

Providers of NHS general practice and
other primary medical services

An overview of registration with CQC

February 2012



Contents

Introduction from Cynthia Bower and David Haslam	2
1. Background	4
2. The registration process	5
3. Key principles of registration	6
What is a provider?	
What are regulated activities?	
What is a location?	
4. The essential standards of quality and safety	13
Guidance about compliance with the essential standards	
Common questions about the essential standards	
5. Key roles required for registration	18
Provider	
Registered manager	
Who should be a registered manager?	
Nominated individual	
Fitness of providers and registered managers	
6. Other things you need to know	21
Criminal Records Bureau (CRB) checks	
Registration fees	
7. Monitoring your compliance once you are registered	23
How we will work with other regulatory bodies and organisations	
8. Keep up to date	25

Introduction

“ This overview of registration is the second piece of guidance that we have published and sent to all providers who need to register (mostly GPs and some other primary medical services such as walk-in centres). It follows on from the introduction to registration, which we sent to you in October 2011. We have produced this guide to introduce some of the key principles and concepts of the new regulatory system created by the Health and Social Care Act 2008, which aims to ensure that essential standards of quality and safety apply across both health and adult social care.



By giving you an overview of the new system, we show how you can start to prepare for registration with CQC. Although your registration has been delayed until 2013, it is important that you begin preparing now as the registration process will start in Summer 2012.

You will no doubt have further questions about how we carry out inspections once you are registered. To determine this process for providers of primary care, we're running pilot schemes in the summer to look at how we check providers' compliance with the essential standards of quality and safety once they are registered, so we'll be in a position to answer this in more detail later this year. This remains a collaborative process, and we need your help to make sure we work together to ensure the best possible care for everyone. ”

Cynthia Bower
Chief Executive

“ General practice has evolved beyond all recognition since the NHS was founded. Conditions that in the past were only treated in hospital are now part of everyday general practice. Indeed, it now has a much more complex and important role within health care, and regulation of health care that in the past only applied to hospitals now applies in primary care.

Our focus is always on the impact of care on patients, and we must ensure that all patients receive safe and good quality care, wherever that care is provided.



We are confident that the majority of practices and providers of primary care are of good quality and are already doing everything that needs to be done to be compliant with the essential standards of quality and safety. However, we also know that some of the language and terms we use regarding regulation are unfamiliar. I hope this guide helps you to understand more about how the CQC registration process applies to you and some of the key concepts that underpin how we regulate.

This guide, and indeed our whole approach to the regulation of general practice, has been informed by our consultation work and engagement both with national stakeholders and with individuals working in primary care. This consultation is not over and although we are finalising key aspects of the registration process, we still have some work to do around how we inspect providers of primary care once they are registered. ”

Professor David Haslam FRCGP
Professional Adviser to CQC

1

Background

What is CQC registration?

The regulation of primary care is being aligned with other health and social care services under the Health and Social Care Act 2008. This legislation means that providers of health and adult social care have to be registered with the Care Quality Commission (CQC).

The aim of regulation is to ensure that patients can expect all health and adult social care services to meet essential standards of quality, to protect their safety and to respect their dignity and rights wherever care is provided. We publish up-to-date information about those that we register on our website, to help the public make informed choices about health and social care services. By being registered with CQC, you can demonstrate to your patients that you are providing a service that meets essential standards of quality and safety.

When registering providers and monitoring how they continue to comply with the essential standards, we will be led by the information we have about them. We will target areas where we have concerns and act in proportion to the level of risk for patients.

When do you need to be registered by?

The Health and Social Care Act (Regulated Activities) Regulations 2010 set out different timescales for when providers from different sectors have to be registered with CQC. These regulations included time-limited exemptions for NHS primary medical services, which are defined as those that are provided using one of the following contracts or agreements:

- General Medical Services (GMS)
- Personal Medical Services (PMS)
- Alternative Provider Medical Services (APMS)
- NHS Act 2006 Section 3 (contracts with the Secretary of State).

In the initial timetable for registration, all providers of primary medical services were required to register with CQC by April 2012. However, following a Department of Health consultation, the Government has now confirmed that providers of NHS general practice and most other primary medical services do not need to be registered until **1 April 2013**.

The overall registration process will begin in **Summer 2012**, so it is important that you start to prepare now. The delay has enabled us to work closely with staff in general practice and primary care as well as national organisations, including the British Medical Association and the Royal College of General Practitioners. Their feedback has been invaluable in helping us to develop our approach to the registration of this sector and to shape the way we communicate with you.

2

The registration process

The following gives you an overview of the timeline for registration and an outline description of the registration process itself.

Registration account set-up – July 2012

We will write to you in **July 2012** and ask you to set up your online registration account. This will simply involve you providing us with basic information such as the name of your organisation or partnership, your contact details and how best we can contact you throughout the registration process.

Once you have set up your account, you will be able to access the full online application form and from this point you will be able to start filling it in. You can save and edit the form as much as you need to until you submit it. You will also be able to print the form at any time to review the details you have entered.

The application form gathers basic information about your practice such as your address, who the partners are, what you do and where you do it. The application also asks you to declare whether you are compliant with the essential standards of quality and safety (see page 13).

Application submission stage – from September 2012

When you set up your registration account in July, you will be asked to pick a 28-day 'window' between September and December 2012 in which to submit your full application form. There will be a limited number of spaces in each application window, so the earlier you set up your account, the more choice you will have.

You will only need to fill in one form to apply for registration, which must be completed online and submitted electronically before the end of your window. The form will ask you for information about all of your services.

The information you provide in the form will create the basis of your registration with CQC, so it is important that it is correct. The form is a legal document and you will be asked to declare that everything you submit is true and accurate.

Processing applications – September 2012 to March 2013

As soon as applications are submitted to us, from September 2012, we will start to process and assess them. We will let you know the outcome of your application as soon as possible.

We'll process the majority of applications quickly. There may be some applications that will need a more in-depth review and we may need to contact or visit you to obtain further information to help us make a judgement on the application.

3

Key principles of registration

CQC registers providers who carry out regulated activities at locations and we monitor their compliance with the essential standards of quality and safety.

The following pages explain the key concepts highlighted in this statement to help you to understand how they relate to NHS general practice and other primary medical services.

It is important to familiarise yourself with these concepts now and to understand how they apply to your practice in preparation for registration in 2013.

What is a provider?

Under the Health and Social Care Act 2008, any individual, partnership or organisation that carries on a regulated activity must register with CQC as a service provider.

The provider is the legal entity that is legally responsible for the regulated activities that are carried on and for ensuring that the essential standards of quality and safety are met. For general practice, we are expecting the provider usually to be a partnership or the individual GP responsible for running the practice.

It is important to register with us as the correct legal entity. You will need to tell us which type of provider you are when you set up your registration account in July 2012.

Each individual GP working in a practice does not need to register with CQC as a provider. Also, any people, including healthcare professionals, that work for a provider do not need to register separately (with the exception of registered managers, see page 18). This includes permanent or temporary employees and other salaried staff, agency staff or locums, volunteers, trainees, and people on secondment. For the purposes of registration, these colleagues are all classed as employees of the provider.

There are three types of provider and you will need to register as one of the following:

1. Partnership

If you provide a regulated activity as a partnership, it is the partnership that must register. The partnership as a whole, as well as each individual partner, is legally responsible for ensuring that the regulated activities provided meet the essential standards.

If you register as a partnership you will be asked to nominate, through the application process, one of the partners to be the key point of contact with CQC. This is not the same as a registered manager, which is described on page 18.

You should only register as a partnership if you have made arrangements for all partners to accept joint and several liabilities for the way the regulated activity is carried on, and each individual partner has agreed to this. This will normally be documented through a written agreement, but this is not a requirement for registration. A partnership that doesn't have these arrangements in place, such as one that is limited only to arrangements for expense sharing, should not register as a partnership. In this case, if each person is carrying on services as an individual without shared liability, they will need to register separately (see 'Individual' below).

For legal reasons, a limited liability partnership (LLP) should register as an organisation, not as a partnership.

2. Individual

You should register as an individual if you are a sole trader or a single-handed GP. Individuals register in their own name and are directly responsible for carrying on the regulated activity.

3. Organisation

You should register as an organisation if you are a limited company or charity, a limited liability partnership (LLP) or other corporate body.

There are many other models of service delivery that may affect how different providers should register and the following are some examples of these:

Joint ventures

Where a regulated activity is provided as a joint venture between two providers, the venture will often be a legal entity in its own right and therefore must register. Where the joint nature of the venture is reflected in contracts or agreements, rather than in organisational form, each party may need to register as a provider depending on the individual case.

For example, if a group of GP practices works in partnership to deliver certain clinical services but each maintains separate accountability for the service they deliver, they would each include this service as part of their GP practice registration. If they formed a separate legal entity to provide this service, that legal entity would need to register in its own right.

Hosting arrangements

Where an activity is carried on by provider A, but hosted by provider B, then provider A will need to register, regardless of its host.

For example, if a provider runs two walk-in centres and one of them is attached to a hospital emergency department, the walk-in centre provider must include this in its registration but the host hospital does not need to.

Renting arrangements

Where provider A rents out its facilities to provider B, then provider B will need to register in its own right if it provides a regulated activity in those facilities.

For example, where a hospital already registered with CQC rents out a room or a clinic to a GP, the GP provider will still need to register in its own right if it is providing services independently of the hospital. Equally, where a GP practice rents out a room to a midwife who provides a weekly maternity clinic, the GP practice is not the provider of the service and therefore does not have to include this in its application.

“What can I be doing now to prepare for registration?”

Look at the three main types of provider and think about which one you will need to register as. You will need to tell us which type of provider you are when you set up your registration account in July 2012.

For full details on the types of providers that need to be registered, please see our guidance: The scope of registration, available at www.cqc.org.uk/scopeofregistration.

What are regulated activities?

A 'regulated activity' is a prescribed activity related to care and treatment that needs to be registered with CQC. Regulated activities are set out in the Health and Social Care Act (Regulated Activities) Regulations 2010. It may be helpful to think of these as reflecting the services you provide.

As a provider, you only need to submit one registration application, which should include all the regulated activities that you carry on. We expect most providers of NHS general practice and primary medical services to register for more than one activity.

The 15 regulated activities are set out in legislation and have strict definitions.

- Personal care
- Accommodation for people who require nursing or personal care
- Accommodation for people who require treatment for substance misuse
- Accommodation and nursing or personal care in the further education sector
- Treatment of disease, disorder or injury
- Assessment or medical treatment for people detained under the Mental Health Act 1983
- Surgical procedures

- Diagnostic and screening procedures
- Management of 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
- Family planning services.

“What can I be doing now to prepare for registration?”

You should start to think about which regulated activities you will need to apply for. Think about all the services that you provide, including any non-NHS services, to ensure you are registered correctly.

You need to check the [Scope of registration](#) guidance and read the full descriptions and definitions of the different regulated activities on our website. This will provide detail around how the regulated activities apply to general practice and primary care.

There are some regulated activities that you may think need to be included in your application. For example, a GP practice will offer advice on contraception and family planning to patients as well as administering contraceptive injections and removing or inserting implants. However, the regulated activity ‘Family planning services’ only relates to services for the insertion or removal of an intrauterine contraception device by, or under the supervision of, a healthcare professional. So, if the practice doesn’t offer this particular service, it won’t need to apply for that regulated activity.

In addition, a GP practice, as well as other primary medical services such as walk-in centres, will employ nursing staff. However, the definition of the regulated activity of ‘Nursing care’ only covers nursing care where it is not part of another regulated activity. In most cases, activities carried out by nurses working in general practice or primary care will be covered by other regulated activities. For example, a nurse may be providing care and advice to patients with long-term conditions such as diabetes, but this activity will be covered under the activity of ‘Treatment of disease, disorder or injury’, and does not require the practice to also register for ‘Nursing care’.

In the following table, we have highlighted the regulated activities we think are most relevant to providers of NHS general practice and other primary medical services. However, this is only a brief overview of the types of care and treatment included within each regulated activity. It is your responsibility to check the definitions of the regulated activities to determine which ones you carry on and include those in your registration.

Regulated activity	Relevance to NHS general practice and other primary medical services
Treatment of disease, disorder or injury	<p>This includes any assessment and treatment undertaken by, or under the supervision of, any specified healthcare professional in relation to disease, disorder or injury. This list of healthcare professionals includes doctors, nurses and midwives.</p> <p>We expect all NHS general practice and other primary medical care providers to be registered for this activity.</p>
Surgical procedures	<p>This covers surgical procedures carried out by a healthcare professional that are for the purpose of treating disease, disorder or injury; or cosmetic surgery; or for religious observance (eg circumcision).</p> <p>The following minor surgical procedures do not trigger this activity:</p> <ul style="list-style-type: none"> • Curettage, cautery or cryocautery of warts, verrucae or other skin lesions undertaken by a medical practitioner using local anaesthesia or no anaesthesia. • Nail surgery and nail bed procedures on the foot carried out by a healthcare professional using local anaesthesia or no anaesthesia. <p>We expect some NHS general practice and other primary medical care providers to be registered for this activity.</p> <p>For example, you may be required to register for surgical procedures if you provide the 'minor surgery enhanced service'; but we would not expect the 'minor surgery additional service' to trigger this activity as it is limited to curettage, cautery and cryocautery.</p>
Diagnostic and screening procedures	<p>This includes a range of procedures related to diagnostics, screening and physiological measurement, including imaging procedures such as ultrasound. It also includes some instances of the removal of tissue, cells or fluids from the body, to diagnose disease, disorder or injury or to monitor its cause or extent. In primary medical care, this activity will be triggered by cervical screening, taking vaginal swabs, ambulatory blood pressure monitoring or the use of ultrasound. If you only perform minor diagnostic tests such as 12 lead ECG, single or repeated blood pressure checks, urine analysis or peak flow measurement, you do not need to register for this activity.</p> <p>We expect all GP practices to be registered for this activity.</p> <p>If you provide other primary medical care services, you must consider whether these may also require you to register for this activity.</p>

Regulated activity	Relevance to NHS general practice and other primary medical services
<p>Transport services, triage and medical advice provided remotely</p>	<p>This activity covers transport services where they involve a vehicle that was designed for the primary purpose of transporting people who require treatment. This excludes vehicles with a different primary purpose, such as taxis, volunteers using their private cars, or mortuary vehicles and Dial-a-Ride vehicles. We would not expect GP practices to be registered for this part of this regulated activity</p> <p>Remote advice is captured by this activity when clinical advice is given over the phone or by email and that advice is for immediate attention or constitutes triage, and it is provided by a body established for that purpose.</p> <p>As the definition highlights that the body registering must be established for the purposes of triage, we would not expect most NHS general practices to be registered for this activity. If you provide out-of-hours services to your own patient list we would not expect you to be registered for this activity.</p> <p>We expect some other primary medical care providers to be registered for this activity.</p>
<p>Maternity and midwifery services</p>	<p>This activity covers maternity and midwifery services, including ante- and post-natal care, where they are carried on by, or under the supervision of, a healthcare professional.</p> <p>We expect some NHS general practice and other primary medical care providers to be registered for this activity.</p> <p>For example, we expect GP practices that undertake the 'maternity services additional service' to be registered for this activity.</p>
<p>Family planning services</p>	<p>This activity only relates to services for the insertion or removal of an intrauterine contraception device by, or under the supervision of, a healthcare professional. It does not include contraceptive injections or insertion or removal of contraceptive implants.</p> <p>We expect some NHS general practice and other primary medical care providers to be registered for this activity.</p> <p>We do not expect a GP practice to register for this activity solely on the basis that they undertake the 'contraceptive services additional service'. This is because the contraceptive services additional service specifically excludes intrauterine contraception devices.</p>

Remember – it doesn't matter how many different regulated activities you provide – you should include them all in one registration application.

What is a location?

When you apply to be registered with CQC we will ask you to declare whether you will comply with all the essential standards of quality and safety for each regulated activity you provide at each location. To do this, you need to understand how a location is defined for registration purposes.

A location is a place in which, or from which, regulated activities are provided or managed. In our definition of a location, we count each place where people may be treated as a location if the regulated activities provided in these places are managed independently.

What does this mean in practice?

As a general rule, each separate walk-in centre, or GP-led health centre will be classed as a location. If you have a single GP practice, this will also be classed as one location.

If you have more than one GP practice, or main GP practice and branch surgeries, you will need to consider the following:

- If you have more than one GP practice, each GP practice will be classed as a location, or
- If you have GP practices that you consider to be main surgery and branch surgeries associated with the main surgery, you can include the branch surgery under the main surgery's location as long as only patients from the same registered patient list are seen or treated at these places. If the branch surgery treats patients from a different registered patient list to that of the main surgery, the branch surgery will need to be included in your registration as a location in its own right.

If you have more than one location, you only need to submit one registration application form, which should include details about all your locations.

Whether or not a branch surgery is included as a location in your registration you are still responsible for ensuring your compliance with the essential standards across all regulated activities that you provide both in your main surgery and in any branch surgeries.

4

The essential standards of quality and safety

When registered with CQC providers of health and adult social care must legally comply with two sets of regulations. These regulations describe the essential standards of quality and safety that people who use services have a right to expect. Throughout this document this is what we mean by being compliant with the essential standards of quality and safety.

There are 28 essential standards, and they are set out in the following regulations:

- Part 4 of the Care Quality Commission (Registration) Regulations 2009, and
- Parts 4 and 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

You can see a full list of the standards at www.cqc.org.uk/listofstandards.

When you apply to register, we will only ask you to make a specific declaration of compliance or non-compliance against 16 of the essential standards. These are the standards that relate most directly to the quality and safety of care and correspond to the Regulations in Part 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These 16 essential standards cover key aspects of care such as safeguarding, consent, staffing and the management of medicines.

The remaining 12 standards relate to the routine day-to-day management of a service and include certain notifications you must make to CQC once you are registered.

When making your declarations of compliance or non-compliance against the 16 essential standards, you need to consider all of the regulated activities you provide at all locations (including any branch surgeries). You do not submit evidence of your compliance to us in the application form, although we may later ask for evidence if we feel we need it to reach a decision on your registration.

The regulations allow you to be registered for 1 April 2013, even if you are not compliant with all of the essential standards.

We will not necessarily refuse your application just because you declare that you are not compliant with any of the essential standards. In most such cases, we anticipate being able to grant registration, although sometimes this may be subject to conditions.

However, if you do declare that you are not compliant with any of the essential standards, you need to submit an action plan to outline how you will achieve compliance, and by when. This action plan should be submitted as part of the application form and should be concise and succinct.

Guidance about compliance with the essential standards

To help providers understand how to comply with the essential standards, we have published a guidance document **Guidance about compliance: Essential standards of quality and safety**. This document also reproduces the relevant regulations that underpin the essential standards and is available on our website at: www.cqc.org.uk/standards. You can also use a tailored online interactive version at: www.cqcguidanceaboutcompliance.org.uk.

Our guidance about compliance describes in detail the outcomes we expect people using a service to experience when a provider is meeting the essential standards, rather than on the policies, systems and processes used to deliver care. Outcomes are the impact care has on a person's health and wellbeing, and the experience they have whilst receiving it. The outcomes relate to important aspects of care such as respecting and involving people who use services, care and welfare of patients and management of medicines. The guidance includes prompts to show how you can achieve each outcome.

Common questions about the essential standards

From our discussions with people working in primary care, Local Medical Committees and some of your representative organisations, we are aware that there are concerns around some of the requirements set out in the essential standards.

Q "Parts of the Guidance about compliance don't seem relevant to general practice and primary care – do I still use the Guidance about compliance to help determine my compliance?"

The guidance applies to all providers of health and adult social care. It aims to provide further information or "prompts" on what compliance with the essential standards might look like. It has a legal status, which means that it has to be taken into account when making decisions under the Health and Social Care Act. This means it should be taken into account by providers, as well as by CQC, when making judgements about compliance with the essentials standards.

Because the guidance is designed to apply to all the different types of providers we regulate (from a two-bed care home to a large hospital trust) not everything included in the prompts will be relevant to you.

The reason we focus on outcomes for patients is so that providers from all sectors, of all shapes and sizes can determine for themselves how the essential standards apply and how they are compliant with them, rather than us providing a checklist of things you should be doing.

Our assessors and inspectors use the guidance when making decisions about registration and ongoing compliance, what regulatory action we may need to take, and any improvement or enforcement action that may be needed.

Q "Some standards don't appear relevant for primary care."

After reviewing the Guidance about compliance you may feel that some of the detailed aspects of the standards are not wholly applicable to you. In this case, you should consider your compliance against the standard as far as it applies to your service and make a declaration of compliance as appropriate.

Of the 16 main outcomes, we would only expect this to be an issue for Outcome 5 'Meeting nutritional needs' for most NHS primary medical service providers.

Q "What should I declare for Outcome 5 'Meeting nutritional needs'?"

This outcome is only relevant where food and hydration are provided to service users or patients as part of the services provided, and this is not the case for most providers of general practice and primary care. This outcome does not include prescribing food supplements or looking after patients on Total Parenteral Nutrition (TPN).

However, this does not mean that you should declare that you are not compliant with this standard even though it may not be wholly applicable to you.

To declare that you are not compliant with this standard would indicate to us that patients may be at risk as a result of a provider not meeting patients' nutritional needs. This will not be the case with most providers of NHS general practice and other primary medical services, so if this is the case, you should declare compliance with this standard.

Q "Where is the guidance for Outcome 8 'Cleanliness and infection control'?"

Unlike all of the other essential standards, CQC is not required to produce guidance about the prevention or control of healthcare-associated infections.

The Department of Health has issued the guidance for this particular regulation *The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance*. You should refer to it when deciding whether you meet this standard. Download a copy of the Code from the Department of Health's website at: www.dh.gov.uk.



"How does Outcome 10: Safety and suitability of premises apply?"

We are aware that there are concerns about practices meeting CQC's requirements in relation to safety and suitability of premises. When considering a practice's compliance with this standard, our primary concern is that patients and staff are safe and not put at risk by unsafe premises.

Compliance with the essential standards does not mean that all primary care has to be provided in modern, purpose-built and state-of-the-art premises. But we need to be assured that the premises from which primary care is provided are safe and accessible for patients.

If there are any risks for patients as a result of issues with the premises that indicate that a practice may not be compliant with the essential standards, then we need to be assured that these risks are being managed and that a practice has taken reasonable and appropriate steps to mitigate them. We recognise that practices may achieve compliance by altering the way they work by, for example, undertaking visits to patients who are unable to access the premises.

We will only take action in relation to this standard if we feel that patients are being put at risk by unsafe premises and where practices have failed to implement necessary and reasonable changes to ensure that these risks are appropriately managed.

We are aware that there are circumstances in which providers have no control over certain elements of the premises where they provide care. However, providers do have a duty to protect patients and staff against the risks associated with unsafe premises.

For example, we know that it may be difficult to expect a practice to be able to make improvements to their premises if they are leaseholders and the landlord is refusing to improve the premises. If a practice is doing everything in its power to make sure patients are not put at risk or disadvantaged by circumstances that are outside of their control, then we would take this into consideration. We would certainly not refuse or revoke a registration unless patients are seriously at risk of harm as a result of unsafe premises.

“What can I be doing now to prepare for registration?”

Now is a good time to start thinking about your compliance with the essential standards of quality and safety. We are confident that most providers of NHS general practice and other primary medical services are already meeting most of these basic standards.

You should start to think about how you already monitor the quality and standard of your practice or service. For example, think about information and evidence you might gather for QOF, PCT contract monitoring or through involvement in any quality schemes such as the Royal College of GPs' Quality Programmes. You could also use some of this work to enable you to determine your compliance with the essential standards. We encourage you to use any information and evidence that you already gather when considering your compliance with these standards rather than duplicating work. In most cases, you will not need to reproduce any of your policies and guidance.

What does compliance mean for a GP practice?

Compliance means that the practice delivers care in a way that meets CQC's essential standards. Demonstrating compliance will mean different things for different practices depending on the way they operate, their premises and their size for example.

It is each provider's own responsibility to make sure these standards are being met – CQC's role is to check whether this is the case. Our standards are outcome-based, which means that when we inspect you from April 2013, we will check the quality of care people that are receiving and what their experience has been like. We do this largely by speaking to patients, their families and carers, and to staff, and by observing care where appropriate. When we inspect, we will be asking GPs, nurses and practice managers how you assure yourselves about the quality of care.

Our staff use our judgement framework to help them make decisions about whether a provider is compliant. It is available online at:

www.cqc.org.uk/judgement.

The judgement framework contains examples about what compliance and non-compliance may look like. These examples relate to a number of different sectors and are not specifically about primary care. We will publish some specific examples for primary care which will help you to determine whether you are compliant with the essential standards.

5

Key roles required for CQC registration

Provider

The provider is the legal entity that is legally responsible for the regulated activities that are carried on and for ensuring the essential standards of quality and safety are met.

For most general practices, the provider will be the partnership and all partners will have legal responsibility for the regulated activities and compliance with the essential standards.

The Health and Social Care Act 2008 also requires providers to nominate a member of staff to fulfil certain roles. You may need to select a member of staff to be a registered manager and/or a nominated individual.

Registered manager

A registered manager is registered with CQC to be in day-to-day management of one or more regulated activities. As a registered manager, they have legal responsibilities in relation to that position (see the Health and Social Care Act 2008 and associated regulations). Registered managers share the legal responsibility for compliance with the regulations with the provider.

The regulations require a provider to have one or more registered managers for its regulated activities if it is:

- A partnership, or
- An organisation, or
- An individual who is not personally in day-to-day charge of carrying on the regulated activities or is not fit to do so.

The registered manager application process will form part of a provider's registration. We'll provide further guidance about this later in the year.

A manager is registered for one or more regulated activities, at one or more locations. There are no restrictions on the number of regulated activities that a manager can be registered for or the number of locations they cover. You can appoint more than one registered manager at the same location if different regulated activities are managed by different individuals or if job share arrangements are in place.

Who should be a registered manager?

You should not need to employ anyone new to be a registered manager.

It is important to think carefully about who you appoint. You should remember that the registered manager:

- Has legal liabilities in relation to the regulated activities that they manage.
- Must be able to demonstrate their ‘fitness’ to carry out their role.
- Should hold a role that enables them to ensure the essential standards are being met across the regulated activities that they are registered for.

The person who you appoint as registered manager should be in day-to-day charge of carrying on the regulated activity or activities they apply to be registered for. After registration, a registered manager has a legal role in enabling and monitoring compliance with essential standards across your regulated activities.

This relationship with the regulated activities means that the registered manager should not be viewed simply as an administrative management role as they will have distinct legal requirements to fulfil.

The registered manager can be one of the partners in the partnership. They can also be the same person as the nominated individual in an organisation.

“What can I be doing now to prepare for registration?”

You can start to think about who will take on key roles both in the application process and when you are registered. Most providers of general practice and other primary medical services will need to select a registered manager.

You should not automatically assume that a practice manager is the appropriate person to be a registered manager. We are aware that the roles and responsibilities of practice managers vary significantly from practice to practice, and although in some cases it may be appropriate for a practice manager to fill this role, this may not always be appropriate.

In most cases, we anticipate that a partner is the most appropriate person for the role of a registered manager. Because a registered manager shares legal responsibility with the provider (for example, the GP partnership) they need to be in a position where they are able to influence compliance with the essential standards across the regulated activities.

Nominated individual

If you are applying for registration as an organisation, the regulations require you to nominate an individual to act as the main point of contact with CQC. A nominated individual should be someone who has responsibility for supervising the management of the regulated activity. They should be an employed director, manager or secretary of the organisation. It is up to you who to nominate, as long as they meet these criteria.

Your nominated individual can cover all or several of the regulated activities you provide. If you wish, you can have a different individual for each regulated activity. The application form will ask you to state which regulated activities each nominated individual will be responsible for.

If you register as an individual or partnership you do not need a nominated individual.

Fitness of providers and registered managers

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 require individual providers and registered managers to be able to demonstrate their personal fitness, and partnerships must be able to demonstrate the fitness of each partner. 'Fitness' means being of good character, having the necessary skills, qualifications and experience, and being physically and mentally fit to carry on or manage the regulated activities.

The registration application for a provider or registered manager asks if you can make certain information available to us to demonstrate the fitness of relevant people if we request it, for example proof of identity. The list of information is set out in Schedule 3 of the regulations.

You don't have to send this information to us or gather it in advance or at the point of making the application, but you must be able to provide it if asked.

We'll provide further information about how we check fitness during the application process later on in 2012. We recommend that you wait to receive this guidance before you prepare any of this documentation or apply for a CQC countersigned CRB check.

6

Other things you need to know

Criminal Records Bureau (CRB) checks

CRB checks as part of the registration process

When registering with CQC, the Health and Social Care Act regulations specify that the registered provider (for example the partners forming the GP partnership) and the registered manager(s) need to make a CRB check available if we request it. We usually do this by requesting that providers and registered managers apply for a CQC countersigned CRB check.

However, we will take a proportionate approach to this when registering providers of NHS general practice and other primary medical services who need to be registered by April 2013. We will accept a General Medical Council number in place of a CQC countersigned CRB check. We'll give you further information on this as soon as possible, but at this stage please do not apply for a CQC countersigned CRB check.

Compliance with the essential standards and CRB checks

Once you are registered with CQC, you are required to be compliant with the essential standards of quality and safety, which include an outcome on requirements relating to workers.

Beyond the requirements for CQC countersigned CRB checks for providers and registered managers during the initial registration process, providers of primary care are responsible for checking the suitability of their staff.

Practices have a responsibility to ensure that they carry out appropriate CRB checks on applicants for any position within the practice that qualifies for such a check. In addition to GPs, this is likely to include nursing staff and may in some circumstances also include front office reception staff, although this depends on their duties, which can vary greatly.

The requirement for a CRB check and the level of that check depends on the roles and responsibilities of the job and the type of contact the person will have with vulnerable groups. Practices themselves are required to determine which staff are required take CRB checks.

The following guidance will help you determine whether members of staff in your practice need a CRB check:

- CQC guidance for all registered providers of health and adult social care (including general practice/primary care): www.cqc.org.uk/crb.
- NHS employment check standards published by NHS employers: www.nhsemployers.org/RecruitmentAndRetention/Employment-checks/Employment-Check-Standards/CriminalRecordChecksStandard/Pages/CriminalRecordChecks.aspx.

Registration fees

There is no 'joining' fee when providers or registered managers apply to be registered. However, providers will be required to pay an annual registration fee once they are registered to cover the costs of our work. This requirement applies to all providers that are registered with us.

Later in 2012, we will consult on our proposals for the registration fees that will take effect for all providers from April 2013, including GP practices and other primary care providers. The proposals will aim to make the fees charged to individual practices and providers of primary care fair and proportionate across all sizes and types of provider. We will provide you with further details about this at the relevant time and encourage you to respond to this consultation.

7

Monitoring your compliance once you are registered

After you are registered, we will monitor whether you continue to meet essential standards.

We do this in a way that centres on the views and experiences of patients, focusing primarily on outcomes, as well as on policies and processes. By outcomes, we mean the experience patients have when they receive care and the impact that it has on their health and wellbeing; this includes clinical outcomes and ensuring that people are safe.

What this means in practice is that when we inspect your service we will usually focus on checking compliance with the essential standards by talking to patients and to staff. If we have any concerns or if we need to explore anything further, we may ask to see documentary evidence.

We are currently developing our methods of monitoring compliance within general practice and primary care. This will explore how we work with other regulatory bodies such as PCTs (the NHS Commissioning Board and Clinical Commissioning Groups in the future). It will test the appropriate length of notice we give before an inspection and how we can use sources of data and information to help us identify risk within providers.

We will be conducting pilot inspections with different types of primary care providers in Summer 2012. These will test our proposed methodology and help ensure that our final approach to inspection is appropriate for providers in this sector.

We will publish further information about what happens once you are registered at a later date.

Under the Health and Social Care Act, CQC has a range of enforcement powers that we can use to ensure providers of health and adult social care meet the essential standards of quality and safety. Any enforcement action we take will be proportionate to the risks posed to people who use services and the seriousness of any breach of the law.

How we will work with other regulatory bodies and organisations

Working with NHS organisations

As you will be aware, the NHS is currently being reformed and reconfigured (subject to the passing of the Health and Social Care Bill).

CQC works with a number of organisations to minimise the risk of poor quality care. As the NHS is reconfigured, we are exploring the ways in which we will work with other regulatory bodies, such as Monitor as well as other organisations with a role to play in commissioning services or ensuring quality in services.

We are currently developing our approach to monitoring and inspecting providers of NHS general practice and primary care, and are working with the NHS Commissioning Board and Clinical Commissioning Groups to explore how we can work locally with them. We'll give you more information on this as soon as we can.

Working with professional regulators

We work closely with the General Medical Council and other professional regulators such as the Nursing and Midwifery Council.

The GMC registers individual doctors to practise medicine in the UK while CQC regulates providers and checks the organisation's compliance with essential standards. It is important that we work closely with the GMC to ensure that the appropriate body responds to concerns about the quality of care and treatment, and we have a memorandum of understanding with the GMC to ensure that this happens.

Whichever body responds always depends on the specific circumstances of each case. However, in general, if we came across an individual GP who is putting patients at risk through poor practice, we would refer this to the GMC. If we believed that the impact of this meant that the practice as a whole was providing care that fell below the essential standards of quality and safety, we would consider taking further actions under the Health and Social Care Act 2008.

8

Keep up to date

Throughout the registration process we'll keep in touch with you in a number of ways:

- Through monthly bulletins.
- Through our provider reference group with live Q&A sessions.
- By attending and speaking at key events and conferences.

Our new website

We have recently re-launched our webpages for providers of NHS general practice and other primary medical services. These will be updated regularly with important information about registration, and will include guidance and tools to help you through this process www.cqc.org.uk/register.

Registration events

We will also be hosting a number of events across the country in May and June. We encourage you to attend these events as they will help you to understand more about registration with CQC and what you need to do. If you can't attend, we'll make sure that you can get the information in other ways, for example, we'll record our presentation and post it on our website. Look out for further details.

Later this year, we will produce detailed guidance to help you to understand:

- How to complete the application form.
- How we will inspect and monitor your compliance with the essential standards.

Get a copy of our **Guidance about compliance: Essential standards of quality and safety**. You can:

- Download from our website at www.cqc.org.uk/standards.
- Use the interactive online version at www.cqcguidanceaboutcompliance.org.uk.
- Order a hard copy from our publications line on 0870 240 7535.

How can you be involved?

- Join our **provider reference group** at www.cqc.org.uk/prg.
- Volunteer to take part in our **compliance pilot** – pmscompliance2012@cqc.org.uk.
- Sign up for our **new e-bulletin** at www.cqc.org.uk/newsletter.

If you have read this guide but you now feel you do not fit the criteria for a provider that needs to be registered by April 2013 and you should already be registered, please contact us using the details below.

Need help?

If you have any questions about registration or you need more information, you can:

Look at our website: www.cqc.org.uk/register

Call our customer services on: **03000 616161** (press option 3 for registration, then option 2 for enquiries about primary medical services).

Email us at: 2012registration@cqc.org.uk

Write to us at:

CQC HSCA Registration
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Please contact us if you would like a summary of this document in another language or format (for example, in large print, in Braille or on audio CD).

CQC-179-15000-STE-022012

