May 2012

# CQC registration – what you need to know

Guidance for GPs

BMA

# CQC registration – what you need to know

## Contents

## PART 1: INTRODUCTION

From July 2012, most primary medical services providers will be invited to apply for registration with the Care Quality Commission (CQC), and will need to be registered by April 2013. The purpose of this guidance is to provide a straightforward explanation of the registration process, to help providers determine whether they are compliant with the CQC's essential standards, and to explain what will happen once providers are registered.

The registration of the majority of primary medical services providers was delayed last year. During this period, the GPC has been in discussions with the CQC about how their essential standards will apply to these providers. There has been general agreement on the need to be proportionate, both in the registration process itself and in the monitoring of compliance following registration. We will continue these discussions with the CQC. We are still of the view that the essential standards for general practice could be fulfilled and demonstrated through a practice's current contractual commitment as outlined in the GMS contract, together with most PMS and APMS arrangements. However, given the legal requirement for primary medical services providers to be registered with the CQC by April 2013, and the commencing of the process leading to registration in July 2012, we have produced this guidance to aid GPs with the process.

This guidance is mainly aimed at providers of NHS general practice who have to register by April 2013. However, other primary medical services providers, including those out of hours providers who had to register by April 2012, may find parts of it useful.

**Please note**: This document should be treated and used as **guidance only**. You should consider the individual circumstances of your provider(s) on all occasions including before making declarations. Equally if there is any legislation or standards not mentioned in this guidance that your provider(s) should be compliant with, you should still comply with that legislation and those standards.

The BMA excludes all liability and has no responsibility for individuals failing to register their practice correctly or at all, or any action taken by CQC, including remedial action, enforcement action and penalties, or action taken by any other body against individuals and/or providers that have used this guidance.

## PART 2: EXPLAINING REGISTRATION

### What is CQC Registration?

According to the CQC, the aim of CQC registration is to ensure that patients can expect all health and adult social care services to meet essential standards of quality.

The regulation of primary care is now being aligned with that of other health and social care services under the Health and Social Care Act 2008. All primary medical services providers will therefore have to be registered with the CQC by April 2013.

### What is the timeline for registration?

The government recently delayed the registration of most primary medical services providers, meaning that the majority of providers are required to be registered by April 2013. The exception to this is Out of Hours primary medical services providers that are not GP practices looking after their own registered patients, who had to register by April 2012. Further information about this is provided in the CQC's *Scope of Registration* guidance.

While most primary medical services providers have to register by April 2013, the overall registration process for those providers begins in **July 2012**.

You can find a full timeline for registration in the CQC's *Overview of Registration* guidance. However, this is summarised below.

*July 2012: Registration Account Set-up*

The CQC will write to you in July 2012 and ask you to set up an online account. This will involve providing the CQC with basic information like the name of your organisation and contact details, but you will also be able to access the full online form and start filling it in.

If you do not receive a letter then you can contact the CQC on 03000 616161.

*From September 2012: Application Submission*

When you set up your online account, you will be asked to pick a 28 day "window" between September 2012 and December 2012 for submitting your application form. There are a limited number of spaces in each window.

*September 2012 – March 2013: CQC processes applications*

The CQC will start to process applications as soon as they are submitted, and have said that they will provide feedback as quickly as possible.

### Who has to register with the CQC?

The Health and Social Care Act 2008 requires all providers that carry out regulated activities to be registered with the CQC. From April 2013 this will include all primary medical services providers.

## What is a provider?

In the terminology of the CQC, a provider is the legal entity that is legally responsible for the regulated activities that are carried out and for ensuring that the essential standards of quality and safety are met. A provider can either be a partnership, individual GP or organisation.

It is important to note that as it is providers that are required to register with the CQC, individual GPs and other practice staff should not register separately. Also, a provider can be the legal entity responsible for more than one GP practice; in this case the different practices should not be registered under separate applications. Each practice premise will often be classed as a separate **location** under the same application, although that is not always the case. Further guidance on this is provided under the "What is a location" section below.

When you register with the CQC, you have to tell them which type of provider you are – a partnership, individual or organisation.

1. *Partnership*

For CQC registration, a partnership is in place where arrangements are in place for all partners to accept joint or several liabilities for the way regulated activity is carried out, and all members of the partnership have agreed to this.

The obvious example of an arrangement for joint or several liabilities is a partnership agreement. The BMA has a partnership agreement drafting service that can be contacted on **020 7383 6128** or emailed at info.pds@bma.org.uk.

If you do not have arrangements for joint or several liabilities in place then you cannot register as a partnership and you and your partners will need to register as individuals. A Limited Liability Partnership should register as an organisation rather than a partnership.

2. *Individual*

You should register as an individual if you are a single-handed GP. Single handed GPs register in their own name.

3. *Organisation*

An organisation is a registered company, charity, limited liability partnership or other body corporate.

It is your responsibility to declare what type of provider you are, and to ensure that your application for registration is accurate. If you register incorrectly then this could result in criminal penalties. Therefore if you are uncertain we advise that you contact the CQC or BMA. You can also find further guidance about this in the CQC's *Overview of Registration* guidance.

## What is a registered manager?

A registered manager is registered with the CQC to be in day-to-day management of one or more regulated activities.

If you are applying for registration as a **partnership** or an **organisation**, you are required to have at least one registered manager. If you apply as an **individual**, you do not need to have a registered manager, unless you are not in day-to-day charge of running and managing the regulated activities.

If you have more than one location then you may have to consider appointing more than one registered manager if one person cannot be in day-to-day charge of all of the regulated activities across the locations. You can also choose to have more than one registered manager at one location, if there is a job share arrangement in place or if different regulated activities are managed by different people.

The registered manager application will form part of the same process and be on the same form as the provider application, but will need to be completed by the registered manager. The CQC have said that they will provide further details on this later in the year.

**Who should be your registered manager?**

You will need to make your own decision about this. However, it is important to bear in mind that, as stated above, your registered manager(s) needs to be someone who is responsible on a day-to-day basis for the management of the regulated activities at the locations you register. After registration, a registered manager also has a legal role in enabling and monitoring compliance with essential standards across your regulated activities.

For this reason, we believe that for most providers it will be appropriate for a partner to be the registered manager, although in some cases you may decide that it is more appropriate for a practice manager to take this role. The registered manager role should certainly not be viewed simply as an administrative management role, due to the legal responsibilities involved.

**What is a nominated individual?**

If you apply for registration as an organisation, you are required to nominate an individual to act as the main point of contact with the CQC. A nominated individual has responsibility for supervising the way that the regulated activity is managed. 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.

You can nominate one individual to cover all or several of the regulated activities you provide, or different individuals for each regulated activity.

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

**What are regulated activities?**

By April 2013, all primary medical services providers will need to be registered with the CQC to provide regulated activities. Therefore when you apply for registration with CQC you must specify which regulated activities you provide. The legal wording for the regulated activities can be viewed in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

There are 15 regulated activities that can trigger the need to register with CQC. The full list of regulated activities is:

1) Personal care
2) Accommodation for people who require nursing or personal care
3) Accommodation for people who require treatment for substance misuse
4) Accommodation and nursing or personal care in the further education sector
5) Treatment of disease, disorder or injury
6) Assessment or medical treatment for people detained under the Mental Health Act 1983
7) Surgical procedures

8) Diagnostic and screening procedures
9) Management of supply of blood and blood derived products
10) Transport services, triage and medical advice provided remotely
11) Maternity and midwifery services
12) Termination of pregnancies
13) Services in slimming clinics
14) Nursing care
15) Family planning services

It is expected that you will need to register for more than one regulated activity. You can find further information about this in the CQC's *Overview of Registration* guidance. Regardless of how many regulated activities you register for, you should register them all in one application.

**What is a location?**

A location is a place in which, or from which, regulated activities are provided or managed. In practical terms, this would commonly mean a GP surgery, walk-in centre, etc.

In the CQC's definition of a location, they count each place where people may be treated as a location if the regulated activities provided in these places are managed independently.

In practice, this generally means that each separate GP surgery, walk-in centre, etc will be classed as a location. If you have a single GP practice, this will also be classed as one location.

However, if you have a main surgery and branch surgeries associated with the main surgery, you can include the branch surgeries under the main surgery's location. This is the case as long as only patients from the same registered patient list are seen or treated at all of these places. If the branch surgery treats patients from a different registered patient list to that of the main surgery, it 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.

**What does the application form look like?**

One of the areas that the GPC and CQC have been discussing during the registration delay is the logistics of the registration process. The GPC has been keen to ensure that the application form is as user-friendly as possible, and has been represented on the CQC's Stakeholder Advisory Group, which has provided input into the content and functionality of the form.

In general, the form will ask for information on the areas covered in this guidance such as what type of provider you are, which regulated activities are being provided and declarations of compliance or non-compliance against the CQC's essential standards. Further details on this will be given when providers are invited to set up an online account in July 2012.

**What is the fee for registration?**

There is no fee for applying for registration before 1 April 2013 but there is an annual fee for being registered (akin to a subscription fee).

The fees for primary medical services providers registering in 2013 have not yet been set. There will be a consultation on these fees later in 2012. The GPC will make a robust response to this consultation, as we have for previous consultations on CQC fees. We have been clear in previous consultation responses that GPs should not be expected to bear the cost of the CQC's

activity, and have lobbied for the GP element of the CQC's costs to be funded directly by the government.

The CQC have recently confirmed the fees for out of hours providers registering by April 2012. The fee for a provider with one location is £800, with this increasing according to the number of locations that a provider has. For example, a provider with 2-3 locations would have their fees set at £1600.

## PART 3 – COMPLIANCE WITH THE CQC'S ESSENTIAL STANDARDS

### What are the CQC's essential standards?

As part of your application to the CQC, you will need to declare whether you are compliant with the regulations that underpin the CQC's main 16 Essential Standards of Quality and Safety for the regulated activities that you provide.

The Essential Standards are the CQC's conversion of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and Care Quality Commission (Registration) Regulations 2009 into patient outcomes. For the purposes of this guidance, standards and outcomes should be viewed as being interchangeable terms. To elaborate on the outcomes, CQC created prompts that provide further detail on the outcomes that patients should have.

Regulation 26 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 requires you to take account of the outcomes and prompts. These outcomes and prompts can be viewed in the CQC's *Guidance about Compliance: Essential Standards of Quality and Safety.*

### What is the relationship between the essential standards and my registration application?

When you apply to register, the CQC will 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 the care you provide.

The remaining 12 standards relate to the routine day-to-day management of a service and include certain notifications you must make to the CQC once you are registered. You will not need to declare compliance with these standards when you apply for registration, but you are still required to meet the outcomes. Information about these standards is provided in Appendix A.

### What happens if I declare non-compliance against any of the standards?

The regulations allow you to be registered for 1 April 2013, even if you are not compliant with all of the essential standards. Your declaration forms the basis of your legal registration with the CQC so it is important that your declarations are true and honest.

It is highly unlikely that the CQC will refuse your application just because you declare that you are not compliant with any of the essential standards. They have said that they anticipate being able to grant registration in the majority of cases, 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 will need to submit an action plan to outline how you will achieve compliance, and by when. This action plan will need to be submitted as part of the application form and should be concise and succinct.

### How do I know whether I am compliant with each of the standards?

In this part of the guidance, we will provide suggestions and examples about how you can decide whether you are compliant with each of the 16 essential standards.

It is important to note that these are **only suggestions**. We believe that most providers will already be compliant with the essential standards. If you believe that you are already compliant

with an essential standard but are not following our suggestions then you should not feel obligated to follow them, or declare non-compliance. CQC registration should not involve the development of large numbers of new policies and protocols.

To help you further, we have included links to relevant policies and guidance. We have also, on occasion, referred to the example policies and protocols in Appendix B of this guidance. You can modify these for use in your practice.

**Outcome 1: Respecting and involving patients**

*This outcome reflects the requirements of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- understand the care, treatment and support choices available to them;
- can express their views, so far as they are able to do so, and are involved in making decisions about their care, treatment and support;
- have their privacy, dignity and independence respected;
- have their views and experiences taken into account in the way the service is provided and delivered.

Those acting on behalf of patients:

- understand the care, treatment and support choices available to the patients;
- can represent the views of the patients by expressing these on their behalf, and are involved appropriately in making decisions about their care, treatment and support.

This is because practices will:

- recognise the diversity, values and human rights of patients;
- uphold and maintain the privacy, dignity and independence of patients;
- put patients at the centre of their care, treatment and support by enabling them to make decisions;
- provide information that supports patients, or others acting on their behalf, to make decisions about their care, treatment and support;
- support patients, or others acting on their behalf, to understand the care, treatment and support provided;
- enable patients to care for themselves where this is possible;
- encourage and enable patients to be involved in how the practice is run;
- encourage and enable patients to be an active part of their community in appropriate settings.

*Your patients should understand the treatment options available to them, be involved in the decisions about their care, respected and be able to influence the way you provide primary medical services.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Involves patients in their care; for example, by establishing patients needs, preferences and decisions and providing information about the available care, treatment and support options so that patients can make informed decisions.

- Provides care with due regard for the patients' age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

- If patients lack capacity to make their own decisions, it follows procedures based on the guidance in the BMA's Mental Capacity Act Toolkit.

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- Knows when to arrange for a patient representative, with the representative being involved in assessment, planning and decisions about the patient's care.

- Maintains, respects and manages the privacy of all patients and their records.

Your practice has the following:

- A chaperone policy.

- A confidentiality and consent policy (see **Appendix B1** for an example confidentiality protocol).

- Information from surveys suggesting that patients feel involved in their care

- A patient participation scheme.

- Records that explain when a patient's preferred treatment cannot be followed (e.g. because their choice would place others at risk of harm, or because services are unavailable).

- A leaflet containing information about your practice's services. An example of such a leaflet is provided in **Appendix B2**.

**Outcome 2: Consent to care and treatment**

*This outcome reflects the requirements of Regulation 18 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- where they are able, give valid consent to the examination, care, treatment and support they receive;
- understand and know how to change any decisions about examination, care, treatment and support that has been previously agreed;
- can be confident that their human rights are respected and taken into account.

This is because practices will:

- have systems in place to gain and review consent from people who use services, and act on them.

*Your patients should be able to make valid consent decisions and you should know how to respond when a patient lacks the capacity to give consent.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Understands and promotes good practice on consent for adults, children and young people.

- Provides information to patients on the care and treatment options available (including the risks and benefits of each option) before they make consent decisions

- Understands how written consent should be recorded and when it should be taken, i.e. when:

i) a treatment or procedure is complex, or involves significant risks;
ii) the procedure involves regional anaesthesia or sedation;
iii) providing clinical care is not the primary purpose of the procedure;
iv) there may be significant consequences for the patient's employment, social or personal life;
v) the treatment is part of a project or programme of research.

- Carries out a regular review of consent decisions to take into account the changing needs of patients

- Can identify when a patient lacks capacity to make their own consent decisions. In those circumstances we suggest that your staff follow the guidance in the BMA's *Mental Capacity Act Toolkit*.

- Identifies patients who are **under 16 years old**. In those circumstances we suggest that your staff follow the guidance in the BMA's *Children and Young People Toolkit*.

Your practice has the following:

- A consent policy. You could use the Department of Health's *Model policy for consent to examination or treatment* and modify it for your practice. Your staff can also refer to the DH's *Reference guide to consent for examination or treatment*.

- Information about your consent procedures on display/available (e.g. a practice notice/leaflet).

**Outcome 4: Care and welfare of patients**

*This outcome reflects the requirements of Regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.

This is because practices will:

- reduce the risk of patients receiving unsafe or inappropriate care, treatment and support by:
  - assessing the needs of patients;
  - planning and delivering care, treatment and support so that patients are safe, their welfare is protected and their needs are met;
  - taking account of published research and guidance;
  - making reasonable adjustments to reflect patient's needs, values and diversity;
  - having arrangements for dealing with foreseeable emergencies.

*Your patients receive care and treatment that is safe and based on an assessment of their needs.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Establishes or reviews the individual health needs and risks of all patients when they have an appointment so that they can plan and/or deliver the appropriate treatment.
- Offers newly registered patients a health check with a healthcare assistant, practice nurse or a GP within six months of registration and provides on request a consultation for any registered patients aged 16-75 that have not attended a consultation in three years.
- Has patient plans for care (or similar) that patients (or their representatives) are involved in planning as appropriate and reviewed on an appropriate timescale.
- Provides lifestyle information to patients when appropriate (see **Appendix B3** for a lifestyle information protocol).
- Conducts regular significant event reviews and analyses and learn from incidents, errors and near misses. We suggest that if there is an adverse event or error during a patient's treatment you offer an apology and give a full explanation of what happened in accordance with paragraph 30 of *Good Medical Practice* guidelines.
- Observes its local incident reporting procedure
- Arranges for patients to be transferred to the appropriate service when a patient becomes/is seriously ill at your practice

Your practice has the following:

- A protocol for reviewing and acting on correspondence, reports and investigation results. An example protocol can be seen in **Appendix B4**.

- A procedure for disseminating the latest national/local clinical guidance, medical device alerts and safety alerts to staff. An example protocol can be viewed in **Appendix B5.**

- A business continuity plan in place to ensure that the needs of patients are met during and after a non-medical emergency (e.g. a power cut). You may wish to refer to NHS Connecting for Health's example business continuity plan.

- Appropriate policies for training reception and other practice staff in respect of dealing with emergencies and seriously ill patients, including resuscitation and anaphylaxis training and procedures.

**Outcome 5: Meeting nutritional needs**

*This outcome reflects the requirements of Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- are supported to have adequate nutrition and hydration.

This is because practices:

- reduce the risk of poor nutrition and dehydration by encouraging and supporting people to receive adequate nutrition and hydration.
- provide choices of food and drink for patients to meet their diverse needs, making sure the food and drink they provide is nutritionally balanced and supports their health.

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 primary care providers.

However, the CQC have said that this does not mean that you should declare that you are not compliant with this standard if it is not applicable to you. To declare that you are not compliant with this standard would indicate to the CQC 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 primary medical services providers so in this case you should declare compliance with this standard.

**Outcome 6: Cooperating with other providers**

*This outcome reflects the requirements of Regulation 24 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- receive safe and coordinated care, treatment and support where more than one provider is involved, or they are moved between services.

This is because practices:

- cooperate with others involved in the care, treatment, and support of a patient when the provider responsibility is shared or transferred to one or more services, individuals, teams, or agencies;
- share information in a confidential manner with all relevant services, individuals, teams, or agencies to enable the care, treatment, and support needs of patients to be met;
- work with other services, individuals, teams, or agencies to respond to emergency situations;
- support patients to access other health and social care services they need.

*You should share information and work with other providers appropriately to ensure that the needs of patients are met.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Discusses with patients the options and arrangements for referral

- Includes in correspondence all of the information that would reasonably be required to treat the patient safely and effectively. For example:

  i) the patient's name, gender, date of birth, home address and NHS Number, where known;
  ii) if applicable, the name and contact details of the patient's representative;
  iii) relevant information about the care and treatment provided to date;
  iv) relevant medical history, allergies, prescribed drugs and patient preferences;
  v) infections that need to be managed (if relevant);
  vi) the reason for the referral and what is required;
  vii) By whom the referral is made and, where different, the person to contact in your practice about the patient and their contact details.

- When a patient leaves your practice, transfers the relevant information to the new provider(s) in a timely manner so that the needs of patients can be met in an appropriate timescale

- In the case of children and patients without the capacity to give consent, ensures that their parents/guardian/representatives are involved and informed about referral decisions.

- When referring patients, ensures that patients know at least what type of information is being transferred.

- Respects the right of patients to request information about them to be transferred to another provider unless there is a good reason for not doing so.

Your practice has the following:

- An emergency preparedness plan including arrangements for sharing information and working with other providers. In the BMA/RCGP/DH's pandemic flu guidance there are model arrangements for working with other providers during long term incidents e.g. a buddying-up system.

- When cooperating with other providers/referring patients, arrangements that ensure that information is transferred and received safely and securely. To underpin this we suggest that you have a confidentiality protocol/information governance protocol that refers to information disclosures (see **Appendix B1).**

- A protocol for acting on correspondence and results, to ensure that your staff are able to respond in a timely manner to incoming information.

**Outcome 7: Safeguarding patients (children and adults) from abuse**

*This outcome reflects the requirements of Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- are protected from abuse, or the risk of abuse, and their human rights are respected and upheld.

This is because practices will:

- take action to identify and prevent abuse from happening in a service;
- respond appropriately when it is suspected that abuse has occurred or is at risk of occurring;
- ensure that Government and local guidance about safeguarding people from abuse is accessible to all staff and put into practice;
- understand how diversity, beliefs and values of people who use services may influence the identification, prevention and response to safeguarding concerns;
- protect others from the negative effect of any behaviour by people who use services.
- where applicable, only use Deprivation of Liberty Safeguards when it is in the best interests of the person who uses the service and in accordance with the Mental Capacity Act 2005.

*Your staff should be in a position to identify abuse and act appropriately in cases of alleged or suspected abuse.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Ensures that staff have had safeguarding training, if appropriate to their role, so that they can recognise the signs of possible abuse

- Takes appropriate action to protect patients in the event that any member of staff exploits a vulnerable adult or child in any way. Healthcare professionals at your practice should be reported to the GMC/Nursing Midwifery Council/HPC in cases where they are in possible breach of their professional guidelines. Performers should be reported to the relevant PCT.

- Ensures that patients can raise concerns and make complaints related to abuse. We suggest that you have a mechanism for patients to make comments and a publicised complaints procedure.

- Shares relevant information with other providers, in accordance with local safeguarding procedures, when there are safeguarding concerns about a patient.

- Complies with the Vetting and Barring Scheme:

    - Practices that knowingly employ someone who is barred to work with children or vulnerable adults will be breaking the law.
    - Practices that dismiss or remove a member of staff/volunteer from working with children and/or vulnerable adults (in what is legally defined as regulated activity)

- Practices are under a legal duty to notify the ISA of relevant information, so that individuals who pose a threat to vulnerable groups can be identified and barred from working with these groups.

Further information about the Vetting and Barring scheme can be found on the BMA website. Information about the referrals process can be found on the Independent Safeguarding Authority website.

Your practice has the following:

- A safeguarding children (child protection) policy. You could base your practice procedures on the BMA's *Child Protection Toolkit* or the RCGP's *Safeguarding Children and Young People* Toolkit for general practice.

- A safeguarding adults policy. Here is an example of a local safeguarding adults policy.

- A patient information leaflet about abuse, containing information on what patients should do if they have suspicions that another person has been abused and what they might expect to happen under safeguarding procedures, is available in your practice. An extensive range of patient information leaflets can be accessed at:

  - The BMJ Evidence Centre webpage;

  - The *Patient UK* website.

**Outcome 8: Cleanliness and infection control**

*This outcome reflects the requirements of Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

To meet this outcome you should observe *The Code of Practice for health and adult social care on the prevention and control of infections and related guidance for primary medical care*.

The relevant sections of the document are Part 3 and Appendix D.

*You should take the necessary steps to reduce the risk of healthcare-associated infections, other infectious diseases, injury and contamination to staff and patients.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Produces an annual statement, including a summary of:

  i) any infection transmission incidents and any action taken (If necessary these incidents should be reported in accordance with your local incident reporting procedure);

  ii) an infection control audit and actions taken;

  iii) at least one Infection Protection & Control risk assessment;

  iv) staff training;

  v) any review and update of policies, procedures and guidance.

- Furnishes premises having regard to national guidance and where possible and reasonable adapts rooms in accordance with risk assessments.

- Publishes up-to-date information in your practice on your IPC programme, staff roles and responsibilities, and current infection issues.

- Has a mechanism for patients to make comments/give feedback/raise concerns about your infection and prevention control and makes changes to practice as a result of this feedback if appropriate.

- Provides advice and treatment to any patient that has an infection and assesses whether there are any communicable disease control issues, consulting local infection control experts or referring the patient for specialist treatment if necessary.

- Ensures that everyone working in the practice understands the need to work to prevent and control infections in their daily work.

- Takes appropriate precautions when a patient is suspected or known to have a transmissible infection.

- Ensures that staff have access to an occupational health service that is commissioned by the PCT and receive appropriate advice on immunisation (i.e. Hepatitis B) according to their role and duties from the service. We suggest that you document your staff's immunity.

Your practice has the following:

- A designated infection prevention and control (IPC) lead, and a lead for ensuring appropriate cleaning of the practice environment and decontamination of practice equipment (they can be the same person).

- An infection prevention and control policy. An example of an IPC policy can be viewed in **Appendix B6.**

- A decontamination policy. An example of a decontamination policy can be viewed in **Appendix B7**.

**Outcome 9: Management of Medicines**

*This outcome reflects the requirements of Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- will have their medicines at the times they need them, and in a safe way.
- wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

This is because practices:

- handle medicines safely, securely and appropriately.
- ensure that medicines are prescribed and given by people safely.
- follow publish guidance about how to use medicines safely.

*You handle and prescribe medicines safely and appropriately. This includes all medicines held on your premises. If you have a dispensing practice then you will need to handle and dispense medicines safely and appropriately.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Takes account of the following when prescribing medicines to patients:

a) age;

b) patient preference;

c) lifestyle of the patient;

d) the cultural and religious beliefs of the patient;

e) allergies;

f) existing medical conditions and prescriptions;

g) history of adverse drug reactions;

h) recommended prescribing regimes.

- Observes the prescribing requirements of the contract governing the services it provides. The BMA has *Prescribing in general practice* guidance.

- Stores all medicines on the premises appropriately and securely e.g. at the right temperature.

- Provides information to patients about the medicines that they are dispensing/prescribing including any risks such as side effects.

Your practice has the following:

- A repeat prescribing policy that covers conducting medication reviews. An example of such a policy can be viewed in **Appendix B8**. However, your repeat prescribing policy should be specifically designed for your practice.

- A procedure for disseminating and acting on local/national clinical guidance, Medicines and Healthcare products Regulatory Agency (MHRA) alerts, national and local formularies and patient safety alerts to staff (see **Appendix B5**).

- Medicines handling procedures that cover the following that are appropriate for your practice: obtaining, storing, prescribing, dispensing, preparation, administration and disposing of medicines.

- A controlled drugs standard operating procedure (SOP) at your practice. The Department of Health's *Safer Management of Controlled Drugs: Guidance on SOPs* can be referred to for advice. This procedure should cover sharing concerns about mishandling and investigations of adverse events, incidents and errors.

**Outcome 10: Safety and suitability of premises**

*This outcome reflects the requirements of Regulation 15 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- Are in safe, accessible surroundings that promote their wellbeing.

This is because practices:

- Make sure that patients, staff and others know they are protected against the risks of unsafe or unsuitable premises by:
  - the design and layout of the premises being suitable for carrying out the regulated activity;
  - appropriate measures being in place to ensure the security of the premises
  - the premises and any grounds being adequately maintained
  - compliance with any legal requirements relating to the premises
- Take account of any relevant design, technical and operational standards and manage all risks in relation to premises.

*Your premises should be safe and secure, and you should manage risks created by their design and layout. The key to this outcome is to recognise risks and manage them. Where possible, make adjustments that are reasonably practical.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- As much as appropriate, has premises that reflect the Department of Health's Health Technical Memoranda. These memoranda can be viewed if you register with http://www.spaceforhealth.nhs.uk. Registration is free for NHS GPs;

- As much as is reasonably practical, meets the requirements of the:

  i) Health and Safety at Work etc Act 1974;

  ii) Management of Health and Safety at work regulations 1999; (Amendment 2006)

  iii) Control of Substances Hazardous to Health Regulations 2002;

  iv) Regulatory Reform (Fire Safety) Order 2005;

  v) and any related health and safety legislation.

  To do so we advise you follow the Health and Safety Executive's (HSE) *Introduction to Health and Safety* guidance and use the template policy.

As part of your compliance with this legislation you should conduct a health and safety risk assessment. We suggest using the HSE's *Five steps to risk assessment guidance* and template.

- When an issue cannot be resolved, seeks to manage those risks. For example, if you are unable to secure funding to make reasonable improvements to your premises to meet the above requirements from the PCT that controls premises funding then we suggest you consider managing that risk by displaying appropriate information (e.g. alternative practices, how to access support), providing appropriate support to patients or adjusting how you use different parts of your premises.

- Takes into account of the needs of patients by having a mechanism for patients to make comments about your premises and acting on appropriate suggestions.

- For the benefit of staff and patients:

a) has appropriate arrangements in place for the collection, classification, segregation, storage, handling, treatment and disposal of healthcare waste;

b) ensures that medical gas cylinders and pipe lines are installed, maintained and serviced in accordance with the manufacturer's instructions and any safety alerts related to them;

c) has a maintenance procedure, a person responsible for organising premises maintenance in response to risks that arise and a maintenance record.

- Ensures that any electrical, heating, safety and building facilities comply with statutory requirements and the manufacturer's instructions.

Your practice has the following:

- Premises that meet your contractual requirements. In the case of GMS practices, your premises should meet, subject to any outstanding arrangements under the Schedule 6 (or equivalent) of the GMS contract, the minimum requirements of the Premises Costs (England) Directions 2004 that can be viewed in Appendix 1 of the BMA's *Future of GP practice premises* guidance;

- A business continuity plan in place to ensure that the needs of patients are met during and after a non-medical emergency (e.g. a power cut). NHS Connecting for Health have produced a business continuity plan that you could use.

- Premises that are reasonably accessible to all patients and where reasonably practicable meet the requirements of the Equality Act 2010 regarding disabled people. Under the Act there is a duty to make reasonable adjustments to your premises for disabled people to be able to use your services. The Equality and Human Rights Commission's starter kit provides further information on the Act.

- Clear information about your fire evacuation procedures and other similar emergencies for patients on display.

- Information for staff about what to do in an emergency in your induction/staff handbook/induction pack.

- Toilet and breast feeding facilities, including facilities for disabled people, if feasible and appropriate in your practice premises.

**Outcome 11: Safety, availability and suitability of equipment**

*This outcome reflects the requirements of Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings);
- benefit from equipment that is comfortable and meets their needs.

This is because practices:

- make sure that equipment is suitable for its purpose, available, properly maintained, comfortable, used correctly and safely and promotes independence;
- follow published guidance about how to use medical devices safely.

*You will need to have and use equipment in a way that is safe, suitable and comfortable for patients.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Ensures it has sufficient equipment for carrying out regulated activities that:

  a) is safe and suitable to use. We suggest that you have a system in place to ensure regular and appropriate inspection, calibration, maintenance and replacement of equipment including a named maintenance lead, a maintenance record, pre-planned schedules and a procedure for reporting faults;

  You may wish to refer to the Health and Safety Executive's *Maintaining portable electrical equipment in offices and other low risk environments* guidance.

  b) is installed, used, cleaned/decontaminated and maintained in accordance with the manufacturer's instructions, legislation and guidance from expert bodies;

  c) is stored safely and securely to reduce risks and prevent theft.

- Addresses any concerns about the safety of equipment being used in a timely manner.

- Conducts risk assessments of equipment and acts appropriately when risks are identified

- Ensures that all staff using equipment have had adequate training and know what to do if a patient refuses to allow the use of equipment

Your practice has the following:

- A business continuity plan such as that produced by NHS Connecting for Health.

- Equipment required for medical emergencies available and accessible on the premises, and in tamper proof packaging.

- A procedure for the dissemination of and acting on medical device alerts and national guidance as appropriate to the primary care setting and regulated activities provided (see **Appendix B5**).

**Outcome 12: Requirements relating to workers**

*This outcome reflects the requirements of Regulation 21 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- are safe and their health and welfare needs are met by staff that are fit, appropriately qualified and physically and mentally able to do their job.

This is because practices:

- have effective recruitment and selection procedures in place;
- carry out relevant checks when employ staff;
- ensure that staff are registered with the relevant professional regulator or professional body where necessary and are allowed to work by that body;
- refer staff that are thought to be no longer fit to work in health and adult social care, and meet the requirement for referral, to the appropriate bodies.

*You should have and recruit staff that are able to meet the needs of your patients.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Recruits staff that have:

  a) the necessary skills, experience and evidence of relevant qualifications and training;

  b) demonstrated that they are legally entitled to work in the UK both from a professional and an employment viewpoint;

  c) provided proof of identity;

  d) given the name of two referees who can give references from previous recent employment;

  e) given reasons for their last position ending;

  f) provided their employment history, with a satisfactory written explanation of any gaps in employment;

  g) if appropriate to the role they will be carrying out, undergone a criminal record bureau check. The CQC's *Overview of Registration* guidance provides further information about this in Chapter 6.

  We believe that much of this information can be gathered from a CV/application or at the interview stage.

  - Recruits healthcare professionals that:

a) are appropriately registered with their professional regulator (GMC/Nursing Midwifery Council/HPC) for the role they will carry out;

b) are not subject to any form of suspension;

c) have provided two referees willing to give clinical references relating to two recent posts as a healthcare professional which lasted for three months without a significant break (or where this is not possible, a full explanation and alternative referees).

d) are not on a Independent Safeguarding Authority barred list.

- Unless contractual exemptions apply, ensures that the GPs it recruits are on a Performers List in England

- Conducts a fair and equal recruitment process that does not discriminate against **any** individuals. We advise that you are observant of the Equality Act 2010 when recruiting staff (see the Equality and Human Rights Commission's guidance)

- Follows NHSE's guidance in only asking for information about candidates' physical or mental health conditions after making a conditional offer.

- Ensures that staff review their skills and knowledge as part of appraisal or in house review.

Your practice has the following:

- A recruitment policy, including the need to comply with the Equality Act 2010. An example of this can be viewed in **Appendix B9**.

- Procedures in place for when staff:

a) are not well enough to work, including appropriate access to and use of occupational health support;

b) behave outside of your policies or professional codes of conduct;

c) are subject to investigations;

d) are suspected to have caused harm or risk of harm to patients;

e) require support to carry out their job.

**Outcome 13: Staffing**

*This outcome reflects the requirements of Regulation 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- are safe and their health and welfare needs are met by sufficient numbers of appropriate staff.

This is because practices:

- make sure that there is sufficient staff with the right knowledge, experience, qualifications, and skills to support patients.

*You should have adequate staffing of your practice at all times to meet the needs of your patients.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Is able adjust staffing to respond to unexpected circumstances such as sickness, vacancies and unpredictable short and long term events such as a flu pandemic.

- Is able to change staffing in reaction to expected changes such as an expansion of the services provided or planned absence.

- Ensures that staff are able to contact senior or supervisory staff.

Your practice has the following:

- An appropriate number of staff with the appropriate knowledge, qualifications, skills, and experience to perform the services you provide to patients (and meet their needs) at the relevant times, including unexpected circumstances such as sickness and vacancies.

- A staffing policy, an example of which can be viewed in **Appendix B10**.

- A recruitment policy an example of which can be viewed in **Appendix B9**.

**Outcome 14: Supporting workers**

*This outcome reflects the requirements of Regulation 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- are safe and their health and welfare needs are met by competent staff.

This is because practices:

- ensure that individual members of staff are properly supported to provide care and treatment to people who use services;
- ensure that individual members of staff are properly trained, supervised, and appraised;
- enable members of staff to acquire further skills and qualifications that are relevant to the work they undertake.

*Your staff should receive adequate support and training to be able to competently care and treat patients.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Provides an induction for new staff.
- Ensures that all staff are appraised on a yearly basis, including the identification of development objectives that reflect the needs of patients.
- Ensures that staff are competent, trained and on the appropriate parts of their register to carry out their roles, and supports staff in taking appropriate training.
- Ensures that staff have a readily available line manager or supervisor that they can talk to about any issues openly and honestly.
- Makes reasonable adjustments to allow staff to perform their role when necessary and appropriate

Your practice has the following:

- Procedures in place for when staff are subject to violence, bullying or harassment from patients or colleagues.

**Outcome 16: Assessing and monitoring the quality of service provision**

*This outcome reflects the requirements of Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- benefit from safe quality care, treatment and support, due to effective decision making and the management of risks to their health, welfare and safety.

This is because practices:

- monitor the quality of service that patients receive;
- identify, monitor and manage risks to patients who use, work in or visit the service;
- get professional advice about how to run the service safely, where they do not have the knowledge themselves;
- take account of:
  - comments and complaints;
  - investigations into poor practice;
  - records held by the service;
  - advice from and reports by the Care Quality Commission.
- improve their service by learning from adverse events, incidents, errors and near misses that happen, the outcome from comments and complaints, and the advice of other expert bodies where this information shows the service is not fully compliant;
- have arrangements that say who can make decisions that affect the health, welfare and safety of people who use the service.

*You should gather information on the services you provide and review how it can be improved.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Collects and reviews information about its services for the purpose of quality improvement through:

a) having a mechanism for patient feedback/comments;

b) having a publicised and robust complaints procedure for handling complaints from patients, which complies with the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009;

c) conducting clinical audits (such as those required for the Quality and Outcomes Framework- see the BMA/NHSE QOF guidance). The RCGP has extensive guidance on conducting clinical audits.

d) conducting regular significant event reviews and analyses. The National Patient Safety Agency has guidance on conducting significant event audits and analyses. There is also guidance on significant event reviews in the BMA/NHSE QOF guidance. A template form for significant event reports can be viewed in **Appendix B11**;

e) conducting risk assessments as and when appropriate. The Health and Safety Executive has guidance on conducting risk assessments;

f) collecting information related to misconduct investigations of its staff.

- Creates an environment where staff feel able, on a confidential basis if necessary, to raise concerns about risks to patients or staff

- Circulates and acts on clinical guidance, medical alerts and safety alerts and any other relevant local or national reports (see **Appendix B5**), so that staff change their working practices, if necessary, for the benefit of patients.

**Outcome 17: Complaints**

*This outcome reflects the requirements of Regulation 19 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients or patient representatives:

- are sure that their comments and complaints are listened to and acted on effectively;
- know that they will not be discriminated against for making a complaint.

This is because practices will:

- have systems in place to deal with comments and complaints, including providing patients with information about that system;
- support patients or others acting on their behalf to make comments and complaints;
- consider fully, respond appropriately and resolve, where possible, any comments and complaints.

*You should have effective arrangements in place for patients to make complaints and comments.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Ensures that complaints are investigated in a proportionate and sufficiently thorough manner, and by appropriate staff (preferably someone not involved in the events leading to the complaints).

- Allows patients to make general comments / suggestions about how the practice's service could be improved, as well as complaints.

- Deals with all patients in a fair and equal way, regardless of whether they have made a complaint.

- Advises patients of their right to refer a complaint to the Parliamentary and Health Service Ombudsman if they are dissatisfied with the outcome of your investigation.

Your practice has the following:

- A complaints procedure that is publicised on the practice premises and complies with the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009. An example of a complaints procedure can be viewed in **Appendix B12.**

- A person responsible for handling complaints.

- Full records of complaints, including a documented audit trail of the steps taken and the decisions reached on each investigation.

**Outcome 21: Records**

*This outcome reflects the requirements of Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients can be confident that:

- their personal records including medical records are accurate, fit for purpose, held securely and remain confidential;
- other records required to be kept to protect their safety and wellbeing are maintained and held securely where required.

This is because practices:

- keep accurate personalised care, treatment and support records secure and confidential for each person who uses the service;
- keep those records for the correct amount of time;
- keep any other records the Care Quality Commission asks them to in relation to the management of the regulated activity;
- store records in a secure, accessible way that allows them to be located quickly;
- securely destroy records taking into account any relevant retention schedules.

*You should keep and store accurate and up to date records securely and confidentially so that you can provide effective care and treatment to patients.*

**Your practice is likely to be compliant if:**

Your practice does the following:

- Updates patient records at the same time as the events they are recording or as soon as possible afterwards

- Makes a note of important points from discussions with patients in their records

- Observes the *Good Practice Guidelines for general practice electronic records version 4.*

- Follows the requirements of the Data Protection Act 1998 and Freedom of Information Act 2000 when a patient requests access to their records. The BMA has guidance on patients accessing health records.

- Follows the Department of Health's Records Management NHS Code of Practice (Part 2)

Your practice has the following:

- A confidentiality protocol or an information governance protocol. You can find an example confidentiality protocol in **Appendix B1.**

## PART 4: MONITORING COMPLIANCE & ENFORCEMENT POWERS

### How will the CQC monitor compliance with their standards after I am registered?

The CQC is currently developing its methods of monitoring compliance within general practice. We are currently in discussions with them about how they will do this, and they have agreed on the need for their methods to be proportionate and appropriate. They will also be carrying out a pilot in the Summer, to test how their model of compliance monitoring will work in primary care.

However, one of the ways in which they will monitor compliance is a site visit. These will generally be planned, with some notice given to the provider. One of the things that will be tested in the CQC pilot is the length of notice given before carrying out such a visit. The visits will not involve simply assessing whether the provider has certain protocols and policies in place, but also whether staff understand and implement them. The CQC have said that the vast majority of their inspectors' time will be spent talking to staff and patients, rather than examining files and protocols.

The CQC might carry out an unannounced review if the local inspectors have concerns about the quality and safety of care. This could be triggered by specific information that they have received. There is a process in place allowing providers to appeal if they have concerns about the outcome of a visit.

The CQC is also likely to monitor compliance by gathering information from patients, public representative groups, agencies and regulators, and publicly available data sources, as well as information from the provider themselves.

### What happens after the information from my practice has been analysed?

Once the CQC compliance inspector has analysed all the information they have gathered then they will make a judgement about whether you meeting the regulations with reference to their *Guidance about Compliance: Essential Standards of Quality and Safety* and their *Judgement Framework.*

We believe that most primary medical services providers will meet the essential standards. If there is an issue that can be resolved quickly and easily, the CQC may simply discuss it with you.

Under previous rules, if you were meeting the Essential Standards, but the CQC had concerns that you may not continue to do so in the future, they were able to set an 'improvement action' and ask you to send a report to them stating how you will make improvements.

The CQC have recently announced changes to these rules. The changes remove the category of "compliant with improvement actions" and mean that providers are simply to be judged as compliant or non-compliant. If you are non-compliant with a regulation, the CQC will assess the impact of this on patients, judging the impact to be minor, moderate or major. Their assessment of the level of impact on patients will help to determine their response.

If you are **not** meeting the Essential Standards, the CQC will take some regulatory action. The circumstances and the impact of the non-compliance on patients will be used to determine what action the CQC takes; either issuing a 'compliance action' or taking enforcement action.

If the CQC issues a 'compliance action' you will be required to send a report to them, stating how you will make the necessary improvements. If the CQC is not satisfied with this report, or that you have made these improvements, then they may decide to take enforcement action.

**What enforcement action can the CQC take?**

The enforcement action that the CQC can take ranges from issuing a warning notice, which demands compliance within a given timescale, to cancellation of registration, which prevents the provider from carrying out regulated activities. The enforcement action that they take depends on the circumstances that they are dealing with. The process is described in detail in the CQC's *Enforcement Policy*.

As part of their Enforcement Policy, the CQC have published an "Enforcement Escalator", setting out the different types of action they can take, when they will take it and what each action means. This is reproduced below:

| | Type | When to use | Aim of use | Next step if aim is not achieved (or other action where more appropriate) |
|---|---|---|---|---|
| **Formal regulatory action** | Compliance action | First breach/offence with minor impact<br><br>First breach/offence with moderate impact | To gain an acceptable report and achieve compliance through least punitive action | If the report is not acceptable, following discussion with the provider and where required a site visit, issue a warning notice<br><br>If non-compliance is identified when followed up, issue a warning notice and/or consider civil enforcement action |
| **Enforcement Action** | Warning notice | First breach/offence with moderate impact<br><br>Multiple breaches/offences with moderate impact<br><br>Any breach/offence with a major impact | To demand compliance within timescale (where appropriate) | Civil enforcement and/or criminal law action |
| **Criminal law** | Penalty notice | Non-compliance with warning notice<br><br>Direct offences<br><br>Multiple breaches/offences with moderate impact | To dispose of liability for offence or breach efficiently and cost effectively without restricting the registered person's registration | If not accepted, move to prosecution and/or consider civil enforcement action |

| | | | | |
|---|---|---|---|---|
| | | Breach/offence(s) with major impact<br><br>Carrying on a regulated activity without registration | | |
| | Simple caution | Non-compliance with warning notice<br><br>Direct offences<br><br>Carrying on a regulated activity without registration | To gain an admission of the offence and dispose of liability for offence/breach efficiently and cost effectively without restricting the registered person's registration | If refused, move to prosecution and/or consider civil enforcement action |
| | Prosecution | Non-compliance with warning notice<br><br>Direct offences<br><br>Carrying on a regulated activity without registration | To hold registered person to account for the breach/offence without restricting registration | Consider civil enforcement action or further prosecution |
| **Civil enforcement** | Imposition, variation, removal of conditions | Non-compliance with warning notice.<br><br>Non-compliance with compliance actions<br><br>Multiple breaches/offences with moderate impact<br><br>Breach/offence(s) with major impact | To restrict the registered person's activity | Cancellation of registration<br><br>Prosecution<br><br>Further imposition/variation/ removal of conditions (which includes variation to remove location) |

| | | | | |
|---|---|---|---|---|
| | | With/after prosecution<br><br>Direct offences | | |
| | Suspension of registration | Non-compliance with warning notice<br><br>Non-compliance with compliance actions<br><br>Multiple breaches/offences with moderate impact<br><br>Breach/offence(s) with major impact<br><br>With/after prosecution | To prevent the registered person from carrying on the regulated activity/activities for a period of time | Extend suspension<br><br>Vary to remove regulated activity(ies)<br><br>Cancellation<br><br>Prosecution |
| | Cancellation of registration | Non-compliance with warning notice<br><br>Non-compliance with compliance actions<br><br>Multiple breaches/offences with moderate Impact<br><br>Breach/offence(s) with major impact<br><br>Continued non-compliance<br><br>Variable compliance over time | To prevent the registered person from carrying on regulated activities | Prosecution if regulated activities continue after the cancellation is confirmed |

| | | | | |
|---|---|---|---|---|
| | Urgent imposition, variation, removal of conditions | Non-compliance that will or may expose any person to the risk of harm | To immediately restrict or prevent some regulated activities being provided immediately | Prosecution if registered person fails to abide by the restriction or prevention of regulated activities |
| | Urgent cancellation of registration | Non-compliance where there is an immediate risk to a person's life, health or wellbeing | To immediately prevent all regulated activities being provided immediately | Prosecution if regulated activities continue after cancellation confirmed |

The CQC have noted that the use of this escalator table may not follow a linear order as every breach is judged on an individual basis, proportionate to the risk for people using the services.

**APPENDIX A**

## Additional CQC outcomes

Besides the main 16 Essential Standards, there are 12 other Essential Standards that relate more to the day-to-day management of your practice, and which you need to be aware of. You will not need to declare compliance with these standards when you apply for registration **but** you are still required to meet these outcomes.

### Outcome 22: Requirements where the practice is an individual or partnership

*This outcome reflects the requirements of Regulation 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- Have their needs met by the service because it is provided by an appropriate person.

This is because practices will:

- Register with the Care Quality Commission the appropriate people or persons who:
  – are of good character
  – are physically and mentally able to perform their role
  – have the necessary qualifications, skills and experience to carry on the regulated activity.

### Outcome 23: Requirements where the practice is a body other than a partnership

*This outcome reflects the requirements of Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- Have their needs met by the practice because the management is supervised by an appropriate person.

This is because practices will:

- Have a nominated individual who:

  – is of good character
  – is physically and mentally able to perform their role
  – has the necessary qualifications, skills and experience to supervise the management of the regulated activity.

**Outcome 24: Requirements related to registered managers**

*This outcome reflects the requirements of Regulation 6 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- Have their needs met because it is managed by an appropriate person.

This is because practices:

- Have a registered manager who:
  – is of good character
  – is physically and mentally able to perform their role
  – has the necessary qualifications, skills and experience to manage the regulated activity.

**Outcome 18: Notification of death of a patient**

*This outcome reflects the requirements of Regulation 16 of the Care Quality Commission (Registration) Regulations 2009*

CQC outcome:

Patients:

- Can be confident that deaths of people who use services are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because:

- Practices notify the Care Quality Commission about the death of a patient

Primary medical services providers will be required to notify the CQC where death occurs within two weeks of care being provided and*:*

- Where the death has or may have resulted from the carrying on of the regulated activity (ie care and treatment provided by the practice) and
- could not be attributed to the course which that patient's illness or medical condition would have actually taken if that patient was receiving appropriate care and treatment.

Changes to the regulation which describe this outcome need to be made so that the outcome can be applied to primary medical services providers. The CQC will be issuing guidance to clarify further how this requirement applies in primary care.

**Outcome 19: Notification of death or unauthorised absence of a patient who is detained under the Mental Health Act 1983**

*This outcome reflects the requirements of Regulation 17 of the Care Quality Commission (Registration) Regulations 2009*

CQC outcome:

Patients who are detained under the Mental Health Act 1983:

- Can be confident that important events that affect their welfare, health and safety are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because practices will:

- Notify the Care Quality Commission about the death or unauthorised absence of a patient detained under the Mental Health Act 1983 who uses services.

**Outcome 20: Notification of other incidents**

*This outcome reflects the requirements of Regulation 18 of the Care Quality Commission (Registration) Regulations 2009*

CQC outcome:

Patients:

- Can be confident that important events that affect their welfare, health and safety are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because practices will:

- Notify the Care Quality Commission about incidents that affect the health, safety and welfare of patients, including:
  - injuries to people
  - making an application to depriving someone of their liberty
  - events which stop the registered person from running the service as well as they should
  - allegations of abuse
  - a police investigation.

Changes to the regulation which describe this outcome need to be made so that the outcome can be applied to primary medical services providers. The CQC will be issuing guidance to clarify further how this requirement applies in primary care.

**Outcome 27: Notice of absence**

*This outcome reflects the requirements of Regulation 14 of the Care Quality Commission (Registration) Regulations 2009*

CQC outcome:

Patients:

- Can have confidence that, if the person(s) in charge of their service is absent, it will continue to be properly managed and be able to meet their needs.

This is because practices will:

- Inform the Care Quality Commission:
  - about any significant planned absences from the service
  - about any significant unplanned absences
  - how the service will be run while they are away
  - when they return from a significant absence.

**Outcome 28: Notice of changes**

*This outcome reflects the requirements of Regulation 15 of the Care Quality Commission (Registration) Regulations 2009*

CQC outcome:

Patients:

- Can be confident that, if there are changes to the service, its quality and safety will not be adversely affected.

This is because practices:

- Inform the Care Quality Commission:
  - when the person who manages or carries on the service changes
  - when the registered details of the service and any individual, partnership or organisation
    who manage or carry it on, change
  - when the registered person becomes financially insolvent
  - when the service closes

**Outcome 3: Fees**

*This outcome reflects the requirements of Regulation 19 of the Care Quality Commission (Registration) Regulations 2009*

CQC outcome:

Patients (or their carers/representatives):

- Know how much they are expected to pay, when and how.
- Know what the service will provide for the fee paid.
- Understand their obligations and responsibilities.

This is because practices will:

- Be transparent in the information they provide about any fees, contracts and terms and conditions, where people are paying either in full or in part for the cost of their care, treatment and support.

**Outcome 15: Statement of purpose**

*This outcome reflects the requirements of Regulation 12 and Schedule 3 of the Care Quality Commission (Registration) Regulations 2009*

CQC outcome:

Patients:

- Will benefit from the knowledge that the Care Quality Commission is informed of the services being provided.

This is because practices:

- Have a statement of purpose that is kept under review, and give a copy to the Care Quality Commission.
- Notify the Care Quality Commission of any changes to their statement of purpose.

**Outcome 25: Registered person - training**

*This outcome reflects the requirements of Regulation 6 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*

CQC outcome:

Patients:

- Have their care, treatment and support needs met because there is a competent person leading the service.

This is because practices will:

- Undertake appropriate training.

**Outcome 26: Financial position**

*This outcome reflects the requirements of Regulation 13 of the Care Quality Commission (Registration) Regulations 2009*

CQC outcome:

Patients:

- Can be confident that the service provider is able to meet the financial demands of providing safe and appropriate services.

This is because practices will:

- Have the financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards.