

A new system of registration

Guide to applying: Providers of primary dental care services



About the Care Quality Commission

The Care Quality Commission is the independent regulator of health and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities, private companies or voluntary organisations, we make sure that people get better care. We do this by:

- Driving improvement across health and adult social care.
- Putting people first and championing their rights.
- Acting swiftly to remedy bad practice.
- Gathering and using knowledge and expertise, and working with others.

Introduction

This guidance will help you to understand the new system of registration and the application process, including the key stages, dates, details about who needs to register and what to include in your application.

The Health and Social Care Act 2008 introduced a new, single registration system that applies to both healthcare and adult social care.

From 1 April 2011, providers of primary dental care services in England that carry on ‘regulated activities’ – in both the NHS and the private sector – must be registered with the Care Quality Commission. See page 7 for our definition of a ‘provider’.

To be registered with us, a provider must show that it is meeting new essential standards of quality and safety in all of its regulated activities. The new regulations are set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

For a general introduction to the new registration system, please read our booklet *Guide for providers of primary dental care services* available from our primary dental care web pages at www.cqc.org.uk/dental. For detailed guidance on who has to be registered and which activities are regulated, please read our document *The scope of registration*, available at www.cqc.org.uk/scopeofregistration.

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Preparing to apply

Primary dental care providers will need to apply for registration between mid November and the end of December 2010. Wherever possible, you should complete your application online. Providers can only apply by electronic 'Word' form or on paper in exceptional circumstances.

You will need to decide who is going to complete your application and determine the 'locations' from which you operate. If you intend to register as an organisation, you will also need to nominate an individual to represent your organisation. This person will be our main point of contact with you. Finally, for each location from which you operate, you will need to ensure that the person responsible for the day-to-day running of the service is registered with us. There is more detailed information about all these points further on in this booklet.

To support you in the application process, we have also published the following guidance on our website:

- *Guidance about compliance: Essential standards of quality and safety*: this tells you what providers must do to meet the new essential standards (www.cqc.org.uk/standards). The guidance document also reproduces the relevant regulations.

Alternatively, you can use our online interactive version, which enables you to collect and print out the guidance that applies to your particular types of service: www.cqcguidanceaboutcompliance.org.uk.

- *The Judgement framework*: this sets out the way we judge whether a provider is compliant with the regulations. You will see that it has a strong focus on checking whether providers involve people in the development of services, ensure that their voices are heard, and that they respect people's dignity and rights. The judgement framework includes case studies from different service types and outlines how our approach will be targeted and proportionate to levels of risk (www.cqc.org.uk/judgement). We are also producing case studies that are specific to providers of primary dental care services, which you can find on the same web page.

Before making your online application, you should:

- Familiarise yourself with the regulations and with the guidance listed above.
- Check your clinical governance systems.
- Prepare the evidence that shows that you meet each of the essential standards of quality and safety.
- Decide who you will appoint as nominated individual(s) and registered manager(s).

Your application form

We will provide your application form online and will give you your own log-in and password details so that you can apply. The application process will be open from mid November 2010, but we will ask you for certain pre-application information before then. If you are unable to access the registration application form online, you will need to tell us so that we can make other arrangements.

Please note:

As a provider, it is your responsibility to ensure that you register and you must make sure that you do so, even if you have not received notification from us.

Each provider must make a single registration application, covering all of its regulated activities that are carried on at all of its 'locations'. (See pages 15 and 18 for information on regulated activities and locations.)

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Applying for registration

All providers are responsible for ensuring that they submit a complete and accurate application for registration. You should consider all the requirements carefully and check that the information you declare is correct.

When to submit your application

We will let you know the dates of when to submit your application and the amount of time you have to do so. These application windows will fall between mid November and the end of December 2010. Submitting your application within your window will help us to process all applications as quickly as possible. It will also give you protection against prosecution for providing regulated activities after 1 April 2011 while unregistered, in case we are unable to make a decision about your application by this date.

If we receive your application after the last day of your application window, we will continue to process it, but we cannot guarantee that we will have reached a decision about registration by 1 April 2011. If we have not reached a decision by 1 April because of a late application, the offence of carrying on a regulated activity while unregistered **will apply** from that date. This means that you could be left operating without being registered, which is an offence, or you might have to cease to operate until your registration has been completed.

Please note: we expect to receive a vast number of applications and we will only assess those received after the end of the window when we have completed all applications that were submitted on time.

If we hold your details, we will let you know your application deadline. However, as we do not have addresses for some new and private providers, we cannot guarantee to notify all providers of primary dental care. It is your responsibility to make sure that you register even if you have not received notification from us.

The application form

The provider and each registered manager will need to complete application forms. The provider's application form includes sections asking for your details as a provider, the services and regulated activities you provide and the locations at which you will provide them.

You will also need to declare that you comply with the regulations for each regulated activity in each of your locations, make a statement on data protection, and declare that you hold the specific information required for your nominated individual(s). See page 15 for more information about regulated activities.

The form also contains sections asking you how your organisation makes sure that it listens to and acts on the views and experiences of people who use services, and actively promotes equality, diversity and human rights. We will be publishing detailed guidance on filling in your application form on our website in due course.

What is a 'provider'?

We will register the provider who is legally responsible for the service. There are some differences in how registration works for different types of provider. The legal provider may be:

- An individual, or
- An organisation, or
- A partnership.

Usually, the type of provider you are is clear, but in some cases you may need to consider this in more detail. This happens particularly when a number of dentists come together in an expense-sharing arrangement and may refer to each other as 'partners' or 'a partnership', but there is no actual formal partnership agreement. There can also be confusion where 'associates' work in a clinic but they are not actually employed by that provider. We explain this in more detail on the next page.

It is your responsibility to declare what type of provider you are, and to ensure that your application for registration is accurate. It is not our responsibility to research a provider's status.

Partners

A partnership must have a formal partnership agreement that includes agreement to share liabilities and profits: this is a key way of differentiating between a legal partnership and informal arrangements to share expenses. Even if expense sharing arrangements are referred to informally as 'partnerships' in everyday language, they do not usually count as legal partnerships unless they have an agreement that includes shared liability and profits.

Please note that for legal reasons, a limited liability partnership (LLP) should register as an organisation, not as a partnership.

Associates

If you are a provider who is not in a legal partnership and you allow other dentists or dental professionals to assess or treat patients as part of the practice (whether or not they are informally referred to as 'associates', 'partners' or some other term), for the purposes of registration they will be regarded in the same way as employees of the provider. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 define employment to include employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract, or the grant of practising privileges.

If you use this associate model, you must make sure that there are suitable arrangements in place for granting permission to the associates to see patients as part of the practice. Such arrangements must meet the requirements set out in Outcome 12 of the essential standards, “Requirements relating to workers”. While the individual associates will still have professional accountability and clinical responsibility for the patients that they treat, you will have responsibilities relating to the overall provision of service, of which the associates are part.

Nominated individual

If you are applying for registration as an organisation, you must nominate an individual to act as the main point of contact with us. A nominated individual must have responsibility for supervising the way the regulated activity is managed and must be in a suitably senior role, such as a director or senior manager of the organisation they represent. Providing the person that you nominate meets these criteria, it is up to you to decide who it should be.

You can nominate one individual to cover all or several of the regulated activities you provide, or different individuals for each regulated activity. The application form will ask you to state which regulated activities each nominated individual will be registered for. You must consider this person’s ability to fulfil the responsibility of supervising the management of each regulated activity for which they are nominated.

Before you submit your application to register, you must have applied for an enhanced Criminal Records Bureau (CRB) disclosure for your nominated individual and be able to confirm that you have done this in your application. Please see page 13 for further information about applying for CRB disclosure.

During the application process, and when you are registered, you must have available the information about your nominated individual that is set out in Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (reproduced on page 254 of our *Guidance about compliance: Essential standards of quality and safety*). This includes items such as proof of identity, qualifications and evidence of conduct. Although you do not need to send this information with your application and we will not routinely ask to see the documentation, you must have it available if we need to do so. The application form also tells you what information you must have available.

If you are an individual or a partnership (other than a limited liability partnership), you are not required to appoint a nominated individual. However, the information that we need from you as individuals or partners is the same as that for a nominated individual. The requirements for an enhanced CRB check apply to each individual or partner involved.

Registered manager

If you are applying to register as a partnership or an organisation, the person who is responsible for managing the day-to-day delivery of the service must also register with us as a registered manager. If you are applying as an individual, you do not usually need to have a separate registered manager, unless you do not intend to be in full-time day-to-day charge of running and managing the regulated activities, in which case the person who will manage the service must apply to be a registered manager.

You should submit an application for a registered manager at the same time as the provider's application. You can download the registered manager's application form from our website.

The person who you appoint as manager, and who must apply to us for registration, must be in full-time, day-to-day charge of the regulated activities they apply to be registered for. The registered manager does not need to be a dentist but must hold a sufficiently senior role within the organisation or partnership, or at the practice, to be able to effectively ensure that the standards of quality and safety are met. A registered manager shares the legal responsibility for compliance with the provider. In order to register a manager, we must be assured that the applicant is competent to manage all aspects of the regulated activity.

There is a difference between the roles of nominated individual and registered manager: the nominated individual has responsibility for supervising the way the regulated activity is managed, while the registered manager is the person who is actually managing the regulated activity on a day-to-day basis.

A person can be both a registered manager and a nominated individual, but they are very different roles under the legislation and the individual will need to be able to demonstrate that they are able to fully and responsibly fulfil both.

Before you submit an application to register a manager, you must have obtained an enhanced Criminal Records Bureau (CRB) disclosure (see page 13 for further information). You must also have information such as proof of identity and qualifications available for each registered manager. Please see the list of information and documentation required on the registered manager application form or in Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

A registered manager must indicate the regulated activities that they are applying to be registered for. Providers will usually, but not always, appoint a different registered manager for each location or clinic. There can be more than one registered manager at the same location if, for example, different regulated activities are managed by different individuals. In some cases, a manager may apply to be registered to manage regulated activities at more than one location. Please bear in mind that, in all cases, the registered manager must be able to demonstrate how they will manage the day-to-day running of the regulated activities at each of the locations that they are

applying to be registered for. There is separate guidance on our website for registered managers who are responsible for more than one location.

Each registered manager will be required to complete a separate application form.

Applying for Criminal Records Bureau (CRB) disclosure

Unless you already hold a PCT countersigned enhanced CRB check before you submit your registration application, you must have applied for an enhanced CRB disclosure for the following key people:

- Yourself, if you are applying as an individual, or
- The nominated individual of an organisation (or a limited liability partnership), or
- All partners in an ordinary partnership.

You will be asked to confirm that you have done this in your application.

You must also have applied for an enhanced CRB disclosure for each registered manager.

We are aware that there may be a delay in actually obtaining the disclosure certificate and you may therefore submit your provider's registration application to us as long as you have **applied** for the disclosure. (Please note that we will not be able to finalise the determination of your application and issue a notice of our decision until we have received and assessed the significance of any disclosure.)

Where you are required to have a registered manager, you should **not** submit his or her application until you have received their disclosure certificate from the CRB. If this delays a registered manager's application beyond 1 April 2011, it would not prevent your registration as a provider, but the registration would be subject to a compliance condition that requires you to submit an application for a registered manager within a prescribed period of time.

You must arrange for the CRB application(s) to be countersigned by a CQC authorised signatory. We have arrangements with the Post Office to undertake all checks on CRB application forms of nominated individuals and registered managers. There are 27 Crown Post Offices that offer this service. See our website for further information about their locations and how to get the CRB application form:
www.cqc.org.uk/crb.

If you already have a PCT countersigned enhanced CRB certificate, we will not ask you to produce another for your application to register as a provider. This applies to individual providers, partners in a partnership and nominated individuals. In all other cases, including all registered manager applications, the CRB application must be countersigned by us and we will not accept an existing disclosure certificate countersigned by someone else.

The enhanced level of check takes into account the new vetting and barring scheme. Please see the CRB website for more information:
www.crb.homeoffice.gov.uk.

Statement of purpose

On your registration application you will need to confirm that you have a statement of purpose. You don't need to submit it with your application but after registration we will ask you to send it in to us. We may also ask to see it if we carry out a site visit. The statement of purpose is a document that tells us the aims and objectives of your organisation, the kinds of services you provide and the locations at which you provide them. It should, of course, agree with the statements you make in your application for registration. After you are registered you will need to inform us whenever you change your statement of purpose.

We have published a template and guidance on how to prepare a statement of purpose. This is available on our website: www.cqc.org.uk/statementofpurpose. Details of what must be included in your statement of purpose are also set out on page 142 of the *Guidance about compliance: Essential standards of quality and safety*.

Which activities should be registered?

Most providers of primary dental care services will provide one, two or all three of the following regulated activities:

- Treatment of disease, disorder and injury – this will cover any assessment and treatment undertaken by a dentist or certain other dental care professionals.
- Diagnostic and screening procedures – this will cover, for example, the use of X-rays.
- Surgical procedures.

A small number of primary dental care providers may also carry on other regulated activities. It is your responsibility as a provider to ensure that you apply for the correct regulated activities and register all services for which you are accountable. If you provide the service described in a regulated activity – even when under exclusive contract to the NHS or another registered provider – you will normally need to register.

If you provide regulated activities in, or from, more than one location, you will need to state in which locations you provide each regulated activity (see page 18 for information on locations). The full list of regulated activity categories is:

- 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.

For detailed information on regulated activities, please read *The scope of registration*, available at www.cqc.org.uk/scopeofregistration, and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

What is a 'location'?

A location is the place in which or from which regulated activities are provided. You may only provide services from the locations you specify in your registration. In general, we define locations so that each place where people may be admitted (for example, as an inpatient or as a resident) or treated (for example, a walk-in centre, a primary medical or primary dental practice) counts as one location. For other services, we either define the location as:

- The head office, or
- The area that each registered manager is responsible for.

For most primary dental care providers, a location will be a dental practice. Where any outreach services such as school-based dental services are offered, these would also be covered by registering the practice from which they are offered. In a small number of cases, community-based services would need to be registered under a head office address if they are not part of the services of a particular dental practice.

The definition of location is important because, in a single application, you will need to declare compliance with each regulated activity at each location. Monitoring this declaration is an important part of how we make judgements about a provider's continuing compliance with the essential standards of quality and safety.

You can find more information about locations on our website at www.cqc.org.uk/locations.

Declaring compliance with the regulations

In your application, you will be asked to declare whether or not you are compliant with each of the essential standards of quality and safety for each regulated activity you provide at each location. We will monitor your compliance against this declaration as part of our decisions about your registration status.

To help you decide about your compliance, you need to take account of our *Guidance about compliance: Essential standards of quality and safety* (www.cqc.org.uk/standards). To navigate your way around the essential standards, you will find it helpful to decide which 'service type(s)' your activities fall under. Service types are different from regulated activities. Details of the different service types are included in the essential standards. Most providers of primary dental care will fall within 'Dental Services'. Once you have determined which service type(s) applies to you, you can download a version of the guidance that only includes the prompts that apply to your particular types of service at www.cqcguidanceaboutcompliance.org.uk.

The regulation that deals with the prevention and control of healthcare-associated infections is one of the regulations that form the essential standards of quality and safety. We have not produced guidance about compliance with this regulation, because the Department of Health issues the guidance in *The Code of Practice for health and adult social care on the prevention and control of infections and related guidance*. This is available from the Department of Health's website (www.dh.gov.uk) and also includes decontamination requirements, such as HTM 01-05. You will need to use this to help you make your decisions about compliance with that regulation.

It is important to consider compliance in terms of the outcomes and experiences of people using your services. You may find that this is different to other monitoring systems that you have experience of. This means that when you consider evidence in the form of policies, procedures and systems, you should think about them in terms of the impact they have on people's outcomes and experiences.

Your own auditing, monitoring, benchmarking against other services, feedback from PCT commissioners and other inspection activity, and feedback from patients are all examples of outcome evidence that you may be able to use in deciding whether or not you are compliant.

Declaring non-compliance

Because this is the first registration of services already in existence, the application form allows providers to declare non-compliance with any of the regulations for any of the regulated activities that they are carrying on. Where you declare that you are not currently fully compliant, you must submit an action plan detailing what you will do to become compliant and the date by which you will do it. We will include information about action plans in the guidance on filling in your application form that we will publish on our website in due course.

You will need to consider carefully whether you should declare compliance or non-compliance, assessing your services against the regulations. We have provided prompts in the *Essential standards of quality and safety* to help you. It is worth noting that you are not legally required to comply with each of the prompts. It is the regulations that you must comply with.

If your service can show evidence that it meets all the prompts for an outcome in the essential standards, you can confidently declare that your service is compliant for that outcome. If there are some prompts that you don't meet, you will need to consider what the regulation actually requires you to do and whether you can show evidence in some other way that you meet that requirement.

All outcomes apply to all service types. It is not within CQC's power to exempt any provider from any part of the legal requirements. You may question how Outcome 5: "Meeting nutritional needs" applies to providers of primary dental services. In order to consider this, it is useful to look at the regulation, reproduced on page 76 of the *Essential standards*, as well as the outcome, set out on page 77. You will see that the regulation sets out the requirements in situations where food and hydration are provided to people. For example, a provider determines whether planned treatment is likely to have any impact on a patient's ability to eat or drink if any specific needs are identified, and has a plan in place of how to meet those needs. The provider must make a judgement, and be ready to explain and justify it.

For some providers, Outcome 5 may not be applicable – for example where people who use services are not required to fast prior to receiving treatment. In this case, providers are advised to declare non-compliance against that particular outcome and insert the reasons why they consider the outcome not to be applicable in the action plan template provided.

Where there is evidence of non-compliance (whether you declare it or not) and the non-compliance is expected to continue after 1 April 2011, we may register you subject to compliance conditions. Non-compliance is a serious issue and we expect it to be resolved by the agreed date to avoid us having to take compliance or enforcement action against you.

Declaring non-compliance does not necessarily mean that your registration will be subject to compliance conditions. We will assess the risk to people using your services and, if the risk is low and you can show that you are taking appropriate steps to become compliant within a relatively short period of time, you may for example only be asked to confirm when you have completed your action plan. The guidance used by our inspectors to assess the risk of the need for compliance conditions is on our website from our primary dental care web pages at www.cqc.org.uk/dental.

Registration fees

Existing providers do not have to pay a 'joining' fee for coming into the new system. However, an annual fee will apply from April 2011.

We will consult on proposals for fees in late 2010. Until then, fees for other providers (NHS trusts, independent hospitals and clinics, and social care providers) are being set on an interim basis and are not benchmarks for future fee levels.

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How we assess applications

Your application will be screened by our Shared Services Centre, and assessed by our regional teams alongside any other information available to us on your service.

We will let you know if we need any additional information to support your application. We may also wish to speak to you or visit some or all of your services. Our activities will be targeted and proportionate. We are more likely to carry out a site visit or request more information from you if we hold little information about your service from other sources. We may also ask for information from third party organisations, including patients and their representatives.

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Our decision

Our registration team will use our *Guidance about compliance* and *Judgement framework* to help make their decision.

We will either:

- Register you without compliance conditions, or
- Register you with compliance conditions, or
- Refuse all or part of your registration.

Some conditions will be routine. For example, they may specify that you can only carry out a regulated activity at a particular location, or if you only offer specific planned clinical services and not emergency services, they may record that this is the extent of your 'treatment' activities. These are called **restrictive conditions**.

Where we have concerns about non-compliance, we may attach conditions that require you to make improvements to your service in order to meet the essential standards of quality and safety. These are called **compliance conditions**.

If we approve your application, we will issue a notice of decision. If you do not agree with our decision (including any conditions we impose), you can make representations to us within 28 calendar days.

If we propose to refuse your application, we will send you a notice of proposal. You will also have 28 days to make written representations if you disagree with our proposal. We will send a final notice of decision either after the representations have been considered, or after the 28-day period has expired.

If you are still not happy, you will have the right to appeal to the independent First-tier Tribunal. You can find further information about this on the website of the Tribunals Service at www.carestandardtribunal.gov.uk.

Services that do not comply with the essential standards of quality and safety

We want providers to make accurate declarations. If your service does not comply with the essential standards of quality and safety, you will need to submit an action plan to address the situation that details what you are going to do, and when you will do it by. We will consider your action plan alongside any other information we hold to make a decision about whether to register your service, with or without conditions. If a provider recognises its non-compliance and is already taking steps to address the problem, we will be proportionate in our response.

If we discover non-compliance and you have declared compliance, we will respond accordingly and take action that is proportionate to the level of concern we have identified. This may mean taking formal enforcement action.

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After you are registered

When your service becomes registered, we will send you an electronic registration certificate.

The certificate will outline the details of the organisation, the regulated activities you are registered to provide and the locations from which these are provided. If the registration has conditions applied, they will be described on the certificate.

We will publish the register of providers on our website and keep it up to date. The register will describe each provider, the date of registration and any conditions applied.

All providers have a responsibility to inform us if they want to make any changes to their registration.

If you want to provide a regulated activity at a new location – for example, carry on the same activity but move to a new building – you must apply to us for a variation of your existing registration.

If you want to offer a new regulated activity, you must apply to us for a new registration in respect of that activity.

If your organisation changes, for example, because of a merger or acquisition, it is likely that the new organisation will need to re-register.

After 1 April 2011 you will need to pay a fee to vary your existing registration or to make a new application. We will provide more information on our proposed approach to fees in a fees consultation document later this year.

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Need help?

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

- Look at our website: www.cqc.org.uk/dental
- Speak to your **local assessment team**
- Call our National Contact Centre on **03000 616161**
- Email us at enquiries@cqc.org.uk
- Write to us at:
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