also holds for a group of medical practitioners all of whom hold NHS contracts, and who together run an independent clinic. This exemption applies to the clinic, and in future, while the NHS establishment will be registered with the Care Quality Commission, the exemption for the independent clinic will still apply. We will continue to work on policy in this area, with a view to introducing an appropriate replacement Regulation.

3.67 We have moved the exclusions relating to services provided under arrangements made by an employer, a government agency or an insurance provider from the 'Treatment of disease, disorder or injury' Regulation into 'General exceptions'.

3.68 We have added a temporary exclusion for non-NHS ambulance service providers. This makes it clear that an otherwise unregulated ambulance service provider should not be inadvertently brought into registration because it carries out a different regulated activity as part of the ambulance service (for example operating an electrocardiograph while taking an emergency patient to an accident and emergency unit). We have also added a clause to remove that exclusion on 1 April 2011.

3.69 We have moved the first aid exemption that we had originally placed within the 'Treatment of disease, disorder or injury' Regulation to here, so that it is a general exception and applies to all the regulated activities. We have also clarified the exclusion to ensure it covers first aid organisations, non-healthcare professionals trained to provide first aid and healthcare professionals providing first aid in unexpected emergency situations that require immediate action.

3.70 Finally, we have added an exclusion so that schools that directly employ a nurse to provide on-site school nursing care do not need to register as healthcare providers. In the majority of schools, any nursing care will be provided under arrangements with the local primary care trust. In these situations, the nursing care will be registered with the Commission. In a number of cases, treatment and nursing care are

9 *Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft Regulations*, Department of Health, March 2009 (www.dh.gov.uk/en/Consultations/Closedconsultations/DH_096991).

provided directly by schools, where a nurse are engaged and directed by the school. In these cases, we have been reassured that Ofsted inspections of the school, together with the professional regulation of the individual nurses, will provide regulatory coverage. For schools providing their own nursing care, we do not think the burden of being regulated by the Commission would be justified.

Family and personal relationships

3.71 A concern was expressed that the 'Family and personal relationships' Regulation would mean that a family member or friend, who received payment for providing care would need to be registered. However, we made clear under the 'Personal care' Regulation, that where such care was wholly under the control of the person receiving it, this would not require registration.

4. What requirements will registered bodies have to meet?

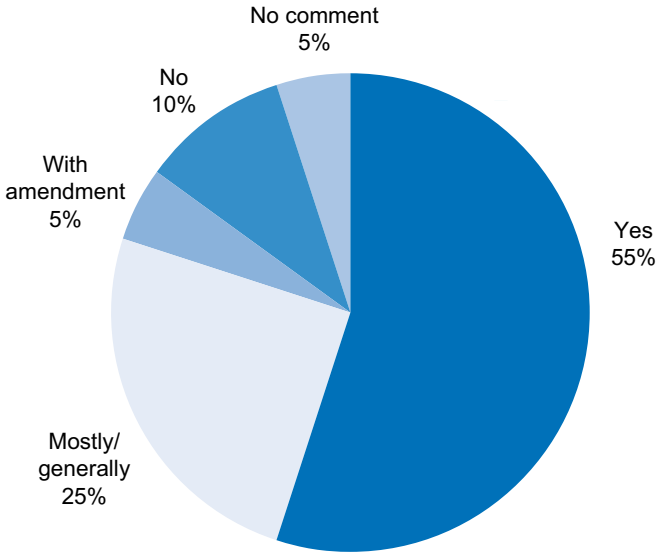
What we asked

4.1 ***Q5.1 Do the draft registration requirement Regulations set out at Annex D accurately reflect the policy set out in Chapter 5 and Annex C?***

4.2 ***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?***

What we heard in answer to Q5.1

4.3 Of the 72 respondents, 40 responded directly to question 5.1. Of those, 55% thought that the Regulations do reflect the policy, 25% stated that they mostly or generally do, 5% thought they would with amendment, 10% said they do not and 5% had no comment.



4.4 Responses were generally favourable with regard to the Regulations' coverage and confirmed that they reflect our policy intention. The inclusion of the nutrition requirement and the complaints requirement were particularly welcomed.

4.5 Two respondents expressed concern that the way in which the draft Regulations are drafted leaves the Commission 'too much leeway', because, although the Commission's guidance about compliance must be consulted upon, the final version will have no external scrutiny (unlike the Regulations). However, the 2008 Act sets out that the Commission must publish its own guidance, and places on it a duty to consult 'such persons as the Commission considers appropriate'. Furthermore, it is in the Commission's interests that the guidance is comprehensive, clear and proportionate, so that service providers have a good understanding of what the Commission will be looking for in deciding whether they meet the registration requirements. This clarity will also support the Commission in bringing successful enforcement proceedings.

What we heard in answer to Q5.2

4.6 Many respondents asked for guidance about how compliance with the registration requirements would be judged in specific care settings. However, the requirements have to be relevant to all the regulated activities. The Care Quality Commission will provide more detailed guidance about compliance.

4.7 A number of changes were suggested to clarify or put particular emphasis on aspects of the individual draft Regulations as follows in the rest of this chapter.

Interpretation

4.8 As we are combining the two sets of draft Regulations, which were presented separately in the consultation document, this Regulation has been merged with the 'Interpretation' Regulation in Chapter 3.

Fitness of registered persons

4.9 In the consultation, we proposed that the contravention of requirements relating to persons carrying on or managing a regulated activity should be an offence, punishable on summary conviction by a fine not exceeding £50,000. Some respondents felt that the failure to comply with these Regulations should not be an offence. As the equivalent requirements under the CSA are not currently offences, we agree with these respondents. Non-compliance with these Regulations will not be a criminal offence. It will, however, be subject to the other available enforcement actions.

Fitness of registered manager

4.10 This Regulation is now titled 'Requirements relating to registered managers'. For technical reasons, non-compliance with this Regulation will not be an offence.

4.11 A few respondents had concerns that any measure of physical and mental fitness in relation to the role to be performed might be applied in a discriminatory manner. However, the term 'fitness' comes from the 2008 Act, under which the registration requirement Regulations are being made. Therefore, the term has been used for consistency. This requirement must be read in conjunction with, and implemented in accordance with, disability discrimination legislation.

Registered person: general requirements and training

4.12 The question was raised as to whether we should detail the qualifications needed by registered managers. We have not put these in the Regulation, as these will vary considerably in different circumstances. The Care Quality Commission will provide guidance about compliance. For technical reasons, non-compliance with this Regulation will not be an offence.

Care and welfare of service users

4.13 Following comment, we have made the need for providers to protect people from the risk of unlawful discrimination more explicit in this requirement, including making reasonable adjustments in service provision. This, along with the Care Quality Commission's ability to take into account compliance with other legislation that it considers relevant to registration, gives a stronger focus on equalities.

4.14 We were asked to consider how the requirements would help in emergencies such as a flu pandemic. We have therefore made explicit the need for providers to plan and prepare for how they will ensure the care and welfare of people using services during reasonably foreseeable emergencies.

4.15 Some respondents asked for services for people whose needs are assessed by a local authority to be exempt from the requirement for a needs assessment. The Regulation requires the registered person to ensure that an assessment of their needs is carried out. Without such an assessment, it will be impossible for a provider to deliver appropriate care or treatment. The Regulation does not specify that the registered provider must perform the assessment. A registered person

can therefore demonstrate compliance by obtaining an assessment from a third party.

4.16 Some respondents asked us to cite National Institute for Health and Clinical Excellence (NICE) guidance in this Regulation. We have not done so, as this would not be relevant to all registered providers. Most NICE guidance supports NHS commissioning and best practice in providing services. Only NICE's interventional procedures guidance is likely to have some relevance to registration; it details safe and appropriate approaches to specific aspects of care. This could therefore be used to describe the essential levels of safety and quality required for registration. So, while not all providers could be required by Regulations to follow this NICE guidance, the Commission could base their judgements of compliance on evidence that a provider follows it.

Assessing and monitoring the quality of service provision

4.17 This requirement requires providers to operate effective systems for assessing and monitoring the quality of their services against the 16 safety and quality requirements. These systems are sometimes called 'governance' or 'quality management' systems. Where clinical activities are carried on, it would refer to 'clinical governance' systems.

4.18 Following comment, we have made it explicit that the views of people who use services, which providers must have regard to, include descriptions of their experiences of their care and treatment. We have also strengthened the link between the need for providers to regularly seek the views of people who use services, and the need to take these views into account.

4.19 We have also expanded this requirement so that it includes the supply of a self-assessment of compliance with registration requirements to the Care Quality Commission. This was previously included in our proposals for 'Provision of information', but has been moved to this Regulation as it relates closely to this requirement. The registered person is required to provide the Commission with a written report on their compliance with the 16 safety and quality requirements, together with any plans for improving the standard of services, in order to ensure continued compliance with those requirements.

4.20 Many respondents sought clarification about how the Care Quality Commission will judge compliance with this requirement. The Commission will provide this information in its guidance about compliance.

Safeguarding vulnerable service users

4.21 This Regulation is now titled 'Safeguarding service users from abuse'.

4.22 We were asked if we should use the more modern term 'safeguarding' rather than 'protection' in this Regulation. We have changed the drafting where appropriate.

4.23 Some respondents asked us to ensure that all allegations of abuse are responded to, not just those from people who use services or their representatives. We have changed the wording to require providers to respond to *all* allegations of abuse.

4.24 Some respondents had concerns about the use of the term 'disturbed behaviour'. We have now changed the wording on the use of restraint to align better with the requirements of other legislation and to remove this reference.

4.25 Some respondents asked for discriminatory abuse to be included in the definition of abuse. However, our definition covers all types of harm, including those arising from discrimination. The prevention of discrimination is also the subject of other legislation, compliance with which the Care Quality Commission may consider relevant to registration.

4.26 We were also asked to define the term 'vulnerability' in relation to people in unsafe, poor quality or abusive circumstances. While we recognise that anyone may be vulnerable in certain circumstances, we have aimed for consistency with key legislation in this area, for example the Safeguarding Vulnerable Groups Act 2006.

Cleanliness and infection control

4.27 Some respondents suggested changes to tailor this requirement to community-based care services, for example domiciliary care agencies. We have changed the requirement to maintain cleanliness and hygiene in relation to equipment; it is no longer confined to equipment in premises used by the registered provider. This recognises that equipment used in the community may also present a risk of transmission of HCAIs.

4.28 We have not made separate requirements for community-based services; the requirement is set at a level appropriate to all services. Guidance about compliance in different circumstances will be included in the supporting code of practice.

Management of medicines and medical devices

4.29 This Regulation is now titled ‘Management of medicines’.

4.30 In response to comments, we have moved references to medical devices into the ‘Safety, availability and suitability of equipment’ requirement.

4.31 We were asked to include safe dispensing of prescribed medicines. This is now covered where it is part of the regulated activity.

4.32 We were also asked to include standards for supporting self-medication. We have not included such a reference in this requirement, as it is already covered in the ‘Respecting and involving service users’ requirement.

Meeting nutritional needs

4.33 This requirement met with particular approval.

4.34 Some respondents suggested we be more prescriptive about the means by which providers assess and meet nutritional and hydration needs. We have not prescribed these, in order to allow a flexible approach relevant to different services.

Safety and suitability of premises

4.35 Respondents asked for mention to be made of the security of premises. We have now added explicit reference to this.

4.36 Following comment, we have also clarified the coverage of this requirement by explicitly including the operation of systems integral to premises (for example, air conditioning or water heating systems).

4.37 Some respondents asked us to exclude certain types of premises, including inaccessible premises where the provider offers home visits as an alternative, and temporary structures.

4.38 We have decided not to exclude temporary premises or structures from the requirement. It is important that providers manage the risk of harm arising from the care environment. The means by which compliance is achieved may differ according to the circumstances.

Safety, availability and suitability of equipment

4.39 Some respondents wanted us to move references to medical devices to this Regulation from the 'Management of medicines and medical devices' requirement. These references are now included here.

4.40 A number of respondents asked for there to be an exemption from this Regulation where equipment used by a provider is owned by another body. We have not confined this requirement only to equipment owned by the registered provider, because it is important that providers satisfy themselves that any equipment they use to deliver the regulated activity is safe and suitable. This includes being satisfied that relevant maintenance and safety checks have been carried out by the relevant organisation where the registered provider does not own the equipment.

Respecting and involving service users

4.41 This requirement met with particular approval.

4.42 Some respondents suggested we set out actions to be taken in particular circumstances, for example to include duties in the NHS Constitution. We have not prescribed how compliance is achieved, in order to allow for flexibility of approach.

4.43 A few respondents asked for wider public involvement to be required, not just that of patients and people using services. However, we have not widened this requirement beyond people who use services and their representatives. Registration focuses on the management of risks to the health, safety and welfare of people who use services. It would not be possible to identify an enforceable level of compliance related to wider public involvement.

Consent to care and treatment

4.44 Where this Regulation was commented on, it was welcomed. We have made no changes.

Complaints

4.45 This requirement was welcomed. However, there were some additional comments, which follow.

4.46 Respondents highlighted the importance to people using services of a co-ordinated response to complaints about care involving more

than one provider. We have therefore made it explicit that registered providers should co-ordinate responses to complaints relating to care that is shared by or transferred between providers.

4.47 There was concern that the duty to resolve complaints to the complainant's satisfaction wherever possible was inappropriate. We have changed the requirement to resolve complaints to the satisfaction of the complainant from 'wherever possible' to 'where reasonably practicable' for a more acceptable legal test.

4.48 We have also extended the requirement to include supply to the Care Quality Commission of a summary of complaints received and responses made. This was previously included in our proposals for the 'Provision of information', but has been moved here, as it relates closely to this requirement.

4.49 A number of respondents stressed the importance of advocacy, although others said that service providers should not have to provide advocates. We have not required registered providers to supply people who use their services with independent advocates. While we fully recognise the value of advocacy in many circumstances, we do not wish to prescribe the use of advocates, as there are many other ways in which providers can engage with people who use services.

Records

4.50 A number of respondents wanted this Regulation to refer to legislation and guidance about data protection and information sharing. We have decided not to do this, as this would duplicate the provisions of other legislation, including freedom of information and data protection legislation. The Care Quality Commission may take compliance with these enactments into account as relevant to registration.

Fitness of workers

4.51 This Regulation is now titled 'Requirements relating to workers'.

4.52 There was concern that drafting of this requirement would allow providers to have good recruitment policies and procedures in place but not put them into practice. We have changed the wording accordingly, so that providers must 'operate', rather than 'have in place', effective recruitment procedures.

4.53 Some respondents thought that references to professional regulation did not accurately reflect other relevant legislation. We have therefore

better aligned these references with other legislation on protection of title and roles.

4.54 A few respondents had concerns that any measure of physical and mental fitness in relation to the role to be performed might be applied in a discriminatory manner. However, the term 'fitness' comes from the 2008 Act, under which the registration requirement Regulations are being made. Therefore, the term has been used for consistency. This requirement must be read in conjunction with, and implemented in accordance with, disability discrimination legislation.

Staffing

4.55 Respondents were divided between those who wanted this Regulation to prescribe qualifications and staffing levels and those who wanted to avoid a rigid national approach. We have not specified staffing levels and staff qualification requirements, as these will vary considerably in different circumstances. The Care Quality Commission will provide guidance about compliance.

Supporting staff

4.56 This Regulation is now titled 'Supporting workers'.

4.57 We were asked to specify training and competency requirements in each of the requirements. We have not done so, as this would involve extensive duplication. Our aim has been to produce a streamlined set of requirements that avoids duplication.

4.58 A respondent also wanted greater emphasis to be placed on health and safety at work. We have not included this, as there is already legislation in this area, primarily enforceable by the Health and Safety Executive.

Co-operating with other providers

4.59 This requirement was welcomed.

4.60 We were asked to specify the bodies with which providers are required to co-operate and for this to include voluntary organisations. We have not done this, as these will vary according to the circumstances. Voluntary organisations will be included, where relevant. The Care Quality Commission will provide guidance about compliance.

Due diligence defence

4.61 Two respondents noted that the registration requirements Regulations were expressed in outcome terms that could be subject to interpretation. Where non-compliance with such requirements is to be a criminal offence, we felt that the implicit availability of a due diligence defence should be made explicit. The Regulation establishing the offences has been made explicit in this respect.

Registered manager condition

4.62 Some respondents commented on the NHS exemption from the registered manager condition, stating that they either disagreed with the exemption or thought it did not reflect the policy of having one system for all providers. A few commented that instead of having a blanket exemption, the Commission should outline the conditions that would make a provider exempt from having a registered manager.

4.63 In light of these responses, we have further considered the rationale for excluding NHS healthcare provision from the requirement for a registered manager. The new system aligns the regulation of health and adult social care providers and ensures that different providers are treated in a consistent and transparent way.

4.64 However, there are existing mechanisms for holding NHS providers to account for the services they provide with external governance arrangements in place. We do not want to duplicate these by placing additional accountability requirements on these providers. As we said in our consultation on the Regulations, NHS trust boards are accountable to the strategic health authority (SHA) or Monitor (for NHS foundation trusts) should they fail to ensure appropriate management of services on their sites.

4.65 While non-NHS providers may have governance arrangements in place, there is no other external scrutiny equivalent to the oversight that Monitor and SHAs provide. The requirement for a registered manager thus provides a mechanism for holding a person who is in day-to-day control of the management of the service to external account, where the registered provider is not in day-to-day control of the service.

4.66 Therefore, the Regulations will set out that, as a condition of registration, the Care Quality Commission will register managers of private and voluntary healthcare and social care regulated activities and hold them to account (as is currently the case under the CSA) where the registered provider is not in day-to-day control of the service.

Managers of NHS healthcare regulated activities will not be subject to these conditions, but will be held to account by the SHA or Monitor, as appropriate.

4.67 It was suggested that registered managers continue to be required for NHS-provided social care and domiciliary care. While registered managers will not be required where the NHS is providing healthcare, the Regulation recognises the very different settings in which social care is provided by the NHS, for example in a care home. There was strong support in response to the consultation on the registration framework, for retaining registered managers for social care activities currently registerable under the CSA. NHS providers of social care regulated activities – that is, services consisting of 'Personal care' or 'Accommodation for persons who require nursing or personal care' – will therefore continue to be required to have a registered manager.

5. Other registration and enforcement Regulations

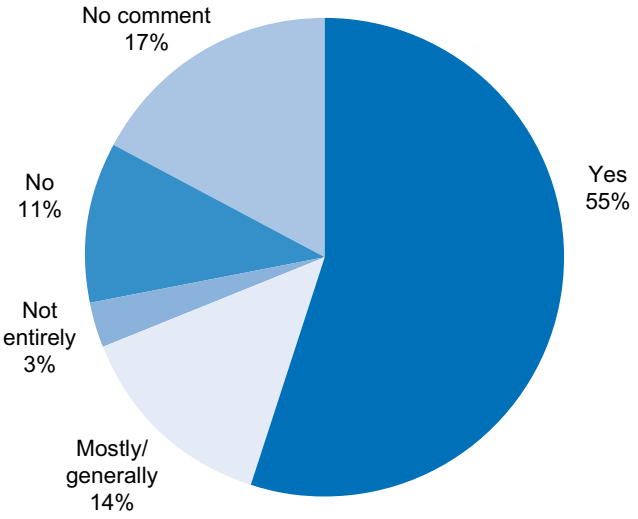
What we asked

5.1 ***Q6.1 Do the proposals set out in Chapter 6 on supporting legislation create a practical framework for registration?***

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

What we heard in answer to Q6.1

5.3 Of the 72 respondents, 31 responded directly to question 6.1. Of those, 55% thought that the proposals do create a practical framework, 14% stated that they mostly or generally do, 3% thought they do not entirely, 11% said they do not and 17% had no comment.



What we heard in answer to Q6.2

5.4 Responses focused on the proposed financial position requirement and the proposals for notifications.

5.5 More detailed comments, and our response, are given in the rest of this chapter.

Provision of information: Notifications

5.6 Many respondents felt that reporting all deaths would be too onerous, particularly for NHS services. We recognise that most people reaching the natural end of their lives receive care from the NHS. Their deaths do not necessarily provide an indication of problems with service safety and quality. We agree that requiring NHS services to report all deaths would be burdensome and would not generate useful information for the Care Quality Commission. We have therefore decided that NHS organisations will only be required to notify those deaths that indicate that there could be a problem with the way services are provided. We have decided that, for the time being, we will keep the current position for private and voluntary healthcare and adult social care providers, who are required to report all deaths that occur in their service. However, we will keep this under review.

5.7 In addition, in response to an undertaking made to Parliament during the passage of the 2008 Act, all providers (including NHS organisations) will be required to report the death of a service user who is detained under the Mental Health Act 1983.

5.8 Some respondents questioned the value of reporting all planning permission applications made by registered providers. We agree. However, we believe it is important that the Commission knows when a service provider makes a change to the premises where they deliver services that significantly affects the regulated activity. We have decided that the best way to capture this information is by requiring providers to inform the Commission of any change which results in an amendment to their statement of purpose.

5.9 Some respondents felt that providers should not be required to report incidents that occur to people receiving care in their own homes. We believe that it is important for the Commission to know about incidents that occur during, or arising out of, a provision of the regulated activity. We accept that other incidents that do not involve the provision of care are not relevant. The only exception to this being any allegation of abuse in relation to a person receiving care, which will always need to be reported.

5.10 Some respondents thought it unnecessary to require providers to notify changes to registered managers. We disagree. Currently, providers registered under the CSA must report such changes. Registered managers have a significant influence over the quality of service provision and therefore it is important that the Commission knows of any changes.

5.11 In our consultation document, we proposed requiring the notification (reporting to the Care Quality Commission) of an illness or infection that might have suggested that there had been a failure in the care provided to service users. We now recognise that the reporting of infections must serve a number of functions. The most pressing would be the introduction of control measures and the safeguarding of public health. After further consideration, we have decided that the Health Protection Agency (HPA), through its local units, would be instrumental in deciding on the adequacy of the response by the provider. We have therefore decided not to create a specific requirement in this area, but to make use of the surveillance and reporting arrangements operated by the HPA through local health protection units. The HPA and Care Quality Commission will share this data to ensure that the Commission has the information it needs. This will avoid the provision of a duplicate reporting mechanism.

The NHS

5.12 The NHS environment is very different to that of organisations currently regulated under the CSA; it has a wide range of reporting mechanisms that provide information. These can also be made available to the Commission to monitor providers' compliance with registration requirements. In particular, patient safety incidents are reported to the National Patient Safety Agency (NPSA). We have therefore decided that where an NHS provider is required to make a notification to the Commission about patient safety, no such notification will be required if the incident in question has already been reported to the NPSA. This will avoid duplicate reporting. The NPSA will process the notifications and share the information with the Commission.

Reporting on the Deprivation of Liberty Safeguards

5.13 In addition to its role of registering providers, the Commission monitors the operation of Deprivation of Liberty Safeguards under the Mental Capacity Act 2005.

5.14 To support this monitoring, and provide information about compliance with registration requirements, hospitals and care homes that are required to operate the safeguards will be required to inform the Commission when they make an application to a supervisory body (a primary care trust or local authority) to deprive a person of their liberty under the provisions of that Act.

Fitness of registered person: Responsible individual

5.15 Organisations regulated under the CSA are required to appoint a 'responsible individual'. The use of this term has led to confusion with the role of the registered person. Therefore, we are changing this Regulation to require an organisation to give notice of a 'nominated individual'. This person will not be registered him/herself, and therefore will not be legally accountable, but will act as an agreed point of contact for the Care Quality Commission to ensure issues can be addressed and resolved. The organisation must ensure that the nominated person meets the requirements relating to workers.

Financial position

5.16 There was some comment that the exemption of public sector providers from this requirement worked against the overall aim of creating a fair regulatory playing field, especially as non-compliance with the requirement is an offence. Equivalent requirements under the CSA are offences and we had proposed that this position be maintained. However, in view of the comments received we have decided to remove the offence from this requirement. It will be subject to the other enforcement mechanisms available to the Commission. We have also reconsidered the public sector exemption in light of the comments, but have decided to retain it. The existing assurance systems for publicly accountable services, that will come into registration from 2010, would make meeting this requirement an unnecessary additional burden on these providers. We will keep this position under review and consider the primary care implications, in advance of those services coming into registration.

Enforcement: Penalty notices

5.17 In light of comments, we have reviewed the monetary amount of penalty notices to be set. In particular, we have reconsidered whether the amount is appropriate and whether the different amount for registered service providers and registered managers is proportionate. As a result, we have made a change to the penalty notice amounts for offences under sections 63 (obstructing an inspector), 64 (failure to provide documents and information) and 65 (failing to require an explanation) of the 2008 Act. Since these offences will not necessarily be related to the Commission's registration system, the setting of penalty notice amounts in relation to registration status is irrelevant. Instead, we will set a single penalty notice amount of £300 for these offences.

5.18 In response to comments, we have also reconsidered whether the proposed penalty notice amounts are proportionate for registered service providers and registered managers. Because any financial penalty notice is likely to have a greater financial impact on a registered manager (an individual) than a provider (an organisation), and because the provider has overall responsibility for the service, it was proposed that penalty notice amounts for registered managers should be set at half the amount of those for registered service providers. We have concluded that this approach is proportionate, with the exceptions set out above in paragraph 5.17.

Enforcement: Publication and notification of enforcement action

5.19 A small number of comments were made about the Commission's power to publish details relating to warning notices. In response to these, we have amended this Regulation, so that the Commission will only be able to publish information about warning notices after it has both received and taken into account representations from the registered provider or registered manager.

Compliance with registration requirements

5.20 Some respondents asked for further advice about how they should achieve compliance with registration requirements. We have therefore decided to add a Regulation that clarifies that in complying with the requirements, registered providers must have regard to the Commission's guidance about compliance and the code of practice for the prevention and control of HCAIs.

6. Next steps

6.1 We have refined the content of the Regulations, taking consultation responses and the outcomes of further stakeholder engagement into account.

6.2 As a result, a set of draft Regulations covering the scope of registration (defining the regulated activities), the registration requirements and penalty notices has been introduced to Parliament. We intend to introduce a second set of Regulations, covering registered managers, financial position, provision of information and further enforcement provisions later in autumn.

6.3 Subject to approval by Parliament, the Regulations will come into force in time for the new system to start being introduced on 1 April 2010.

6.4 The Commission will issue its guidance about compliance in December 2009. This will enable NHS providers to make their applications in January 2010 and to prepare for registration prior to them being registered under the new system from 1 April 2010.

6.5 Also due to be published prior to the application process is the Department of Health's guidance on compliance with the 'Cleanliness and infection control' requirement, in the form of a code of practice.

6.6 Providers of private and voluntary healthcare and adult social care (including social care provided by NHS bodies), currently registered under the CSA, will be brought into the new system in October 2010. So too will any services not previously registered, but now within scope. Similarly, the few registered services not captured by the new system will cease to be registered with the Care Quality Commission from this date.

6.7 Primary dental care and private ambulance services will come into the registration system on 1 April 2011. Primary medical care provision will follow on 1 April 2012.

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