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THE NHS CONFEDERATION

briefing

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The new registration system for health and adult social care

Key points

- The new system of registration will introduce mandatory registration for all providers, NHS and independent sector, under a common framework of legally enforceable registration requirements.
- The requirement to register is defined by the type of activity or care provided. Activities will require registration depending on the level of activity-associated risk.
- A single set of registration systems for both the NHS and the independent sector, and for health and social care should bring benefits of regulatory simplification.
- The broad definitions of activities requiring registration offer greater flexibility to include new types of service or new settings for provision of care within the scope of registration.
- The registration framework aims to provide independent assurance of the safety and quality of care.

From April 2010, a new system of regulation for health and adult social care in England comes into force for the NHS. This will require all providers of certain health and adult social care activities to register with the Care Quality Commission in order to provide services.

The Department of Health is now consulting on the draft regulations. The draft, which is subject to parliamentary approval, will provide the detailed legal basis for the new system together with some associated policy proposals to support the registration framework.

This *Briefing* summarises the main proposals and their implications for providers of NHS care and its commissioners.

The new regulatory framework

From April 2010, the Care Quality Commission (CQC) will begin to operate the new system of registration for providers of health and adult social care in England. This will introduce for the first time mandatory registration for all providers, NHS and independent sector, under a common framework of legally enforceable registration requirements. It will be illegal for any body not registered with the CQC to provide any health and adult social care service that comes within the scope of registration.

Alongside this consultation, the CQC is developing the principles of its methodology and guidance about compliance with the registration requirements and will be consulting on them later this year. A formal consultation on these proposals is expected to be launched in summer 2009.

The registration system will operate alongside the wider quality

improvement framework. The CQC is expected to contribute to ongoing quality improvement as part of this quality framework, by publishing comparable information in periodic reviews, and conducting special reviews into areas of particular interest.

Under the new system, the requirement to register is defined by the type of activity or care provided. This means that providers will be required to register on the basis of the type of care provided, irrespective of where the care is provided or which organisation provides it. This will include, for the first time, GP practices and high-street dental services, although they will not be required to register until 2011/12 at the earliest.

The definitions of the activities requiring registration are based on the level of risk posed to the individual patient or person using the service, either as a result of their vulnerability or the risks innately associated with the activity. Underpinning principles include:

- 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
- the cost of regulation, including administration costs and indirect costs arising from providers ceasing to provide certain services to avoid regulation.

Who will need to register?

Under the new registration system, providers will be required to register with the regulator on the basis of the type of care provided or broad service areas. For the first time, this will require NHS providers to register with the regulator on the same basis as independent sector providers. It will also bring some new providers of healthcare services within the scope of healthcare regulation, such as primary care medical and dental services, and private ambulance services.

Responsibility for regulating children's social care services remains with Ofsted, which regulates those (primarily children's) social care establishments and agencies that fall under the Care Standards Act 2000. The Department of Health (DH) is working with Ofsted, the CQC and the Department of Children, Families and Schools to ensure services are appropriately regulated. It is recognised that the CQC and Ofsted must work together effectively to prevent duplication and overlap, ensure assurance of the safety and quality of services, and prevent services falling through a gap.

The regulations define what is included in the scope of registration and what is not. They provide a detailed definition of what is considered personal care, and clarify what is meant by 'treatment'. They also provide detailed explanations of what is covered under each heading of activity or type of service.

Some services not previously regulated under the Care Standards Act will be required to register with the CQC. These include private ambulance services and diagnostic services in non-hospital settings.

Some family planning services will also come within the scope of registration, under 'nursing care', such as fitting of intrauterine devices (IUDs) and contraceptive caps.

Perhaps the most encompassing activity within the scope of registration is 'treatment of disease, disorder or injury', including physical and mental disorders. Although this is limited to treatment by or under the supervision of a healthcare professional, it is still a broad category. Treatment is defined as including:

Proposed scope of registration

- personal care
- accommodation for persons who require nursing or personal care
- accommodation for persons who require treatment for substance misuse
- accommodation and nursing or personal care in the further education sector
- treatment of disease, disorder or injury (by or under the supervision of a healthcare professional)
- assessment or medical treatment for persons detained under the Mental Capacity Act 1983
- surgical procedures
- diagnostic procedures
- management and supply of blood and blood derived products
- transport services, triage and medical advice provided remotely
- maternity and midwifery services
- termination of pregnancies
- services in slimming clinics
- nursing care.

- a diagnostic or other investigative procedure
- nursing, personal and palliative care
- the giving of vaccinations and immunisations.

'Healthcare professional' is defined as the member of any profession covered by the Health Act 1999; this means those professions subject to statutory professional regulation such as doctors, nurses and dentists. However, certain registered healthcare professionals are excluded from this definition, including osteopaths, chiropractors, and several professions currently regulated by the Health Professions Council, such as physiotherapists, chiropodists and podiatrists, unless they are providing services as part of a care package delivered by a multi-disciplinary team with certain other healthcare professionals. This is intended to exclude services such as high-street physiotherapy, osteopathy and chiropody services, which are felt to be well covered by existing professional regulation.

Current proposals for the scope of registration have taken on board some earlier concerns and questions. They have tried to provide sufficiently tight definitions of service that provide clarity and are not open to interpretation, but are not so broad as to include some inappropriate services within the scope of regulation.

Patient transport services

Earlier definitions of patient transport services had tried to separate patient transport services into 'high dependency' and 'non-urgent' transfers, and exclude 'non-urgent' patient transport services from the registration requirements of the CQC. The Government agrees that to exclude 'non-urgent' patient transport services from registration would have excluded some providers that should be within the registration scope. The Government has decided to revise the definition of patient transport services that are within 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.' This definition has been set out in the draft regulations. The aim is to ensure that all vehicles used for this purpose will be covered, with the exception of taxis, hospital cars and other similar services.

The Government has also concluded that extending regulation beyond transport that is required for medical need to consider the vulnerability of the patients being transported would not add to the controls and safeguards that should already be in place. It has argued that it would also create a situation where healthcare providers could not commission taxis or volunteer cars to transport patients to and from hospital unless they were registered with the CQC.

Specialist mental health services

Following the 2008 consultation on the proposals for registration, the activity of 'specialist mental health services' has been included under the activity 'treatment of disease, disorder or injury', and the definition of services that are required to register revised. This is intended to address concerns raised in the earlier consultation, but will still leave many psychological therapy services outside the scope of registration. Services such as psychotherapy, counselling and those services provided by psychologists or social workers will only be covered by the regulations if they are delivered as part of a care package provided by a multi-disciplinary team that includes the designated registered healthcare professionals, such as nurses or doctors.

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 not currently in one of the registered healthcare professions. The DH will, therefore, keep the regulation of counselling and psychotherapy under review with a view to bringing some services into regulation, either within these regulations or at a later date.

Which services do not have to register?

Initially, primary medical and dental care services, including surgical services, are excluded from the scope of registration. However, these will be brought within the scope of registration at a later date, primarily under the activity 'treatment of disease, disorder or injury' and 'surgical procedures'. Private ambulance services are also initially excluded but will be required to register from April 2011.

Organisations that only provide services or staff to a registered provider will not have to register. Nursing agencies that only provide staff to registered hospitals will not have to register, but the service provider will be responsible for ensuring that the agency only sends appropriately qualified and trained staff.

Several other types of service, that might be included under the broad heading of 'treatment of disease, disorder or injury', are specifically excluded from the scope of registration, such as:

- alternative and complementary medicine
- first aid treatment
- treatment carried out in sports facilities and work places
- certain services provided by lay-people such as ante-natal classes and befriending
- activities licensed by the Human Fertilisation and Embryology Authority.

As well as high-street physiotherapy, osteopathy and chiropody services, primary ophthalmic and pharmaceutical services are also excluded, as are services that are provided in 'family and personal relationships'. Other notable exclusions include:

- counselling and psychotherapy services not provided under the direction of a registered healthcare professional such as a nurse or doctor
- certain cosmetic procedures, body and ear piercing and tattooing
- tests that only involve pin-pricks or do not require specialist analysis
- nursing care provided by a nurse directly employed by the person receiving care.

The DH has undertaken to keep certain services currently excluded from the scope of registration under review. These include mental health services delivered by teams that do not include registered healthcare professionals, patient transport services, and developments in tele-health and telemedicine. Overall responsibility for the regulation of children's services is also being kept under review.

Care or personal assistance that is purchased under direct payments or personal budgets is not specifically covered in the proposals. If the care purchased is a regulated activity, then the provider will need to be a registered provider, unless they are a friend or family member. The intention is to allow the person with the personal budget to decide what care best suits their needs. The DH felt it would be counter-productive to require all providers of such care to be registered with the CQC.

Registration of primary care

All providers of primary medical and dental care will be required to register with the CQC, regardless of whether they provide wholly private or wholly NHS services, or a mix of both. This will bring approximately 8,500 GP practices and 9,000 high-street dental practices within the scope of registration.

The CQC's role in relation to primary care is intended to complement primary care trusts' (PCTs') responsibilities for oversight of primary care services. This will link with the framework for managing poor performance and driving up quality set out in the NHS Next Stage Review primary and community care strategy, and local action by PCTs and primary care practitioners and their practices to improve quality.

Other primary care services, such as high-street pharmacy or ophthalmic and audiology services, are not included within the scope of registration at this stage. However, the DH recognises these services are changing significantly and it may be appropriate to require their registration in future. The DH will keep this issue under review and assess the need for registration, depending on the level of risk.

All primary medical and dental care will have to comply with the same registration requirements as all other registered providers. The CQC will develop detailed compliance proposals for primary medical and dental care at a later stage. This will use existing sources of data, such as the Quality and Outcomes Framework and practice accreditation, where possible to demonstrate compliance with the registration requirements.

Timetable for registration

The new system of registration will start to come into force from 1 April 2010. However, the requirement to register will be phased, depending on the type of provider.

All NHS providers have been registered with the CQC since 1 April 2009, but only in relation to healthcare associated infections (HCAI) regulations. They will be required to register with the CQC under the new framework from 1 April 2010, demonstrating compliance with the full set of registration requirements.

Independent sector providers, currently registered under the Care Standards Act 2000, will become subject to the new registration system on 1 October 2010. Until then, National Minimum Standards will continue to apply.

During 2011/12, registration will be introduced for a range of other providers including:

- private ambulances (April 2011)
- independent midwives (April 2011)
- high-street dental services, both NHS and private (April 2011)

Registration requirements on quality and safety

- care and welfare of service users
- assessing and monitoring the quality of service provision
- safeguarding vulnerable adults
- cleanliness and infection control
- management of medicines and medical devices
- meeting nutritional needs
- safety and suitability of premises
- safety, availability and suitability of equipment
- respecting and involving service users
- consent to care and treatment
- complaints
- records
- fitness of workers
- staffing
- supporting staff
- cooperating with other providers.

- all primary medical care providers (by April 2012).

Following the conclusion of this consultation, draft regulations will be laid before Parliament for approval later in 2009.

Registration requirements

Under the new system of registration, there will be 16 requirements that all providers of health and adult social care must meet in order to be registered with the CQC and provide services that fall within the scope of registration. Following the 2008 consultation, the DH has revised some of the registration requirements.

These registration requirements relate to the quality and safety of service provision of a regulated activity, and set out essential levels of quality and safety that will apply to all providers of any regulated activity. Of necessity, they are broad categories, but these will be underpinned by guidance about compliance, currently being developed by the CQC.

They are intended to address the main risks associated with provision of health and social care services, and have been developed from the most appropriate, existing regulations and standards. These include existing core Standards for Better Health regulations and National Minimum Standards under the Care Standards Act, which will be replaced by the registration requirements. They are in addition to other legal requirements such as human rights, equalities, and health and safety at work legislation, which the CQC can take into account when making decisions about registration. Registration requirements will be legally enforceable by the CQC. Failure to comply may result in conditions on registration, suspension or refusal of registration and/or fines up to £50,000. The CQC consulted earlier in 2009 on its proposed enforcement regime.

Other regulations to support the registration framework

In addition to the registration requirements relating to quality and safety, other registration requirements and regulations are needed to provide the legal basis for the practical operation of the registration framework. New regulations will have to be developed to put these provisions into law. These include:

- regulations setting out registration requirements relating to:
  - the fitness of registered persons
  - provision of information
  - financial position
- regulations relating to the termination of pregnancy
- the registration process, including the keeping of a register, making applications for registration and the power to require an explanation

Demonstrating compliance

The CQC is developing its guidance and methodology on compliance, and will be consulting on its proposals in summer 2009. This is intended to reflect the particular and more detailed elements of how a service is run and delivered, such as the differences for a large acute hospital and a small care home. Guidance on compliance with registration requirements will be outcome-focused and based more closely on people's experiences of using the services.

In developing its compliance requirements, the CQC is required to be both appropriate and proportionate to the particular risks presented by the activity. It is also required to work closely with other regulators to minimise the burden of inspections on providers.

- enforcement, including issuing of penalty notices, cancellation of registration and the notification of other bodies on certain matters.

Regulations on the fitness of registered persons providing or managing will cover:

- the fitness of the service provider
- the registered manager
- the fitness of the registered manager
- the registered person: general requirements and training.

Detail on the fitness of the service provider and the general requirements and training of the registered person (see box below) is still subject to consultation and will be published after the consultation has ended.

Provision of information

Regulations are proposed requiring two types of information from registered providers:

- information that they must give to the CQC
- information that they must provide to people using their services more widely.

Failure to provide the required information will be an offence and may result in fines.

Regulations will set out certain information that providers must submit to the CQC. This will help to inform the CQC's work, and identify where it should be targeting its efforts on providers that warrant closer inspection or review. It will also help to assure the CQC that services are being provided and managed appropriately.

They will also set out categories of information that providers will need to submit, which the CQC will develop in further detail as part of its compliance guidance.
These include:

- circumstances where patients have suffered harm (including death) potentially as a result of a failure in compliance with registration requirements
- circumstances that seriously call into question the providers' ability to continue to provide safe and quality care, such as a serious fire, police investigations and allegations of abuse
- any changes in the way any regulated activities are carried on, or in the leadership and management that have implications for registration compliance.

The CQC will develop detailed guidance about the types of information that must be notified to the CQC and timescales.

It is recognised that the CQC must take steps to ensure that its requirements do not duplicate other existing mechanisms. For example, NHS providers are already required to notify serious incidents to the National Patient Safety Agency (NPSA). The DH is working with the CQC and NPSA to ensure the data is collected through the most appropriate body and encourage them to work together.

The type of information that providers must make available to people who use services is intended to ensure that people paying for all or part of the costs of their care or treatment have information about the terms, conditions and fees of the services provided.

Financial position

Responses to the 2008 consultation identified financial viability as a significant gap in the proposals. As a result, new regulations are proposed to introduce an additional requirement of registration, which will require all providers to maintain their financial viability in order to achieve their stated purpose. This will be important in ensuring the continuity of safe and effective services for patients.

This requirement will not apply to publicly accountable services, such as NHS providers. It is recognised that there are existing systems providing public assurance of the financial viability of these bodies.

Registered managers

All providers of regulated adult social care services and independent sector providers of health services will be required to appoint a 'registered manager,' where the registered provider is not in direct day-to-day control of the service. The CQC will also be able to determine whether any manager can be registered for more than one registered activity.

NHS providers will not be required to appoint a registered manager as NHS trust boards are already accountable to either their strategic health authority (SHA) or Monitor if they fail to ensure appropriate management of services on each of their sites.

Enforcement action

The CQC has a broad range of statutory enforcement powers set out in the Health and Social Care Act 2008, including:

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

The maximum fine that can be levied by the courts for breaches of the regulations under the Health and Social Care Act 2008 is £50,000. Offences include the failure to be registered or comply with registration requirements, providing false statements or information, and obstructing an inspector.

The regulations also allow the CQC to issue a monetary penalty notice instead of prosecution for some specified offences. This is intended to provide incentives to achieve compliance rather than damage the service provider or remove large sums of money from the care system. If the offence is committed by an individual, including registered managers, the amount is set at half the level it would be if the offence is committed by a service provider. The regulations will set out the process and timings that must be followed in issuing a fixed penalty notice.

The CQC is required to follow set processes when it takes enforcement action, which are set out in the regulations. These include formal notification of certain relevant bodies where it proposes to take action, including PCTs, Strategic Health Authorities (SHAs) and Monitor. This will usually be just the body covering the geographical area to which the enforcement action relates, but it could also be bodies wider than the local geographical area if the enforcement action relates to more systemic failures.

Registration fees

All providers will be required to pay registration fees to the CQC. The CQC will consult on these at a later date. Any proposed fee structure will have to be approved by the Secretary of State for Health.

Confederation viewpoint

Moving to the new system of registration will be a significant challenge for many NHS providers. Lessons must be learnt from the 2009 registration process for NHS providers in relation to HCAIs. Although all NHS providers registered by the deadline, some did not fully comply with the requirements and had conditions imposed on their registration. Registration will not be automatic, and NHS providers must be preparing now if they are to be registered without any restrictions or conditions by 1 April 2010.

The move to a single registration system for the NHS and the independent sector, and for health and social care, is especially welcome for certain providers as it will help to remove overlap and duplication that exists currently. For example, for independent sector providers of NHS services, the change will remove the duplication of compliance with Standards for Better Health and the National Minimum Standards under the Care Standards Act. For many NHS mental health partnership trusts or care trusts, the changes will also bring significant benefits of regulatory simplification. However, we are concerned that in the coming year there will be an element of 'double-running' as providers have still to comply with the current system and also prepare for the new system.

The NHS Confederation welcomes the steps that the DH has taken to address some of the key concerns we raised in our response to the consultation on the scope of registration and the registration requirement proposals in 2008. While some progress has been made, there are, however, still issues to address.

The revised definitions of activities that require registration are broader and offer greater flexibility to include new types of service or new settings for provision of care. This should facilitate a more dynamic approach to regulation. However, it will be vital that the DH continually monitors key areas of services and service development to ensure that emerging services are easily and speedily brought within the registration framework if necessary.

We are concerned at the continued exclusion of psychological therapies, such as counselling and psychotherapy, that are not provided as part of a multi-disciplinary team. This is likely to exclude many services provided under the Improving Access to Psychological Therapies initiative, and standalone counselling and psychotherapy services. It also fails to relate the current competence of the team to the service provided, so

while the team may include a nurse or doctor they will not necessarily be specialist mental health professionals, which may have significant implications for the quality and safety of services provided.

We recognise that developing definitions for those ambulance and patient transportation services that should be registered has been challenging. We welcome bringing private ambulance services within registration as these are playing an increasingly important role in delivering 999 and emergency care for the NHS. However, we would argue strongly that these services should be brought within regulation sooner to ensure quality and safety, and a level playing field.

The regulations will provide the broad framework for the new system of registration, but much of the detail is still to be developed by the CQC. We are encouraged that the CQC is trying to work with providers in developing these criteria, and continue to do our utmost to support this work.

The new system of registration offers a great opportunity to tackle some of the problems inherent in the current regulatory system and to reduce some of the burden on healthcare providers. Despite the obligations on the CQC to work in accordance with better regulation principles, there is still significant potential for overlap and duplication. Particular attention must be paid to children's services where there is not only potential for overlap but also for service problems to fall through the gap.

For more information on the issues covered in this *Briefing*, contact frances.blunden@nhsconfed.org

The DH consultation on the draft regulations closes on 29 May and you can respond directly at registration.consultation@dh.gsi.gov.uk

The NHS Confederation response to this consultation will be available on our website.

Further information

Response to consultation on the framework for the registration of health and adult social care providers and consultation on draft regulations. DH, 2009. www.dh.gov.uk/en/consultations/liveconsultations/DH_096991

The future regulation of health and adult social care in England: a consultation on the framework for the registration of health and adult social care providers. DH, 2008. www.dh.gov.uk/en/consultations/closedconsultations/DH_083625

The NHS Confederation

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