

May 2011

CQC registration toolkit

Guidance for GPs



FOREWORD

GP practices have a long tradition of providing high quality and safe care to their patients and, as a result, patients already experience excellent outcomes. The existing focus on quality and safety which most practices currently have in place already means we have little doubt that almost all practices will be able to fulfil and demonstrate requirements of the Care Quality Commission's (CQC) Essential Standards by what they currently do.

This guidance is intended to help those of you who are uncertain about what you should be doing before having to declare compliance in autumn 2011. For those of you who believe your practice is already meeting the outcomes then you will need to do nothing more than maintain what your practice already has in place.

The lists of evidence for the demonstration of compliance in this toolkit are **only examples** based on **our** interpretation of CQC's current guidance, the methods of assessment proposed and what we have suggested for meeting the outcomes.

At present we believe that you are most likely to be asked to submit self-assessments of your practice. CQC have said that practices can submit their own form of self-assessment but that you can also complete their Provider Compliance Assessment Tool. The fact that this tool requires its own accompanying guidance on how to complete it demonstrates that it is not straightforward. Furthermore we believe the nature of the questions in the tool will only encourage a creative writing exercise. We do not believe this is the way that compliance should reliably be demonstrated and we are not convinced of the benefit of the CQC Provider Compliance Assessment Tool.

The GPC has serious concerns that the CQC's current expectations for the demonstration of compliance from 1 April 2012 will create an additional and unnecessary administrative burden that will disrupt GP practices and divert time away from patients. Instead we believe 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, and that that CQC should reconsider their current plans and dramatically simplify them. We will continue to discuss this with them over the coming months with the intention of minimising the work required for demonstrating compliance. **We therefore advise you not to commence significant work on preparing to demonstrate compliance at this time.**

Despite this, we know that many of you will want to set aside time to give the matter thought and have discussions within your practice. I therefore hope you find the contents of this toolkit useful for considering what you may be required to state in your practice application for registration and assessing whether you are meeting CQC's Essential Standards.



Laurence Buckman
Chairman, BMA's General Practitioners Committee

CQC registration toolkit for GPs

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Care Quality Commission registration toolkit for GPs

PART 1: INTRODUCTION

From 1 October 2011, all GP practices and other NHS primary medical services providers will be invited to apply for registration with the Care Quality Commission (CQC) and will need to be registered by 1 April 2012. The purpose of this GPC toolkit is to attempt to reduce the burden of the application process by providing a straightforward, plain English explanation of CQC registration, provide information on applying for registration and suggestions on what you could be doing to meet the CQC's [Essential Standards of Quality and Safety](#). This toolkit also highlights the current situation regarding demonstrating compliance.

Please note: This toolkit 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 that your practice should be compliant with that are not specifically mentioned in this toolkit then you should still comply with those legislation/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.

The guidance in this toolkit will be updated if and when the expectations from CQC change. If you have any queries about CQC registration then BMA members can contact the BMA on **0300 123 1233**. Local Medical Committees should contact the General Practitioners Committee secretariat.

Please note: Our use of the word **practice** in this guidance is a replacement for CQC's word **provider**. We have only done so to make the guidance easier to follow.

A provider is the legal entity that provides the regulated activities to patients that must register with CQC. Therefore provider means GP practice, GP-led health centre, OOH care provider etc. However, a provider can also be the legal entity responsible for more than one practice. A provider can be an individual, a partnership or an organisation.

Therefore you should read references to practice as referring to your own determined provider status. See **Part 2** for further information on providers.

PART 2: EXPLAINING REGISTRATION

What is the Care Quality Commission?

The Care Quality Commission is the independent regulatory body for healthcare, adult social care and the operation of the Mental Health Act 1983 in **England only**.

What is the legislative background to the CQC and registration?

CQC was established by the [Health and Social Care Act 2008](#). On 1 April 2009, the Commission legally took on the responsibilities of the Healthcare Commission, the Commission for Social Care Inspection, and the Mental Health Act Commission.

The regulations that underpin CQC registration are the [Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2010](#), and the [Care Quality Commission \(Registration\) Regulations 2009](#). The key regulations are the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 because they set out the main standards for CQC registration. However, your practice still needs to comply with the Care Quality Commission (Registration) Regulations 2009.

What is CQC registration?

CQC registration is the legal licence for all health and social care providers, including practices, to operate. For your practice to be registered with CQC you will need to successfully apply for registration when sent a statutory notice inviting you to do so after 1 October 2011. CQC intend to send out the statutory notices in fortnightly batches. After you have received your notice you will have 28 days from the date of notice to submit your application.

As part of that application you will need to declare compliance with the regulations that underpin the CQC's main 16 Essential Standards of Quality and Safety for the regulated activities you provide at every location.

The Essential Standards are 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 your practice 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](#). In **Part 5** of this toolkit we have translated the outcomes and prompts into guidance for NHS general practices.

When your practice is registered it will be monitored by CQC and on occasion you will be asked to demonstrate compliance either as part of a responsive review or a planned review. You will only need to apply for your practice to be registered once but you will be monitored by CQC from 1 April 2012 onwards.

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 Care Quality Commission (CQC). From 1 April 2012 this includes all providers whose sole or main purpose is NHS primary medical services i.e. GMS, PMS, APMS and NHS Act 2006 Section 3 (contracts with the Secretary of State) contractors.

A provider can be a GP practice, walk-in centre, OOH care provider etc. However, a provider can also be the legal entity responsible for more than one practice, OOH care provider etc. In the terminology of CQC, an individual GP practice premise is referred to as a location. If your provider has more than one surgery then they would each be registered as separate locations but in the same registration application, although we understand that this interpretation is subject to review.

Our use of the word 'practice' in this guidance is a replacement for CQC's word 'provider'. We have done this to make the guidance easier to follow. Therefore you should read references to 'practice' as referring to your own determined provider status.

When you apply for registration you should do so either as an individual, a partnership or an organisation.

A **partnership**, for CQC registration, is a practice with GP contractors that have arrangements in place for joint or several liabilities which all members of the partnership agree to. A Limited Liability Partnership is not a partnership but an organisation.

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 on info.pds@bma.org.uk.

If your practice does not have arrangements for joint or several liabilities in place then you can not register as a partnership and you and your partners will need to register as individuals.

We have asked CQC to publish specific guidance for GP practices on this issue as it did for dental practices.

The main example of an **individual** is a single handed GP practice. Individual GPs do not have to register with CQC but single handed GPs need to register their practice.

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 there could be criminal penalties for your practice and/or registered manager. Therefore if you are uncertain we advise you to contact the BMA or CQC.

Registered managers

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. Your registered manager shares the legal responsibility for compliance with your practice.

The person who you appoint as registered manager needs to be an individual who is in day-to-day charge of the regulated activities at a location. 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 at each practice. 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.

Your registered manager will need to submit an application at the same time as your practice application. For information on the form used for registered manager applications for other

providers see **Part 4**. However, it is worth noting that CQC are considering integrating the application for practices with that for registered managers.

Who should be your registered manager?

Based on the CQC requirements we believe that for many practices it will be appropriate for a partner to be the registered manager, but you may decide that it should be your practice manager. You will need to make your own decision based on the knowledge that your registered manager(s) needs to be someone who is in charge the day-to-day running of the regulated activities at the locations you register.

What is and who should be 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 the regulated activity is managed. You can nominate one individual to cover all or several of the regulated activities you provide, or different individuals for each regulated activity.

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

Who should be a nominated individual?

Your nominated individual should be someone in a suitably senior role such as a director or senior manager of your organisation.

What are regulated activities?

From 1 April 2012 your practice needs to be registered with CQC to provide regulated activities. Therefore when you apply for registration with CQC you must specify which regulated activities you provide at your practice. 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](#).

CQC state that it is your responsibility to apply for registration correctly (and remain registered correctly afterwards). Our guidance on which regulated activities to register for can be found in **Part 3** of this toolkit.

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

A summary of each regulated activity can be viewed in **Appendix A**.

What is a location?

A location is a place in or from which you provide regulated activities and therefore, in practical terms, means a GP surgery, walk-in centre etc. It will not be uncommon for contractors to have more than one location (practice). Each practice that belongs to the same legal entity (i.e. partnership, LLP) should be registered in the same application.

If you have a branch surgery you will need to register it as a separate location if it is a static and fully functioning surgery where the activities are managed from that site, i.e. it is managed independently of the main practice. If the premises are not equipped primarily as a clinical area (e.g. a community hall) or the regulated activities are managed from the main surgery then you will not need to register it as a location but you will need to say in a statement of purpose that these services are managed from your main practice.

Similarly, you should not register a prison as a location unless the care is provided in a purpose-built health centre within the prison and the regulated activities provided there are managed independently of any other service (e.g. your main GP practice).

The CQC is currently updating its guidance on locations. The revised guidance will have more detail about locations for GP practices.

What happens if I fail to register?

If you fail to register then the CQC can force your practice to stop providing primary medical services (see enforcement powers) and CQC believes that you could be in breach of your contractual requirements.

Do I have to register if I start up a new practice after 1 April 2012?

Yes. Your practice must be registered before it starts to do any regulated activity.

How will CQC monitor my practice's compliance with the CQC standards after my practice is registered?

CQC will monitor the compliance of your practice with their standards by gathering information from patients, public representative groups, agencies and regulators, publicly available data sources, as well as planned and responsive reviews of your practice.

Some of the information sources that CQC will use are QOF, NHS Choices, the GP Patient Survey, Parliamentary and Health Service Ombudsman and PCTs (as well as their replacements). They will also react to notifications of incidents that your practice is required to tell CQC about by law.

This information will be put into a Quality and Risk Profile. The Quality and Risk Profile (QRP) is a dashboard that presents information held by CQC about your practice and is for the use of your local CQC compliance inspector. The compliance inspector will use it to make judgements about the level of risk of your practice not meeting the essential standards, the frequency of planned reviews and whether to follow up on concerns.

What is a planned review?

A planned review is a full check of the 16 Essential Standards. Planned reviews will happen at least once every two years. However, your local CQC compliance inspector will carry out planned reviews more frequently – the shortest time span is every three months – when they are concerned about the quality of care at your practice or where your practice is carrying out high risk activities.

The compliance inspector will start by reviewing the information they hold about your practice in your Quality and Risk Profile. If, having analysed this information, they cannot confirm that you are meeting the essential standards, they will gather more information.

They may:

- 1) Call your registered manager for an oral discussion
- 2) Contact patients and their relatives or carers
- 3) Ask for information from other regulators
- 4) Ask for a self-assessment (They will suggest that you complete their [Provider Compliance Assessment Tool](#) although it is not obligatory to do so and you can submit your own type of self-assessment)
- 5) Carry out a site visit

The CQC has said that the reviews will be targeted and proportionate and in reality most will not involve a site visit. However, as stated in more detail in the **foreword** we have significant concerns about the workload for practices for demonstrating compliance. Therefore we are continuing to discuss the details with the CQC.

What is a responsive review?

A responsive review will be carried out by local compliance inspectors when they have concerns about the quality and safety of care. They can be triggered by specific information. The inspector will also carry out a responsive review when following up on enforcement action they have taken. The CQC will not normally give advance notice of these reviews.

A responsive review is not a full check of compliance with the 16 essential standards. Instead it targets the area[s] of concern and the standards to which they relate and may involve the actions stated above for planned reviews.

Again, as stated in more detail in the **foreword** we have significant concerns about the workload for practices for demonstrating compliance. Therefore we will continue to discuss the details with the CQC.

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

Once the CQC compliance inspector has analysed all the information that it has gathered then they will make a judgement about whether your practice is meeting their Essential Standards with reference to their [Guidance about Compliance: Essential Standards of Quality and Safety](#) and their [Judgement Framework](#).

Where issues can be resolved quickly and easily, the CQC may simply discuss them with you.

If your practice **is** meeting the Essential Standards, but they have concerns that you may not continue to do so in the future, they may set an 'improvement action' and ask you to send a report to them stating how you will make improvements.

If your practice **is not** meeting the Essential Standards then the inspector may set a 'compliance action'. This will require you to send a report to the CQC stating how you will make the necessary improvements.

If the CQC is not satisfied that you have made these improvements then they may decide to take enforcement action.

What are the enforcement powers of the CQC?

The CQC has the power to:

- 1) Restrict your practice from offering services from a particular location
- 2) Issue a penalty notice in lieu of prosecution
- 3) Suspend your practice's registration (this means you can not perform regulated activities at your practice)
- 4) Cancel your practice's registration (this means you can not perform regulated activities at your practice)
- 5) Prosecute for specified offences (your practice and your registered manager can be fined)

The above is described in more detail in the CQC's [Enforcement policy](#).

The amounts of the penalty notices can be viewed in [Schedule 4 of the Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2010](#).

What is the fee for registration?

There is no fee for applying for registration before 1 April 2012 but there is an annual fee for being registered (akin to a subscription fee). This annual fee will cover any costs associated with changing your practice's registered details during the year.

The fees for GP practices have not yet been set. There will be a consultation on the fees for practices in autumn 2011. The GPC will make a robust response to this consultation, indeed we have already made our position clear that GPs should not be expected to bear the cost of CQC's activity. The fees for [dental providers from April 2011](#) have been set following an earlier consultation. The fee for a dental provider with only one location was set at £800 for April 2011-April 2012. The fees increase for providers with more than one location. For example providers with more 2-3 locations have had their fees set at £1600.

Is my practice's registration information published anywhere?

The CQC will publish any information about your practice that you have provided when applying for registration on its website.

The fact that a planned or responsive review of your practice has taken place and the outcome will be published too. Before doing so they will send the report to you, which will set out their findings, their judgements about your compliance and whether they have asked you to send a report to them on the improvements you are making. You will have 14 days to check their report for factual accuracy before they finalise and publish it.

If the CQC proposes to take enforcement action against your practice then it will publish its report once the representations and appeals process have concluded, unless it takes urgent enforcement action. If it takes urgent enforcement action then it will state this on its website immediately, whilst making it clear that this action may be appealed.

If the CQC cancels your registration, then it will remove information about your practice and registered manager from its website.

What is the timeline for registration?

The following is a summary of the various stages:

June 2011- September 2011 – Enrolment – The CQC will contact you to validate the details about whom the provider you will be registering. This will involve completing a short online form. The BMA will publicise when this process is occurring.

From 1 October 2011 – Applying for Registration – The CQC will issue a statutory notice inviting your practice to apply for registration at some point after this date. The CQC intends to send out fortnightly batches of statutory notices. After you have received your notice you will have 28 days from the date of notice to submit your application. For further information on the information that dental practices had to provide for registration please view **Part 3**.

The aim is for all practices to be registered by 1 April 2012. The CQC has said that it is important for practices to meet the statutory notice deadline set by the CQC because then they will be protected from practising without registration if the CQC does not manage to process your application before 1 April 2012.

As part of the application process you will be asked to declare compliance with the regulations underpinning the main 16 Essential Standards for the regulated activities you provide at every location. For advice on how to meet the standards view **Part 5**.

At the same time as you submit the application for your practice, you will also need to submit your application for your registered manager(s). For information on the registered manager form completed by other providers go to **Part 4**. However, it is worth noting that the CQC has indicated that for GP practices the registered manager application will be merged into the practice application.

1 April 2012 – Compliance monitoring begins – For further information on compliance monitoring see the relevant sections above.

PART 3: APPLYING FOR REGISTRATION

The following is for **information only** and should not be considered to be an exact representation of the questions that you will be asked in your application for registration. These questions are those that dentists were asked when they were applying to register their practices. However, the only major change we expect at present is that the registered manager application form will be merged with the application form for practices. Therefore we have provided suggestions on how you would answer these questions if and when they arise.

It is important to note that the information below should be treated and used as **guidance only**. You should consider the individual circumstances of your practice/provider when applying for CQC registration and complete the form accordingly.

PLEASE NOTE: The CQC will not be in a position to answer questions about the application process until they have published their application form for GP practices and their accompanying guidance.

Section 1: Information about your practice

Question 1: Type of entity (this means practice)

I am registering as:

1. An organisation
2. An individual
3. A partnership

How to answer question 1:

A **partnership**, for CQC registration, is a practice with GP contractors that have arrangements in place for joint or several liabilities to which all members of the partnership agree. A Limited Liability Partnership is not a partnership but an organisation.

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 on info.pds@bma.org.uk.

If your practice does not have arrangements for joint or several liabilities in place then you can not register as a partnership and you and your partners will need to register as individuals.

We have asked the CQC to publish specific guidance for GP practices on this issue as it did for dental practices.

The main example of an **individual** is a single handed GP practice. Individual GPs do not have to register with the CQC but single handed GPs need to register their practice.

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 there could be criminal

penalties for your practice and/or registered manager.

Question 2: Please state all of the regulated activities you wish to register

Dental care practices were asked to declare the regulated activities that were performed at all of their locations. The regulated activities are:

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

Summaries of the regulated activities and a list of types of practices/providers that may need to register for them can be viewed in **Appendix A**. For the full legal definitions of the regulated activities refer to [Schedule 1 of the Health and Social Care Act 2008 \(Regulated Activities\) Regulations](#)

How to answer question 2:

We suggest that all practices (and other NHS primary medical services providers e.g. GP-led health centres) will need to register for the following regulated activities:

1. Treatment of disease, disorder or injury
2. Diagnostic and screening procedures (please note the exception for OOH care providers below)

The following may also apply to your practice (and/or other NHS primary medical services provider) but this will depend on the services you provide:

1. Surgical procedures
2. Maternity and midwifery services
3. Family planning services

If you are an out-of-hours care provider we suggest that you also register for:

1. Transport services, triage and medical advice provided remotely.

OOH care providers will need to give consideration to whether they need to register for Diagnostic and screening procedures.

You will need to make your own decision for your practice based on the services that you provide. For summaries of the regulated activities please refer to **Appendix A**.

Question 3: Name, address and contact details

Dentists were asked to provide the following details dependent on whether they were an organisation, individual or partnership:

Individual (i.e. single handed GP practice):

The name, address and contact details of the individual

Partnership:

- 1) The name and contact details of your partnership
- 2) The names and postal addresses of your partners (this does not have to be a home address)

Organisation:

- 1) Name and contact details of your organisation
- 2) Name and contact details of your nominated individual(s)
- 3) The regulated activities for which the nominated individual(s) will supervise the management
- 4) Your registered company number and/or registered charity number
- 5) You will have to state whether your organisation is a subsidiary of another company, and if yes, the address and contact details of the parent company.

Section 2: Further information about your practice

Question 1: Invoice and financial contact details

Dental practices were asked to provide the following details:

The name, job title and contact details of the person to whom should be sent the invoices for the annual fees for being registered with the CQC

Question 2: Statement of purpose

Dental practices were, and your practice will be, required to have a statement of purpose under Regulation 12 and Schedule 3 of the Care Quality Commission (Registration) Regulations 2009. You will not need to submit the statement with your application but it must be available if CQC request it.

The aim of the statement of purpose is to provide information about:

- 1) What your practice wants to achieve in carrying out regulated activities;
- 2) The services you provide and the premises ('locations') from which you provide them.

How to answer question 2:

The statement of purpose should have enough detail to enable the CQC to have a good understanding about the specific nature of your services. We believe that the details in your practice leaflet and website will assist you with writing this statement. The [CQC has a template for the statement of purpose](#).

The BMA will be discussing this requirement further with the CQC because of our concerns and we advise you not to start working on this yet.

Question 3: Information about individuals

Dental care practices were asked to provide the following (this is under review by the CQC so practices should await the application form for GP practices before acting):

Individuals were asked to confirm that they could provide the list of information below if requested.

Partnerships were asked to confirm that each partner could provide the list of information below if requested.

Organisations were asked to confirm that their nominated individual could provide the list of information below if requested.

1) An enhanced CRB certificate. The certificate must be countersigned by CQC.

Please note: Currently the CQC require these certificates to be new ones but in light of their experience with dental practices they are reviewing their policy. We are discussing this with the CQC and will update this toolkit once the policy is confirmed.

2) Proof of identity including a recent photograph (e.g. passport)

3) References from relevant previous employment in health care or social care or providing services to children or vulnerable adults

4) If you worked in a previous position that involved work with adults and children, information about why the position ended

5) Documentary evidence of any relevant qualifications (i.e. certificates)

6) A full employment history with a satisfactory written explanation of any gaps (i.e. a CV)

7) Information about any physical or mental conditions which are relevant to your ability to perform regulated activities (i.e. care for and treat patients)

Question 4: Respecting and involving people who use services

Dental care practices were asked the following questions (They are under review).

How do you ensure the views and experiences of patients are listened to and acted upon when running your service/s? (This question does not need to be directly answered)

a) How have the views and experiences of patients, their carers and representatives influenced your practice priorities and plans? (Max 2000 characters – not words)

b) How have their views and experiences influenced how you deliver the services (across the range of regulated activities you are registering for)? (Max 2000 characters – not words)

c) What is your practice doing to increase the influence people have on the planning or delivery of services? (Max 2000 characters – not words)

How to answer Question 4:

See Part 5, Outcome 1 of this guidance for ideas on what to include in your answers to (a), (b) and (c).

Question 5: Equality, diversity and human rights

Dental care practices were asked the following questions (They are under review).

How do you ensure people's equality, diversity and human rights are actively promoted in your services? (This question does not need to be directly answered)

a) How do you ensure that the promotion of equality, diversity and human rights influence your service priorities and plans? (Max 2000 characters – not words)

b) How does the promotion of equality, diversity and human rights influence how you deliver services across the range of regulated activities that you are registering for? (Max 2000 characters – not words)

c) What are you doing to increase the influence of equality, diversity and human rights issues on the planning and delivery of services? (Max 2000 characters – not words)

How to answer Question 5:

See **Part 5**, Outcome 1 of this guidance for ideas on what to include in your answers to (a), (b) and (c).

Section 3: Regulated activities and locations

A location is a place in or from which you provide regulated activities and therefore, in practical terms, means a GP surgery, walk-in centre etc. It will not be uncommon for contractors to have more than one location (practice). Each practice that belongs to the same legal entity (i.e. partnership, LLP) should be registered in the same application.

If you have a branch surgery you will need to register it as a separate location if it is a static and fully functioning surgery; this means it is managed independently of the main practice. If the premises are not equipped primarily as a clinical area (e.g. a community hall) or the regulated activities are managed from the main surgery then you will not need to register it as a location but you will need to say in a statement of purpose that these services are managed from your main practice.

Similarly, you should not register a prison as a location unless the care is provided in a purpose-built health centre within the prison and the regulated activities provided there are managed independently of any other service (e.g. your main GP practice).

CQC is currently updating its guidance on locations. The revised guidance will have more detail about locations for GP practices.

For **each separate location** dental care practices were required to answer the questions below.

Question 1: Name, address and contact details of the location

Question 2: The regulated activities being performed at the location

Dental care practices were asked to declare the regulated activities that were performed at all of their locations. The regulated activities are:

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

Summaries of the regulated activities and a list of types of practices/providers that may need to register for them can be viewed in **Appendix A**. For the full legal definitions of the regulated activities refer to [Schedule 1 of the Health and Social Care Act 2008 \(Regulated Activities\) Regulations](#).

How to answer question 2:

We suggest that practices (and other NHS primary medical services providers e.g. GP-led health centre) register for the following regulated activities:

1. Treatment of disease, disorder or injury
2. Diagnostic and screening procedures (please note the exception for OOH care providers below)

The following may also apply to your practice (and/or other NHS primary medical services provider) but this will depend on the services you provide:

1. Surgical procedures
2. Maternity and midwifery services
3. Family planning services

If you are an out-of-hours care provider we suggest that you also register for:

1. Transport services, triage and medical advice provided remotely.

OOH care providers will need to give consideration to whether they need to register for Diagnostic and screening procedures.

You will need to make your own decision for your practice based on the services that you provide. For summaries of the regulated activities please refer to **Appendix A**.

Question 3: The types of service being performed at your location

You will need to declare which types of services are performed at the location. Registering for these service types is a CQC requirement rather than a legislative one. The service types are:

1. Acute service
2. Prison health care service
3. Hospital services for patients with mental health needs, learning disabilities or problems with substance misuse

4. Hospice services
5. Rehabilitation services
6. Long-term conditions services
7. Residential substance misuse treatment and/or rehabilitation service
8. Hyperbaric chamber
9. Community healthcare service
10. Community-based services for patients with mental health needs
11. Community-based services for patients with a learning disability
12. Community-based services for patients who misuse substances
13. Urgent care services
14. Doctors consultation services
15. Doctors treatment services
16. Mobile doctors services
17. Dental service
18. Diagnostic and/or screening service
19. Care home service without nursing
20. Care home service with nursing
21. Specialist college service
22. Domiciliary care service
23. Supported living service
24. Shared Lives
25. Extra Care housing services
26. Ambulance service
27. Remote clinical advice service
28. Blood and transplant service

Summaries of the main service types and a list of the types of practices that may need to register for them can be viewed in **Appendix B**. The service types not listed in the appendix are also not relevant to practices.

How to answer question 3:

We suggest that practices (and other NHS primary medical services providers) register each location for the following:

1. Doctors consultation services (DCS)
2. Doctors treatment services (DTS)

For a minority of practices the following could also apply to each location:

1. Prison healthcare services
2. Community healthcare services
3. Community-based services for people with a learning disability
4. Community-based services for people who misuse substances

We suggest that out-of-hours care providers and walk-in centres also register that they provide:

Urgent Care Services

You will need to make your own decision for your practice based on the services that you provide. For summaries of the service types please refer to **Appendix B**.

Section 4: Declaration of compliance

In this section dental care practices were required to declare compliance or non-compliance with the regulations underpinning the 16 main CQC standards for the regulated activities that they provided at **every** location. If you declare non-compliance with any of the regulations during your application then the CQC will set an 'improvement action' or a 'compliance action' and ask you to send a report to them stating how you will make improvements. If you fail to make the improvements in the timescale agreed in the plan then the CQC may take enforcement action.

Dental care practices had to answer the questions below for each location.

Question 1: Name, address and contact details of the location where you carry out regulated activities

Question 2: Declaration of compliance or non-compliance

Dental practices were asked to declare compliance or non-compliance with the regulations that relate to the following outcomes for each regulated activity at the location:

Outcome 1: Respecting and involving patients
Outcome 2: Consent to care and treatment
Outcome 4: Care and welfare of patients
Outcome 5: Meeting nutritional needs
Outcome 6: Cooperating with other providers
Outcome 7: Safeguarding users from abuse
Outcome 8: Cleanliness and infection control
Outcome 9: Management of medicines
Outcome 10: Safety and suitability of premises
Outcome 11: Safety, availability and suitability of equipment
Outcome 12: Requirements relating to workers
Outcome 13: Staffing
Outcome 14: Supporting workers
Outcome 16: Assessing and monitoring the quality of service provision
Outcome 17: Complaints
Outcome 21: Records

How to answer question 2:

Please see **Part 5** of this toolkit if you wish to seek advice on what a practice could be doing to meet the outcome.

Please note that we do not believe that Outcome 5 is normal general practice. If you wish to state that this is non-applicable then you should declare non-compliance and indicate that it is not applicable because you do not provide food or drink in your application form.

Dental practices that declared **non-compliance** with any of the regulations had to answer the following questions for **each** outcome that they were non-compliant with at **each** location:

Question 3: Declarations of non-compliance

a) Describe in what ways you are not compliant with the outcome (Max 2000 characters – not words)

- b) What will you do to become compliant? (Max 2000 characters – not words)
- c) When will you do this by? (dd/mm/yyyy)
- d) How will you make sure that you continue to be compliant? (Max 2000 characters – not words)

How to answer question 3:

To answer this question we suggest that you use the guidance in **Part 5** of this toolkit, which contains suggestions on what you need to do to meet each outcome.

Section 5: Practice application declaration

Dental practices were asked to agree to declare the following:

This declaration must be signed by the applicant. Where this is an organisation, it must be signed by an individual who is duly authorised.

Before signing this declaration, you are advised to check that the regulated activities you have identified in Section 1: Service provider, correspond to those you have identified for each location in Section 3: Regulated activities and locations.

I hereby declare that the information detailed in this application is true and accurate. I understand that Section 37 of the Health and Social Care Act 2008 makes it an offence to knowingly make a statement which is false or misleading in a material respect in this application, or in any of the documents submitted with this application.

I understand that to knowingly make a false declaration could render me liable to prosecution and could lead to the refusal of this application.

I have kept a copy for my records of all the documentation submitted for my application.

In making this application for registration with the Care Quality Commission, I agree to comply with the Health and Social Care Act 2008 and associated regulations. I understand that non-compliance with the relevant legislation could lead to conditions being imposed on my registration or the refusal of my application.

From the date I send you this application and until you make a decision about it, I will let you know about any changes to the information I have supplied.

I confirm that I am aware of and will comply with the legislation and associated regulations. I will meet the outcomes in the Essential standards of quality and safety and understand that you may take this into account in decisions relating to my registration.

Partnerships were asked to declare that the content of the application and declaration had been discussed and agreed by all partners.

Organisations were asked to declare that all of the directors had discussed and agreed the content of their application and declaration.

PART 4: REGISTERED MANAGER APPLICATION

This section of the guidance is addressed to potential registered managers.

The CQC has indicated that the application process for registered managers will be merged with that for practices. However, for your information the following is a list of the questions in the application form for new registered managers that has been used for other providers and advice on how you might answer the questions if they arise in your application form.

After the application form has been submitted registered managers are interviewed by the CQC on the telephone or in person. The timescale for GP practices is unknown at present.

It is important to note that the information below should be treated and used as **guidance only**. You should consider your individual circumstances when applying for CQC registration and complete the form accordingly.

Please note: The CQC will not be in a position to answer questions about the application process until they have published their application form for registered managers for GP practices and their accompanying guidance.

Section 1: Details about the applicant

Question 1: Registered managers that intend to manage the regulated activities **at more than one location** have needed to answer these questions for each location.

- a) Registered managers have been asked to provide their name and personal address, as well as the name, address and contact details of the individual, partnership or organisation they are registering for
- b) Registered managers have been asked to state which regulated activities they will be responsible for managing.

Summaries of the regulated activities and a list of types of practices/providers that may need to register for them can be viewed in **Appendix A**. For the full legal definitions of the regulated activities refer to [Schedule 1 of the Health and Social Care Act 2008 \(Regulated Activities\) Regulations](#).

Question 2: Please confirm that you have received your CRB disclosure that has been countersigned by the CQC

You are required to obtain an enhanced CRB disclosure that has been countersigned by the CQC.

Please note: Currently the CQC requires these certificates to be new ones but in light of their experience with dental practices they are reviewing their CRB checks policy. We are discussing this with CQC and will update this toolkit once the policy is confirmed.

Question 3: Personal background

Registered managers for other providers have been asked to confirm that they have the following **available** if requested:

Please note that the following may not be the case for registered managers for practices. We will update our guidance when it is clear what is expected.

- 1) Proof of identity including a recent photograph (e.g. passport)
- 2) References from relevant previous employment in health care or social care or providing services to children or vulnerable adults
- 3) If they worked in a previous position that involved work with adults and children, information about why the position ended
- 4) Documentary evidence of any relevant qualifications (i.e. certificates)
- 5) A full employment history with a satisfactory written explanation of any gaps (i.e. a CV)
- 6) Job description detailing what duties and delegate authority they will perform
- 7) A completed [medical report form](#)
- 8) A completed [professional reference form](#)

The following questions are currently under review by the CQC.

Question 4: Previous involvement in registered establishments or agencies

Have you ever been employed in an establishment, or by an agency or service registered under any of the following legislation:

- Registered Homes Act 1984
- Registered Homes (Amendment) Act 1991
- Children Act 1989
- Nurse agencies Act 1957
- Care Standards Act 2000

Question 5: Previous involvement in the management of a relevant service

Have you ever been registered to run or manage a service under the above legislation?

Question 6: Refusal or cancellation of a relevant service

Have you ever had an application to register under the above legislation refused, or have you had an existing registration cancelled?

Question 7: Please give details of how you are skilled and competent to manage the regulated activities you are applying to be registered for

How to answer Question 7:

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 state that registered managers must be of good character, physically and mentally fit, and have the qualifications, skills and certificates to carry out the regulated activities that your practice is registered for.

When completing this section we suggest that you state:

- Your role within the practice
- What you will do to check that the practice continues to meet the essential standards (this can be based on the guidance for each CQC outcome in **Part 5**).

Question 8: Are you currently the subject of any investigation or proceedings being taken by any professional body with regulatory functions in relation to health or social care professionals, including by a regulatory body in another country?

This is self-explanatory.

Question 9: Have you ever been disqualified from the practice of a profession or required to practice subject to specified limitations following a fitness to practise investigation by a regulatory body in the UK or another country?

This is self-explanatory.

Question 10: If you are to manage more than one site, please give details of how you will ensure the day to day management is carried out at each location and the additional management arrangements that may be in place.

Please give information for each location you are applying to manage.

How to answer Question 10:

We suggest that you outline:

- Your supporting management arrangements
- The time you will spend at each location
- The details of deputising arrangements for when you are not at the practice(s)

Question 11: Please give details of other job share registered manager(s) if known

The title and name of the job share registered manager(s) is required only.

Question 12: If you are applying as part of a job share position, please describe how the arrangements will cover the day-to-day running of the service

We suggest that you outline:

- Your supporting management arrangements
- The time you will spend at each location
- The details of deputising arrangements for when you are not at the practice(s)

Section 2: Application declaration

You are likely to be asked to declare the following:

I hereby declare that the information detailed in this application is true and accurate.

I understand that Section 37 of the Health and Social Care Act 2008 makes it an offence to knowingly make a statement which is false or misleading in a material respect in this application, or in any of the documents submitted with this application. I understand that to knowingly make a false declaration could render me liable to prosecution and could lead to the refusal of this application.

I understand that it is my responsibility to inform the Care Quality Commission of any information that is relevant to my application, and which may not have been asked for and to update this information accordingly.

I have kept a copy of all the documentation submitted for my application for my records.

In making this application for registration with the Care Quality Commission, I agree to comply with the Health and Social Care Act 2008 and associated regulations.

I understand that non-compliance with the relevant legislation could lead to the refusal of this application or cancellation of registration if I do not comply following registration.

I agree that the information contained in this form may be used as conditions of registration

PART 5: MEETING THE CQC OUTCOMES AND DEMONSTRATING COMPLIANCE

Meeting the core 16 outcomes

In this part of the toolkit we have suggested what a practice might do to meet each of the core 16 outcomes. For each of the outcomes our suggestions are based on a consideration of the detailed outcomes and prompts in the CQC's [Guidance about Compliance](#). These suggestions should assist you in considering whether you are meeting the outcomes and therefore compliant with the regulations before making a declaration of compliance during your application for registration because you can compare them with what your practice already does.

The reason that we have interpreted the detailed outcomes and prompts is that the CQC has stated that the outcomes and prompts indicate what providers should be doing to meet the requirements of the regulations but they are generic to all providers. Although you are not legally bound to use their outcomes and prompts, if you decide to follow alternative arrangements then regulation 26 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 still requires that you consider them when judging your compliance. Furthermore if you do not refer to their prompts then the CQC will still look for evidence that you are meeting the needs of your patients and the standards that the regulations require when they monitor compliance from 1 April 2012 onwards.

Considering all of the above, we believe that you will find the 'Meeting the outcomes' sections of our guidance useful but it is important to note that it contains **only suggestions**. If you believe that your practice is already meeting the outcomes or complying with the regulations then you should not feel obligated to follow our suggestions. On the other hand if you are uncertain about what you could be doing to be compliant then you can refer to this toolkit. Importantly you should focus on continuing to do what you already do wherever possible as long as you are satisfied that you are compliant.

Equally **you should not create extra work for your practice by following our suggestions if you are already satisfied that you are compliant**. The large majority of our suggestions or similar will be in place in most practices, but if we suggest something that you do not already do then you are likely to identify that you are meeting the outcomes through alternative arrangements that you have in place. Despite this, we would advise that you follow guidance that relates to legislation/standards with which you should already be compliant regardless of the existence of the CQC.

To assist practices in the 'Meeting the outcome' sections we have included links to relevant policies and guidance, and on occasion, referred to the policies and protocols in Appendix C of this toolkit, which you could modify for use in your practice.

Demonstrating compliance with the core 16 outcomes

It is crucial to note that you will **not have to start demonstrating compliance until after 1 April 2012** unless you declare non-compliance with any of the outcomes during your application for registration. Even if you declare non-compliance during your application then the CQC will only contact you if they have concerns about the reasons you give and only about the outcome that you have declared non-compliance with. For example, if you declare non-compliance with outcome 5, meeting nutritional needs, and say that it is non-applicable then the CQC will not contact you about it during this interim period.

As explained in **Part 2**, you could be asked to demonstrate compliance as part of a planned review or a responsive review. A planned review is a full check of the 16 Essential Standards. Planned reviews will happen at least once every two years. However, your local CQC compliance inspector will carry out planned reviews more frequently – the shortest time span is every three months – when they are concerned about the quality of care at your practice or

where your practice is carrying out high risk activities. The compliance inspector will start by reviewing the information they hold about your practice in your Quality and Risk Profile. If, having analysed this information, they cannot confirm that you are meeting the essential standards, they will gather more information.

A responsive review of your practice would be carried out by your local compliance inspector if they have concerns about the quality and safety of care provided at your practice. They can be triggered by specific information. The inspector would also carry out a responsive review when they are following up on enforcement action they have taken. The CQC will not normally give advance notice of these reviews. A responsive review is not a full check of compliance with the 16 essential standards. Instead it targets the areas of concern and the standards to which they relate and may involve the actions stated above for planned reviews.

If the local compliance inspector cannot confirm that you are meeting the essential standards, they may gather more information by:

- 1) Call your registered manager for an oral discussion
- 2) Contact patients and their relatives or carers
- 3) Ask for information from other regulators
- 4) Ask for a self-assessment (They will suggest that you complete their [Provider Compliance Assessment Tool](#) although it is not obligatory to do so and you can submit your own type of self-assessment)
- 5) Carry out a site visit

As stated in the **foreword** we have significant concerns about the workload for practices from demonstrating compliance. Our concerns are that the CQC's current expectations for the demonstration of compliance from 1 April 2012 will create an additional and unnecessary administrative burden that will disrupt GP practices and divert time away from patients. The CQC has said that you should be able to provide evidence that is based on activity that you already do but we still have concerns that all three proposed forms of assessment will create extra workload for practices because, although you will not need to submit evidence, you are likely to have to do additional work such as collation and recording to have evidence available that you can refer to or use. This is compounded by that fact that the CQC will not be prescriptive in the amount of evidence that is required for any of the forms of assessment and that the CQC look for evidence that demonstrate outcomes rather than processes.

At present we believe that you are most likely to be asked to submit self-assessments of your practice. The CQC has said that practices can submit their own form of self-assessment but that you can also complete their Provider Compliance Assessment Tool. The fact that this tool requires its own accompanying guidance on how to complete it demonstrates that it is not straightforward and the nature of the questions in the tool will only encourage a creative writing exercise which we do not believe is the way compliance should reliably be demonstrated. Therefore we are not convinced of the benefit of their Provider Compliance Assessment Tool and believe that alternatives should be used.

Within this context we have suggested some examples of evidence that you could refer to or use when demonstrating compliance with the core 16 outcomes based on the CQC's current [Using evidence of outcomes to demonstrate compliance guidance](#), the methods of assessment used by CQC for other providers and our interpretation of the CQC's *Guidance about Compliance*. It is important to note that lists of evidence are **only examples** because we will be continuing to discuss the methods of assessment and expectations further with the CQC with the intention of minimising the work required for practices. We would advise you not to commence work on preparing to demonstrate compliance at this time but you will no doubt want to give the matter some initial thought and discussion in your practice. You could do so by considering our suggestions in the *Meeting the outcomes* sections.

Meeting the 12 additional outcomes

At the end of this part we have also provided advice on how to meet 12 additional outcomes that relate to the day to day management of your practice. You will not need to declare compliance with the regulations relating to these 12 Essential Standards when you apply for registration **but** you are still required to meet these outcomes. You are likely to be only asked about these outcomes if CQC has concerns.

Please note: This toolkit 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. If there is any legislation or standards that your practice should be compliant with that are not specifically mentioned in this toolkit then you should still comply with those legislation/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 the 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.

Who can use this part of the toolkit?

This part is aimed at NHS GP practices (GMS/PMS/APMS) providing essential, additional and standard enhanced services. The additional prompts that have been considered are those related to the Doctor Consultation Services and Doctor Treatment Services (see **Part 3** and **Appendix B** for further information on service types). Therefore if you are another NHS primary medical services provider, such as an OOH care provider, or provide enhanced services that are covered by different service types you will find some or all of this part useful but will want to consider your own additional prompts related to your service types.

Please note: Our use of the word **practice** in this guidance is a replacement for the CQC's word **provider**. We have only done to make the guidance easier to follow.

A provider is the legal entity that provides the regulated activities to patients that must register with the CQC. Therefore provider means GP practice, GP-led health centre, OOH care provider etc. However, a provider can also be the legal entity responsible for more than one practice. A provider can be an individual, a partnership or an organisation.

Therefore you should read references to practice as referring to you our own determined provider status. See **Part 2** for further information on providers.

Involvement and Information

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Involving patients

- 1) Healthcare professionals at your practice should respect the right of patients **with capacity** to make or influence decisions about their care. They should also promote the dignity and independence of these patients. To do this, we suggest that, in line with accepted modern professional practice philosophy, healthcare professionals at your practice:
 - a) establish patients needs, preferences and decisions and place them at the centre of their assessment, planning and delivery of care to patients;
 - b) explain the outcomes of diagnostic tests and assessments in a way that patients can understand so that they can make informed choices;
 - c) discuss and provide information about the available care, treatment and support options so that patients can make informed decisions;
 - d) respect patients' rights to take an informed risk and make decisions about their care (including self care), whilst balancing this need for choice with safety;
 - e) give patients time to make decisions to the extent that the circumstances allow;
 - f) know when to arrange for aids that allow patients to understand clinicians' explanations and be involved in decisions about their care (applicable to all staff);
- 2) When a patient **lacks capacity** to make their own decisions we suggest your staff follow procedures based on the guidance in the [BMA's Mental Capacity Act Toolkit](#).

Furthermore, staff can refer to the [BMA's guidance on when statutory advocacy services should be involved when patients lack the capacity to represent their own interests](#)

Your staff should know when to arrange for a patient representative and that the representative should be involved in assessment, planning and decisions about the patient's care.

- 3) When a patient is **under 16 years old** we suggest that your staff refer to procedures based on the guidance in the [BMA's Children and Young People Toolkit](#).
- 4) Your staff should understand the importance of respecting the privacy of all patients. We suggest that you underpin good practice by having a confidentiality protocol. This protocol should cover the need for confidential information to be discussed with patients in a private setting and guidance on when to disclose information/maintain confidentiality. An example of a confidentiality protocol can be viewed in **Appendix C1**.

For further information on disclosure of information your staff can follow the guidance in the [BMA's Confidentiality and Disclosure of Health Information Toolkit](#).

- 5) To promote the independence of all patients we suggest that you have information available on how to contact independent advocacy services such as the Patient and Advice Liaison Service (PALS), direct patients to these services when appropriate and cooperate with these services when necessary.

Managing risk

- 1) Patients or their representatives should be involved in decisions about their care and their needs should be met as much as possible. Therefore we suggest that you have procedures in place so that staff know how to:
 - a) arrange patient aids, such as interpreter services, that allow patients to understand healthcare professionals' explanations and be involved in decisions about their care, when necessary. Certain services, such as interpreting, should be made available by your PCT (or replacement body). If, for whatever reason, such services are not made available to your practice, you may need to consider referring the patient to the PCT (or replacement body);
 - b) arrange for patient representatives/chaperones when necessary;
 - c) organise any other reasonable adjustments so that patients can be involved in decisions about their care or treatment.
- 2) At the same time as encouraging the involvement of patients in their care your healthcare professionals should:
 - a) discuss the risks and benefits of the various care and treatment options with patients;
 - b) explain when a patient's preferred treatment cannot be followed (e.g. because their choice would place others at risk of harm).

Promoting rights and choices

- 1) Besides the information provided about care and treatment options in consultations your patients should be able to make informed decisions because there is adequate information available in the practice. We suggest that you have:
 - a) a leaflet containing information about your practice's services, such as that specified in **Appendix C2**. You may wish to provide the leaflet, or extracts, in other languages if this is appropriate for your area.
 - b) a notice that specifies when patients will be charged a fee for services from the practice, the fee amounts and the methods by which patients are able to pay the fees (it is considered good practice that any fee charged is known to the patient before they commission work);
 - c) lifestyle information available for patients who have lifestyle behaviours that are placing their health at risk and/or a procedure for providing such information to patients when appropriate. An example of a provision of lifestyle information protocol can be viewed in **Appendix C3**;
 - d) any other useful information on display about services available at your practice or in the area.
- 2) Your staff should be able to promote the rights of patients because they are aware of, understand and recognise the importance of patients' social and cultural diversity, values and beliefs and do not allow their own views to affect their treatment of patients; and report any concerns about another. (GPs at your practice should be observant of the [GMC's Good Medical Practice guidelines](#)).

- 3) Your patients should be able to influence the service that you run because you have a mechanism for patients to offer comments and suggestions as well as raise concerns. You could have one or more of the following in place (or similar):
 - a) a suggestion box in the reception for comments. These comments should be regularly reviewed and acted on if appropriate;
 - b) a regular practice-run survey of patients, of which the results are reviewed and acted on if appropriate;
 - c) a patient group with which you have regular meetings and interaction with, and from which suggestions are reviewed. The BMA has guidance on [setting up patient groups](#).

We suggest that you maintain a written record of suggestions for service improvement, how and when you have considered them and, if appropriate, acted on them. As good practice we suggest that you discuss comments with your staff at team meetings and keep a record of learning and development points that you identify.

- 4) Your patients should also know how to make complaints because you have a publicised complaints process, as described in our guidance for **outcome 17**. We suggest that you review complaints and act if appropriate.

Demonstrating compliance

When the CQC is monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Patient feedback and your handling of complaints;
- 2) Your arrangements for ensuring that the needs of patients are met e.g. the arrangements for ensuring that confidentiality and privacy of patients is respected and for patient representatives/chaperones;
- 3) Your procedures for making reasonable adjustments so that patients can be involved in decisions about their treatment e.g. arranging patient aids;
- 4) Information that is on display about your practice e.g. your practice leaflet, fees notice and notice on your complaints process;

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

GMC *Good Medical Practice*

http://www.gmc-uk.org/guidance/good_medical_practice.asp

Nursing and Midwifery Council Code

<http://www.nmc-uk.org/Nurses-and-midwives/The-code>

BMA's *Mental Capacity Act* Toolkit

http://www.bma.org.uk/images/MentalCapacityToolKit%20July2008_tcm41-175571.pdf

BMA's *Developing general practice: Listening to Patients* guidance

http://www.bma.org.uk/employmentandcontracts/independent_contractors/managing_your_practice/listenpatient.jsp

BMA's Patient Liaison group (PLG) guidance on *patient participation groups in primary care*

http://www.bma.org.uk/patients_public/ppgintro.jsp

BMA's *Confidentiality and Disclosure of Health Information* Toolkit

<http://www.bma.org.uk/ethics/confidentiality/confidentialitytoolkit.jsp>

BMA's *Consent* Toolkit

http://www.bma.org.uk/images/consenttoolkitdec2009_tcm41-193139.pdf

BMA's *Children and Young People* Toolkit

http://www.bma.org.uk/ethics/consent_and_capacity/childrentoolkit.jsp

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety](#) guidance, Appendix B)

- The NHS Constitution (DH, 2009)
- Confidentiality: NHS code of practice (DH, 2003)
- Confidentiality and Disclosure of Information: Code of Practice (DH, 2005)
- Relevant national strategies, national service frameworks, and nationally agreed policy guidance and recommendations about involving people published by the Department of Health and other Government departments, including:
 - Human Rights in Health Care – A Framework for Local Action (DH)
 - Valuing People: a new strategy for learning disability for the 21st century (HM Government, 2001)
 - Valuing People Now: a new three-year strategy for people with learning disabilities – Making it happen for everyone (HM Government, 2009)
 - Real involvement: working with people to improve services (DH, 2008)
 - Independence, Choice and Risk: A Framework for Supported Decision Making (DH, 2007)

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 your staff should know how to respond when a patient lacks the capacity to give consent.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Managing risk

- 1) To ensure that your patients **with capacity** give valid consent we suggest that your staff know:
 - a) to provide information to patients on the care and treatment options available (including the risks and benefits of each option) before they make consent decisions;
 - b) that there should be a comprehensive explanation (including the risks and benefits) before significant procedures and the use of imaging equipment;
 - c) that patients should be given enough time to think about their consent decisions except in an emergency;
 - d) that even in emergencies valid consent should be obtained wherever possible;
 - e) that consent should be sought from a patient by healthcare professionals who have sufficient knowledge about the patient and the treatment options available;
 - f) how written consent should be recorded and it should be taken, i.e.:
 - i) when 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;
- g) the circumstances when oral or implied consent can be taken;
- h) that they should act in accordance with decisions made by patients and respond professionally when the patient's wishes conflict with their care, safety and welfare needs;
- i) that there should be a regular review of consent decisions to take into account the changing needs of patients;
- j) that patients can have a representative to help them understand their options and make decisions if necessary;

We suggest that you put the above in place by having 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](#).

- 2) Healthcare professionals at your practice should be able to 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](#).
- 3) Healthcare professionals at your practice should be able to identify when patients **under 16 years old**. In those circumstances we suggest that your staff follow the guidance in the BMA's [Children and Young People Toolkit](#).
- 4) You could have information about your consent procedures on display/available (e.g. a practice notice/leaflet).

Demonstrating compliance

When CQC are monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Your consent procedures;
- 2) Patient feedback.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

GMC's guidance on consent
http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

BMA's guidance documents on consent and capacity

http://www.bma.org.uk/ethics/consent_and_capacity/index.jsp?page=1

BMA's *Consent* Toolkit

http://www.bma.org.uk/images/consenttoolkitdec2009_tcm41-193139.pdf

BMA's *Mental Capacity Act* Toolkit

http://www.bma.org.uk/images/MentalCapacityToolKit%20July2008_tcm41-175571.pdf

BMA's *Children and Young People* Toolkit

http://www.bma.org.uk/images/childrenyoungpeopletoolkit2011_tcm41-203018.pdf

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety guidance, Appendix B](#))

- Reference guide to consent for examination or treatment (DH, 2009);
- Good practice in consent: achieving the NHS plan commitment to patient centred consent practice (Health Service Circular HSC 2001/023);
- Seeking consent: working with children (DH, 2001);
- Research governance framework for health and social care: Second edition (DH, 2005);
- Mental Health Act Code of Practice (2007);
- Mental Capacity Act Code of Practice (2008)

Personalised care, treatment and support

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Assessment, planning and delivery of treatment and care

- 1) We suggest that your staff establish or review the individual health needs and risks of all of your patients when they have an appointment so that they can plan and/or deliver the appropriate treatment. The health needs of patients could be physical, mental, social, emotional etc.

All patients registered with your practice that medically need a consultation should be able to have one at the earliest appropriate appointment time. Also we suggest that newly registered patients have a health check with a healthcare assistant, practice nurse or a GP within six months of registration and that you provide a consultation to any registered patients aged 16-75 that have not attended a consultation in three years and request one.

During consultations/examinations, your staff should respect the diversity, rights, privacy, dignity, and independence of patients and involve them in decisions about their care, and balance patient safety with the right for patients to take informed risks. Reasonable adjustments should be made for patients as appropriate (see **outcome 1**).

For patients under 16 years old the involvement should be to the fullest extent possible. We suggest that your staff follow the guidance in the [BMA's Children and Young People Toolkit](#).

- 2) When appropriate, patients should have plans for care (or similar) that they (or their representatives) are involved in planning as appropriate and reviewed on an appropriate timescale.
- 3) We also suggest that lifestyle information is provided to patients when appropriate/is available in your practice (see **Appendix C3** for lifestyle information protocol).
- 4) When the care and treatment of a patient requires co-operation between two or more individuals/providers (e.g. secondary care, social care) then you should have arrangements to ensure that there is effective information sharing and your staff should work with the other providers as appropriate (see **outcome 6**).
- 5) So that your practice is able to provide care to patients based on reliable and up-to-date information we suggest that you have a protocol for reviewing and acting on correspondence, reports and investigation results. An example protocol can be seen in **Appendix C4**.

Managing risk

- 1) Your patients should receive appropriate and safe treatment at all times. To ensure this we suggest that you:
 - a) observe your local incident reporting procedure;
 - b) conduct regular significant event reviews and analyses and learn from incidents, errors and near misses (see **outcome 16**). 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](#);
 - c) have 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 C5**;
 - d) have 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). An example of a [business continuity plan](#) is that produced by NHS Connecting for Health;
 - d) ensure that the analysis of the results of diagnostic tests and assessments are undertaken by trained and appraised staff.
- 2) When a patient becomes/is seriously ill at your practice then your staff should treat or arrange for the patient to be transferred to the appropriate service.

Promote rights and choices

Your patients should be informed about the various care options (as well as the risks and benefits), involved in decisions about their care and be able to make informed choices, including where they are unable to do this by themselves (see **outcome 1**).

Demonstrating compliance

When CQC are monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Patient feedback;
- 2) Incident reporting and significant event review/analyses and evidence of learning/action taken (e.g. minutes of practice team meetings);
- 3) Your assessment of patients followed by individual care plans when appropriate, such as those for Mental Health indicator 10, which are reviewed on an appropriate basis;
- 4) Your assessments of patients followed by personal action plans where appropriate, such as for Asthma indicator 6, which are reviewed on an appropriate basis;
- 5) Lifestyle information leaflets in your practice; you could also point to the lifestyle advice provided to patients with hypertension as part of Primary Prevention indicator 2.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

National Institute for Health and Clinical Excellence
<http://www.nice.org.uk/>

National Patient Safety Association
<http://www.npsa.nhs.uk/>

The Medicines and Healthcare products Regulatory Agency
<http://www.mhra.gov.uk/>

The Central Alerting System
<https://www.cas.dh.gov.uk/Home.aspx>

GMC's Good Medical Practice
http://www.gmc-uk.org/guidance/good_medical_practice.asp

Nursing and Midwifery Council Code
<http://www.nmc-uk.org/Nurses-and-midwives/The-code>

BMA's Developing general practice: Listening to Patients guidance
http://www.bma.org.uk/employmentandcontracts/independent_contractors/managing_your_practice/listenpatient.jsp

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety guidance, Appendix B](#))

- The NHS Constitution (DH, 2009)
- Mental Capacity Act Code of Practice (2007)
- Mental Health Act Code of Practice (2008)
- Being open – communicating patient safety incidents with patients and their carers (NPSA, 2006)
- National Service Framework for Mental Health (DH, 1999)
- National Service Framework for Older People (DH, 2001)
- Diabetes National Service Framework (DH, 2003)

- Choosing Health: Making healthy choices easier (DH, 2004)
- Healthy Lives brighter futures: The children strategy for children and young people's health (DH, 2009)
- Valuing People Now: a new three-year strategy for people with learning disabilities – Making it happen for everyone (HM Government, 2009)

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.

The following is a suggestion on how you might meet this outcome. However, you may identify alternative ways of doing this. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

We do not view this outcome as being normally applicable to GMS, PMS and APMS practices that provide essential, additional and standard enhanced services because they do not provide food and drink to patients as part of their regulated activities.

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Personalised care

- 1) Staff at your practice should act in the best interests of patients, be responsive to their changing needs, refer when clinically appropriate and work to minimise disruptions to the continuity of care.

For the benefit of patients, we suggest that when referring healthcare professionals at your practice:

- a) discuss with the patient the options and arrangements for the referral (respecting and involving the patient as for **outcome 1**);
- b) include 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, NHS Number, where known, and emergency contact details;
 - 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) whom to contact in your practice about the patient and that their contact details.
- c) transfer 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;
 - d) in the case of children and patients without the capacity to give consent, ensure that their parents/guardian/representatives are involved and informed about referral decisions.
- 2) Your staff should work and share information with other providers (e.g. OOH care providers, social care services) as and when appropriate and participate in cross-sector activities, such as local safeguarding children and adults boards, when necessary. Healthcare professionals at your practice should be involved in care plans (or similar) and the planning of the movement of children to adult services, which require input from various providers, when and to the extent appropriate. We suggest that you staff keep an appropriate record of treatment they give to patients and, if applicable, know who the coordinating lead.

Leading effectively to manage risk

- 1) Your practice should have 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.
- 2) When cooperating with other providers/referring patients we suggest that you have 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 C1**).

We suggest that your confidentiality protocol includes:

- a) a requirement to report any loss, inappropriate storage or incorrect disclosure of confidential information to the information governance lead or Caldicott Guardian; and to inform the patient if the information is shared inappropriately or lost;
 - b) the need for disclosures of confidential information about patients to a third party or organisation being made in accordance with the principles of the Data Protection Act 1998, the NHS Confidentiality Code of Practice and the GMC's Good Medical Practice;
 - c) how patients should be informed and asked for consent before information is disclosed about them to a third party owing to safeguarding concerns/public interest, unless it would be unsafe or not practical to do so. In the circumstances that you are unable to obtain consent you should be clear about the reasons and necessity for sharing.
 - d) ways that information should be documented, copied, stored and transferred, which have been agreed with another provider (if applicable).
- 3) So that your staff are able to respond in a timely manner to incoming information we suggest that you have a protocol for acting on correspondence and results (see **Appendix C7**).

Promoting rights and choices

- 1) We suggest that when referring patients healthcare professionals at your practice ensure that patients know at least what type of information is being transferred and be able to provide a copy of the information to patients if they request it.

- 2) Healthcare professionals at your practice should respect 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.
- 3) Relevant information about health and social care services in the area could be on display in your practice and your patients should be offered a choice of provider where possible in consultations.

Demonstrating compliance

When CQC are monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Referral letters containing the appropriate information about patients;
- 2) Reports, care plans or case reviews that show examples of you working cooperatively with other providers;
- 3) Patient feedback;
- 4) Your arrangements for emergency situations;
- 5) Evidence that you transfer information securely and in a timely manner;
- 6) The information about other local providers you display in your practice.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

GMC's *Good Medical Practice*

http://www.gmc-uk.org/guidance/good_medical_practice.asp

BMA *Confidentiality Toolkit*

<http://www.bma.org.uk/ethics/confidentiality/confidentialitytoolkit.jsp>

Confidentiality: NHS Code of Practice 2003 -

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253

The Information Commissioners' Office guide to data protection

http://www.ico.gov.uk/for_organisations/data_protection/the_guide.aspx

BMA/RCGP/DH's *Pandemic influenza: Guidance for GP practices Swine flu H1N1 preparedness*

http://www.bma.org.uk/images/panfluguide_tcm41-192666.pdf

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety guidance, Appendix B](#))

- The NHS Constitution (DH, 2009)

- Records management: NHS code of practice (DH, 2006)
- Discharge from hospital pathway, process and practice (DH, 2003)
- Information security management: NHS code of practice (DH, 2007)
- The NHS Emergency Planning Guidance (DH, 2005), and associated supplements (DH, 2005, 2007)
- Pandemic Influenza: A National Framework for Responding to an Influenza Pandemic (DH, 2007)

Safeguarding and Safety

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Leading effectively

- 1) To make sure that your staff are able to identify abuse of adults and children and act appropriately we suggest that your staff (including temporary staff):
 - a) have had safeguarding training, if appropriate to their role, so that they can recognise the signs of abuse;
 - b) observe 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](#).
 - c) observe a safeguarding adults policy. Here is an example of a local [safeguarding adults policy](#).
 - d) know who to contact in the circumstances of suspected abuse or alleged abuse;

- e) work collaboratively with other providers on safeguarding matters and participate in safeguarding children and adult boards when appropriate.
- 2) You should take 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 (or replacement holders of the Performers List).
- 3) To ensure that patients can raise concerns and make complaints related to abuse we suggest that you have a mechanism for patients to make comments (see **outcome 1**), and a publicised complaints procedure (see **outcome 17**).
- 4) So that your practice learns from incidents related to abuse we suggest that you conduct significant event reviews and analyses when appropriate (see **outcome 16**).
- 5) We suggest that you regularly review the information gathered from significant event reviews, concerns and complaint investigations and discuss them with the practice team.

If during investigations/reviews your responsible individual identifies non-compliance with any of the CQC outcomes then you should take action to return to compliance.

- 6) We also suggest that staff have violent patient training and you have procedures for handling violent and abusive patients.

Ensuring personalised care

- 1) Staff at your practice should be able to provide personalised care to the patients covered by this outcome because they involve them in their care, they respect them (see **outcome 1**) and all of the suggestions above have been fulfilled.
- 2) Your staff should feel confident to report any concerns because they are aware of their rights under the Public Interest Disclosure Act 1998 (this can be covered in the safeguarding policies).

Promoting rights and choices

- 1) The provision of appropriate information to patients is important (see **outcome 1**). Victims of abuse could be provided with information on local support/advocacy services proactively by staff and/or on request.

We suggest that 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:

- a) The [BMJ Evidence Centre webpage](#);
- b) The [Patient UK website](#).
- 2) When you have safeguarding concerns about a patient the relevant information should be shared with other providers in accordance with local safeguarding procedures (taking into account the sensitive nature of the information).

Demonstrating compliance

When CQC are monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked

to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Your local safeguarding procedures/policies and any example of when you have had to take action;
- 2) Documentation that indicates that any agency staff have had adequate safeguarding training to fulfil their role;
- 3) Significant event review/analyses, complaints handling, patient feedback and evidence of learning/action taken (e.g. minutes of practice team meetings);
- 4) Reports or case reviews that show examples of you working cooperatively and sharing information with other providers on safeguarding matters;
- 5) Information related to abuse that is available in the practice for patients;
- 6) Patient feedback.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

BMA's *Child Protection Toolkit*

http://www.bma.org.uk/ethics/consent_and_capacity/childprotectiontoolkit.jsp

BMA's guidance on the *abuse of older people*

http://www.bma.org.uk/health_promotion_ethics/health_ageing/HealthAgeing.jsp?page=2

BMA's *Domestic abuse* report

http://www.bma.org.uk/health_promotion_ethics/domestic_abuse/domesticabuse.jsp

BMA's *Violence and health* guidance

http://www.bma.org.uk/health_promotion_ethics/domestic_abuse/vioheal.jsp

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety guidance, Appendix B](#))

- No secrets: Guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse (DH and Home Office, 2000)
- Working together to safeguard children (HM Government, 2006) and supplementary guidance published by government departments
- Statutory Guidance on making arrangements to safeguard and promote the welfare of children under section 11 of the Children Act 2004 (DCSF, 2007)
- Safeguarding Adults: A National Framework of Standards for good practice and outcomes in adult protection work (Association of Directors of Adult Social Services, 2005)
- What to do if you're worried a child is being abused (HM Government, 2006)
- Information Sharing: Guidance for practitioners and managers (DCSF, 2008)
- Statement on the duties of doctors and other professionals in investigations of child abuse (DCSF and DH, 2007)
- Mental Health Act Code of Practice (DH, 2008)

- Mental Capacity Act Code of Practice (DH, 2007)
- Guidance on when to suspect child maltreatment (CG89, NICE, 2009)

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Criterion 1: *Systems to manage and monitor the prevention and control of infection. These systems use risk assessments and consider how susceptible patients are and any risks that their environment and other users may pose to them.*

To meet this criterion we suggest that as part of an 'infection control programme' you:

- a) have a designated infection prevention and control (IPC) lead;
- b) have and implement an infection prevention and control policy that includes:
 - i) a commitment to minimising the risks of infection and to ensure the safety of patients;
 - ii) what infection prevention and control measures are needed in your practice;
 - iii) how the policy will be kept up-to-date and monitored;
 - iv) when IPC audits and risk assessments will occur;
 - v) what initial and ongoing training staff receive;
 - vi) references to all other relevant policies in your practice e.g. waste management, cleanliness;
 - vii) a record of the names and contact details of healthcare professionals at your practice and at your PCT (or replacement body) that can provide advice on IPC, and guidance to staff on the circumstances when they should be contacted.

An example of an IPC policy can be viewed in **Appendix C6**.

- c) produce an annual statement that includes 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) at least one infection control audit and actions taken;
- iii) at least one IPC risk assessment;
- iv) staff training;
- v) any review and update of policies, procedures and guidance.

This statement should be accessible to anyone that requests it. If your IPC lead identifies actions that need to be taken in the annual statement then you should be able to demonstrate taking action on them.

Criterion 2: Provide and maintain a clean and appropriate environment in managed premises that facilitates the prevention and control of infections.

To meet this criterion we suggest that you:

- a) have a designated lead accountable for ensuring appropriate cleaning of the practice environment and decontamination of practice equipment (for simplicity this could be the person who is your IPC lead);
- b) furnish your premises in accordance with [national guidance](#) and where possible and reasonable adapt rooms in accordance with risk assessments;
- c) examine wounds and other infection sites in suitable rooms;
- d) have and implement a decontamination policy. An example of a decontamination policy can be viewed in **Appendix C7**;
- e) have and implement a cleaning plan and schedule based on the [NHS Cleaning Manual](#) and the National Patient Safety Agency's [National Specifications on Cleanliness](#).

Criterion 3: Provide suitable accurate information on infections to patients and their visitors.

To meet this criterion we suggest that you:

- a) publish up-to-date information in your practice on your IPC programme and staff roles and responsibilities;
- b) have a mechanism for patients to make comments/give feedback/raise concerns about your infection and prevention control and make changes to practice as a result of this feedback if appropriate (see **outcome 1**);
- c) have information on display about current infection issues (e.g. Catch it, Bin it, Kill it campaign).

Criterion 4: Provide suitable accurate information on infections to any person concerned with providing further support or nursing/medical care in a timely fashion.

To meet this criterion we suggest that you share relevant and accurate information on infections about patients with other health and social care providers when necessary and appropriate (e.g. pre- and post- admission to hospital). For further guidance on sharing information with other providers see **outcome 6**.

Criterion 5: Ensure that patients who have or develop an infection are identified promptly and receive the appropriate treatment and care to reduce the risk of passing on the infection to other people.

To meet this criterion we suggest that in accordance with modern authoritative practice:

- a) healthcare professionals at your practice provide advice and treatment to any patient that has an infection and assess whether there are any communicable disease control issues;
- b) your healthcare professionals consult the local infection control experts if necessary or refer the patient for specialist advice.

Criterion 6: Ensure that all staff and those employed to provide care in all settings are fully involved in the process of preventing and controlling infection.

To meet this criterion we suggest that you ensure that everyone working at your practice understands the need to work to prevent and control infections in their daily work by:

- a) covering infection control in a practice induction and/or induction/staff handbook;
- b) covering infection control in staff job descriptions;
- c) have infection control updates from the IPC lead at practice team meetings as appropriate;
- d) ensure that all staff have the adequate infection control training to carry out their work.

Criterion 7: Provide or secure adequate isolation facilities.

Your practice is not required to have isolation treatment rooms but if a patient is suspected or known to have a transmissible infection then healthcare professionals at your practice should take appropriate precautions.

Criterion 8: Secure adequate access to laboratory support as appropriate.

This requirement will be met by your PCT's (or replacement body's) contracting arrangements. Should you become aware that a laboratory has not maintained its accreditation then you should inform the PCT and ask that they find an alternative provider.

Criterion 9: Have and adhere to policies, designed for the individual's care and provider organisations that will help to prevent and control infections.

To meet this criterion we advise that you:

- 1) have policies, which cover the topics listed below, implemented. (Further advice on the content of these policies refer to Appendix D of the Code of Practice).

The following could be covered in your infection prevention and control policy (see **Appendix C6**):

- a) standard infection prevention and control precautions e.g. hand hygiene, proper use of personal protective clothing and dress code;
- b) safe handling and disposal of waste and sharps devices (in conjunction with your waste management policy);

- c) the need for all staff who perform clinical procedures to be trained in aseptic technique appropriate to the procedures they carry out;
- d) packaging and handling of specimens;
- e) prevention of occupational exposure to blood-borne viruses, including prevention of sharps injuries;
- f) management of occupational exposure to blood-borne viruses and post-exposure prophylaxis;
- g) use and care of invasive devices;
- h) the immunisation of patients.

The following could be covered in your decontamination policy:

- a) disinfection;
- b) decontamination of reusable medical devices and equipment;
- c) disposal of single-use devices.

You should also have the following policies from the PCT (or replacement body):

- a) antimicrobial prescribing policy;
- b) policies that minimise the risk to patients from specific alert organisms e.g. the antimicrobial prescribing policy;
- c) infection incident reporting procedures;
- d) isolation procedures for patients with an infection;
- e) how to respond to outbreaks of communicable infections.

We suggest that you also observe the [Advisory Group on Dangerous Pathogen's Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection guidance](#) that covers the handling of instruments and devices in procedures on patients with known or suspected CJD/vCJD, or at increased risk of CJD/vCJD.

Criterion 10: Ensure, so far as is reasonably practicable, that care workers are free of and are protected from exposure to infections that can be caught at work and that all staff are suitably educated in the prevention and control of infection associated with the provision of health and social care.

We suggest that your staff have access to an occupational health service that is commissioned by the PCT (or replacement body) 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.

Advice on the Hepatitis B immunisation of staff can be found in the BMA's [Hepatitis B immunisation guidance](#) and the UK Health Departments' [Guidance for Clinical health care workers protection against infection with blood borne viruses](#).

We also suggest that you consider having a policy for managing needle stick (see infection prevention and control policy) and other patient related injuries to ensure rapid access to appropriate post exposure prophylaxis.

Demonstrating compliance

When CQC are monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Your infection prevention and control and decontamination procedures, your cleaning plan/schedule, as well as related audits and risk assessments and any examples of action taken as a result;
- 2) Your annual infection prevention and control statement;
- 3) Information on display in your practice about your IPC programme and current infection issues (e.g. public information campaigns);
- 4) Your arrangements for information sharing and evidence that information has been shared securely and in a timely manner;
- 5) Examples of your staff taking action to prevent or control infection in your practice.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

BMA's *Guidance on Healthcare associated infections*

http://www.bma.org.uk/health_promotion_ethics/diseases/index.jsp

Other relevant publications

NICE's Infection control: *Prevention of healthcare-associated infection in primary and community care* (2003)

http://www.nice.org.uk/nicemedia/pdf/Infection_control_fullguideline.pdf

Vaccine Administration Task force's *Guidance on Best Practice in Vaccine Administration* (2001)

http://www.rcn.org.uk/_data/assets/pdf_file/0010/78562/001981.pdf

HMSO (1996) *Immunisation Against Infectious Diseases - The Green Book*

<http://www.dh.gov.uk/en/PublicHealth/Immunisation/Greenbook/index.htm>

National Patient Safety Agency's *The national specifications for cleanliness in the NHS: Guidance on setting and measuring performance outcomes*

<http://www.nrls.npsa.nhs.uk/resources/?EntryId45=75241>

The NHS Cleaning Manual (2009)

<http://www.nrls.npsa.nhs.uk/resources/?entryid45=61830&q=0%c2%accleaning%c2%ac>

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 published 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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Personalised care

- 1) To ensure that patients receive appropriate medicines, we suggest that healthcare professionals at your practice take 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.

They should also involve patients as much as possible in decisions about their care and provide sufficient information for patients to make informed choices (see **outcome 1**).

- 2) To underpin the monitoring of prescriptions we suggest that you have a repeat prescribing policy that covers conducting medication reviews. An example of such a policy can be viewed in **Appendix C8**. However, your repeat prescribing policy should be specifically designed for your practice.
- 3) We suggest that you also have 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 C5**).

Managing risk

- 1) You must observe the prescribing requirements of your contract. Equally, if you have a dispensing practice then you must observe the dispensing requirements of your contract. The BMA has [Prescribing in general practice guidance](#).
- 2) We suggest that you have medicines handling procedures that cover the following that are appropriate for your practice: obtaining, storing, prescribing, dispensing, preparation, administration and disposing of medicines. These procedures should cover any of the following that are appropriate for your practice:
 - a) training for staff;
 - b) the arrangements for reporting adverse events, adverse drug reactions and incidents;
 - c) your arrangements for sharing and acting on patient safety alerts;
 - d) having up-to-date medicines lists for patients when they seek services at your practice e.g. when they join, when they are discharged from hospitals etc;
 - e) the recording of the dispensing of medicines to patients;
 - f) any other relevant procedures.
- 3) All medicines on your premises should be stored appropriately and securely e.g. at the right temperature. You should have medicines required for resuscitation or other medical emergencies readily accessible in tamper evident packaging.
- 4) There should be 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.
- 5) We suggest that your practice have a procedure for significant event reviews and analyses (see **outcome 16**) and observe local incident reporting procedures.

Promote rights and choices

Practices should provide information to patients about the medicines that they are dispensing/prescribing including any risks such as side effects i.e. the manufacturer's information.

Demonstrating compliance

When CQC are monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Your repeat prescribing policy and medication reviews; you could also point to the indications for repeat medicines required for Records indicator 9;
- 2) Evidence of monitoring of elements of your prescribing to make sure that it is clinically appropriate and any examples of action taken as a result; you could point to:
 - a) your report (containing evidence of change to your prescribing) produced for the PCO adviser for Medicines indicator 10 if the changes relate to clinical appropriateness;
 - b) your report from your internal review (clinical appropriateness is relevant) of your prescribing and the action plan agreed with the PCT for Quality and Productivity indicator 1;
- 3) Significant event review/analyses and incident reporting related to controlled drugs and other medicines and any evidence of learning/action taken;

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

BMA's *Prescribing in general practice* guidance

http://www.bma.org.uk/health_promotion_ethics/drugs_prescribing/InfoOnPrescrib0904.jsp

Guidance from the Dispensing Doctors Association

<http://www.dispensingdoctor.org/listing.php?pid=8&pg=1>

Quality and Outcomes Framework guidance

http://www.bma.org.uk/employmentandcontracts/independent_contractors/quality_outcomes_framework/qof0309.jsp

Other relevant publications (from [*Guidance about Compliance: Essential Standards for Quality and Safety*](#) guidance, Appendix B)

- Safer management of controlled drugs: Guidance on standard operating procedures for controlled drugs (2007).

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Adequate premises

- 1) You should ensure that the premises that you carry on regulated activities from are safe and suitable and meet the needs of patients. When you can not resolve an issue then you should manage the risks. When you move into new premises we suggest that you make sure that they will be compliant. We suggest that you:
 - a) have 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](#);
 - b) as much as appropriate, have 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;

- c) have premises that are reasonably accessible to all patients and where reasonably practicable meet the requirements of the [Equality Act 2010](#) regarding disabled people (most of the provisions of the Disability Discrimination Act 1995 have been incorporated into the Equality Act). 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.
- d) as much as reasonably practical, meet 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.

For further information about the Control of Substances Hazardous to Health Regulations we advise that you read the HSE's [Working with Substances Hazardous to Health](#) guidance.

For further information on the Regulatory Reform (Fire Safety) Order 2005 we suggest that you read the Department of Communities and Local Government's (DCLG) [Fire Safety: Risk Assessment](#) guidance.

For further information on controlling legionella bacteria we suggest that you read the HSE's [Legionnaires' disease: The control of legionella bacteria in water systems](#): Approved code of practice and guidance.

- e) have reasonable security arrangements so that your premises are secure. We suggest that you assess the risk of unauthorised access. To do so you could use this [NHS Connecting for Health toolkit](#).

If you share premises with other individuals/practices/organisations then we suggest that you consider conducting joint assessments or have a lease agreement that details who is responsible for doing the assessments. In the circumstances that you lease premises then we advise that you have a lease agreement that details the responsibility of each party.

When you alter or change the use of a section of your premises we suggest you consider conducting appropriate risk assessments of the affected area.

When you can not resolve an issue then you should seek to manage those risks. For example, if you are unable to secure funding to improve your premises to meet the above requirements from the PCT (or replacement body) 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. This management of risk should be documented in your risk assessment.

- 2) We suggest that you also take into account of the needs of patients by having a mechanism for patients to make comments (see **outcome 1**) about your premises and acting on appropriate suggestions. Your premises should, to the extent that is practicable, allow you to protect your patients' right to privacy and dignity.

Leading effectively

- 1) For the benefit of staff and patients we suggest that you:
 - a) have appropriate arrangements in place for the collection, classification, segregation, storage, handling, treatment and disposal of healthcare waste;
 - b) ensure 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) have a maintenance procedure, a person responsible for organising premises maintenance in response to risks that arise and a maintenance record.
- 2) When you identify that it is necessary to develop your premises we suggest that you agree a premises development plan with the PCT (or replacement local body responsible for allocating funding).

We suggest that your premises be developed, as much as appropriate, in line with Health Building Note 11, which can be accessed if you register with <http://www.spaceforhealth.nhs.uk>. Registration is free for NHS GPs.

- 3) We suggest that you have 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.
- 4) We would also suggest having clear information about your fire evacuation procedures and other similar emergencies for patients on display and cover what to do in an emergency for staff in your induction/staff handbook/induction pack.
- 5) Your practice should have toilet and breast feeding facilities if feasible and appropriate in your practice premises.
- 6) We also suggest that you make sure that any electrical, heating, safety and building facilities comply with statutory requirements and the manufacturer's instructions.

Demonstrating compliance

When the CQC is monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (these are just examples):

- 1) Health and safety-related/security risk assessments and any examples of action that you have taken as a result;
- 2) Evidence of any adjustments you have made to your premises for the benefit of patients;
- 3) Patient feedback;
- 4) Information on display (for patients and staff) about what to in emergencies, your business continuity plan and evidence that staff aware of and what to do in emergencies;

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;

- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

BMA's *practice premises* guidance

http://www.bma.org.uk/employmentandcontracts/independent_contractors/practice_premises/index.jsp

Other relevant publications (from [*Guidance about Compliance: Essential Standards for Quality and Safety* guidance, Appendix B](#))

- All currently valid Health Technical Memoranda (HTMs) published by the Department of Health;
- All currently valid Health Building Notes (HBNs) published by the Department of Health;
- Legionnaires Disease: The control of legionella bacteria in water systems, approved code of practice and guidance (Health and Safety Executive, 2000);
- A professional approach to managing security in the NHS (NHS Security Management Service, 2003).

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Adequate equipment

- 1) We suggest that you make sure that you have sufficient equipment for carrying out your regulated activities that:
 - a) is safe and suitable to use. We suggest that you having 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.
- 2) Your staff should meet the needs of and promote the dignity and independence of patients by:
 - a) listening to patients and responding where professionally appropriate to their preferences on how equipment is used;

- b) explaining to patients how and why equipment will be used;
 - c) using equipment so that patients are comfortable.
- 3) Your staff should address any concerns they have about the safety of equipment they are using in a timely manner.

Managing risk

We suggest that you manage and reduce the risk to patients by:

- a) conducting risk assessments of your equipment and acting appropriately when risks are identified;
- b) making sure that all of your staff using equipment have had adequate training and know what to do if a patient refuses to allow the use of equipment (relates to **outcome 1**);
- c) observing local incident reporting procedures and learning from incidents. To make sure that all of your relevant staff learn from incidents we suggest that you discuss them at team meetings;
- d) having a business continuity plan such as that produced by [NHS Connecting for Health](#);
- e) having equipment required for medical emergencies available and accessible on the premises, and in tamper proof packaging;
- f) having a procedure for the dissemination of and acting on medical device alerts and national guidance (see **Appendix C5**).

Effective use of medical devices

We suggest that you ensure that medical devices are:

- a) available for use and stored appropriately;
- b) not reused if they are manufactured for single use only;
- c) permanently installed if appropriate in accordance with the manufacturer's requirements;
- d) modified, maintained and repaired by individuals who are competent to do so;
- e) in accordance with any legal requirements and have technical information supplied with them;
- f) disposed of safely and securely.

Demonstrating compliance

When the CQC is monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) A risk assessment of your equipment and any examples of action you have taken as a result;
- 2) A risk assessment of the equipment in your practice and any action you have taken as a result;

- 3) Incident reporting procedures at your practice, evidence of learning from incidents (e.g. minutes from team meetings) and any action taken as a result;
- 4) Your system for disseminating and acting on guidance and medical device alerts and evidence that they have been acted on;
- 5) Patient feedback.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety guidance, Appendix B](#))

- MHRA DB 2006 (4) Single-use Medical Devices: Implications and Consequences of Reuse (MHRA, 2006);
- MHRA DB 2006(5) Managing Medical Devices: Guidance for health care and social care organisations (MHRA, 2006).

Suitability of Staffing

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Managing quality

- 1) For the benefit of patients and to meet regulatory requirements we suggest that you recruit staff that have:
 - a) the necessary skills, experience and evidence of relevant qualifications and training (i.e. certificates);
 - 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 (see more specific requirements for healthcare professionals below);
 - e) given reasons for their last position ending (i.e. why did they leave their job);
 - 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 list above is from [Schedule 3 of the Health and Social Care Act 2008 \(Regulations\) 2010](#). Much of this information can be gathered from a CV/application or at the interview stage.

These regulations also require that you ask for satisfactory information about any physical or mental health conditions, which are relevant to the regulated activities that staff will perform (paragraph (h) of Schedule 3 of the Health and Social Act 2008 (Regulations) 2010). **However**, the Equality Act 2010 forbids employers to ask a candidate about their health or disability until they have been offered the job, except in certain circumstances, as explained in the [Government Equalities Office guidance](#). Therefore we advise you to follow [NHSE's guidance](#) that you only ask for information about candidates' physical or mental health conditions after making a conditional offer. If the candidate does have conditions that affect their ability to perform their role then you should first attempt to make reasonable adjustments where necessary.

- 2) In addition we suggest that you recruit 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). Where you employ or engage the same person on more than one occasion within a period of three months you may rely on the references provided on the first occasion, provided that those references are not more than twelve months old;
 - d) are not on a Independent Safeguarding Authority barred list (For further information view the BMA's [Vetting and Barring scheme guidance](#)).

You must ensure that all GPs recruited for your practice are included on a Performers List in England. GPs should provide the name and address of the PCT on whose Performers List that they appear. *Where appropriate the inclusion on the Performers List could be used as an equivalent to items required above.*

Where a GP is included on a Performers List or on a medical register subject to conditions you should ensure that the conditions are complied with when they work at your practice.

- 3) Please note the following exceptions apply to GMS/PMS contractors (other contractors should check their contracts for additional/different requirements or exceptions):
 - a) a GP trainee who has applied to be included on a Performers List but not yet received approval can work at your practice for up to two months from the date that their vocational training scheme began;
 - b) where the employment of a healthcare professional is urgently needed then they can be employed on a temporary basis for a period of up to 7 days whilst checks are undertaken to ensure that the healthcare professional's registration with a relevant regulatory body is not suspended and their Performers List status;
 - c) where the employment of a healthcare professional is urgently needed then they can be employed on a temporary basis for a period of up to 14 days whilst reference checks are conducted. The period can be extended for a further 7 days if you believe that the persons supplying the references are temporarily unavailable.

- 4) If you would like further guidance on checks for recruitment you may wish to refer to the [NHS employment check standards](#) that are used by NHS Trusts. However, **these NHS employment check standards are not mandatory** for general practice.
- 5) After recruitment we suggest that you ensure that all staff continue to be able to work at your practice (e.g. GPs continue to be registered with the GMC) and continue to have the appropriate knowledge, skill and experience to fulfil their role.

All staff, but particularly healthcare professionals, at your practice should be reviewing their skills and knowledge as part of their appraisal and/or in house annual review, and any learning and development needs should be identified during the process. For guidance on conducting an in-house review you can refer to the relevant chapter of BMA's [Salaried GP handbook](#).

We suggest that you involve your staff in regular team meetings where you discuss matters such as the results of clinical governance activity, patient feedback, alerts, new guidance and other information from which lessons can be learnt. For further guidance on supporting workers see **outcome 14**.

- 6) Trainees and students should only be given tasks that are appropriate for their stage of training and competence.

Leading effectively

- 1) The recruitment process that your practice conducts must be fair and equal to all so that you do 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](#))

In your recruitment process there should be an application stage and an interview stage. Records should be kept of all of these stages. As good practice, when advertising a position, we suggest that you include an up-to-date job description. An example of a recruitment policy that could be used to underpin your recruitment process can be viewed in **Appendix C9**.

- 2) We suggest that you ask all new staff about their Hepatitis B status (and if appropriate any other relevant blood borne viruses) and this should be recorded. When necessary the new staff member should be immunised. Again, the Equality Act 2010 does not allow for you to ask for this before you make a conditional offer.

Advice on the Hepatitis B immunisation of staff can be found in the BMA's [Hepatitis B immunisation guidance](#) and the UK Health Departments' [Guidance for Clinical health care workers protection against infection with blood borne viruses](#).

- 3) As good practice, we also advise that you give an induction to new permanent and temporary staff, (see **outcome 14**), in which the roles and responsibilities of other members of staff are explained.
- 4) For consistency and the safety of patients all temporary, agency and voluntary staff should be subject to the same level of checks as permanent staff. If you do not hire the staff directly then you should be satisfied that the agency recruiting on your behalf is asking for and recording the relevant information (i.e. by asking for written confirmation that all relevant checks have been carried out).
- 5) For the standards of your staff's service to be maintained we suggest that you have procedures in place for when staff:
 - a) are not well enough to work;

- b) behave outside of your policies or professional codes of conduct;
- c) are subject to investigations (including suspected abuse);
- d) are suspected to have caused harm or risk of harm to patients;
- e) are barred by the Independent Safeguarding Authority but able to work in a Safeguarding Vulnerable Groups Act 2006 "controlled activity" (For further information view the BMA's [Vetting and Barring scheme guidance](#)).
- f) require support to carry out their job (this could be addressed by a personal development plan);

Demonstrating compliance

When the CQC is monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Evidence of learning from clinical governance activity, patient feedback etc (e.g. minutes of team meetings);
- 2) Written confirmation from an agency recruiting on your behalf that temporary staff are subject to the same checks as your permanent staff;
- 3) In-house appraisal documents and development objectives; for Education indicator 8 your nurses will have learning plans and appraisals, and for Education indicator 9 your non-clinical staff will have appraisals.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in relevant areas.

Useful information:

Equality and Human Right's Commission guidance on recruitment

<http://www.equalities.gov.uk/pdf/Pre-Employment%20Questions%20-%20FINAL.pdf>

Equalities Office's *Guide to the ban on questions about health and disability during recruitment*

<http://www.equalities.gov.uk/pdf/Pre-Employment%20Questions%20-%20FINAL.pdf>

BMA's *Vetting and barring scheme guidance*

http://www.bma.org.uk/images/vettingbarringschemeaug2010_tcm41-199283.pdf

BMA's *Salaried GP handbook*

http://www.bma.org.uk/employmentandcontracts/employmentcontracts/sessional_gps/salariedgpbook.jsp

BMA's *GP Trainees guidance*

http://www.bma.org.uk/careers/training_trainers/gp_trainees/index.jsp

GMC's Information on the GP register

http://www.gmc-uk.org/doctors/register/gp_register.asp

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety guidance, Appendix B](#))

- NHS employment check standards published by NHS Employers
- Code of practice for the international recruitment of healthcare professionals (DH, 2004)
- The Healthcare Professionals Alert Notices Directions 2006 (DH, 2006)
- CRB Code of Practice
- Safeguarding Vulnerable Groups Act 2006
- Protection of vulnerable adults scheme (POVA)
- ISA Referral Guidance (Independent Safeguarding Authority, 2009)

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Leading effectively

For your patients to receive safe and appropriate treatment and have their needs met we suggest that you:

- a) have 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.

We suggest that you base your level of adequate staffing on a risk assessment and the needs of your patients. For the risk assessment you may find it helpful to use the [Health and Safety Executive's guidance and template](#). To ascertain the needs of your patients we suggest that you have a mechanism for obtaining comments and feedback from patients (see **outcome 1**).

Your decisions on staffing should be supported by a recruitment policy (see **outcome 12** and **Appendix C9**).

- b) be able to adjust your staffing to respond to unexpected circumstances such as sickness, vacancies and unpredictable short and long term events such as a flu pandemic;
- c) be able to change your staffing in reaction to expected changes such as an expansion of the services that you provide or planned absence;
- d) ensure that your staff are able to contact senior/supervisory staff.

To achieve the above you may want to consider using a staffing policy which makes clear what the appropriate staffing is for your practice, in terms of skills, qualifications and knowledge only, and what should be done in different circumstances. Practices must not discriminate on grounds such as race, age, gender, disability, sexual orientation, religion or belief in any staffing policy or decision. An example of a staffing policy can be viewed in **Appendix C10**.

Demonstrating compliance

When CQC are monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to (these are just examples):

- 1) Your procedures for ensuring that there are adequate staffing levels, which are based on an assessment of risk and patient feedback;
- 2) Your risk assessment and review of patient feedback, and any evidence of action taken as a result.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in these areas.

Useful information:

GMC's *Good Medical Practice guidelines*

http://www.gmc-uk.org/guidance/good_medical_practice.asp

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Leading effectively

- 1) When anyone joins your practice we suggest that you give them an induction and an induction pack/staff handbook. We suggest that as a minimum your induction, induction pack or staff handbook cover:
 - a) a statement of objectives (or similar document produced by your practice);
 - b) information on the roles and responsibilities of colleagues in your practice, including who is their line manager/supervisor;
 - c) whom to speak to about human resources and personal development matters;
 - d) whom to speak to about concerns related to other staff members or patients, including when they are being subject to violence, harassment or bullying;
 - e) relevant procedures, policies and protocols (e.g. confidentiality), and information about where they are stored;
 - f) the action to take in emergencies and health and safety information;
 - g) how to report incidents, errors and near misses;

- h) whom to speak to about concerns about the practice not meeting the CQC standards or any other standards.
- 2) All staff at your practice should be appraised on a regular basis, usually annually, and develop a personal development plan. In the case of GPs at your practice, they should take part in the appraisal process organised by a PCT (or replacement body) and/or in addition an in-house annual review, and any personal development needs should be identified during the process. For guidance on conducting an in-house review you can refer to the relevant chapter of BMA's [Salaried GP handbook](#). For other practice staff you may wish to use the [guidance from NHS Employers](#). To support nurses at your practice you may wish to also use the guidance in the RCN's [General Practice Nurse Toolkit](#) and for healthcare assistants the RCN's [HCA Toolkit](#).

Your staff should be encouraged to identify development objectives and approach the individual responsible in your practice for staffing if they believe they have development needs.

We suggest that the development objectives for healthcare professionals at your practice are to an extent related to what is required for them to:

- a) provide safe and effective care and treatment to all patients;
- b) maintain their professional registration;
- c) meet the needs of patients;
- d) comply with the CQC standards.

Some of your healthcare professionals' personal development objectives could be also drawn from clinical governance activity and patient feedback. Some of the objectives for your non-clinical staff could also be based on the information you have on the needs of your patients.

- 3) All of your staff should be competent, trained and on the appropriate parts of their register to carry out their roles. We suggest that you support your staff in taking appropriate accredited training and have arrangements for accommodating expected absence in a staffing policy (see **outcome 13**).

You should support healthcare professionals in collecting information that is needed to maintain their professional registration or for their appraisal. At the same time your healthcare professionals have a responsibility to maintain their competence to perform procedures and review/update the procedures they carry out as and when appropriate.

If none of your nursing staff are on the appropriate part of their register to care for children then we suggest that you be able to access a children's nurse if necessary and when appropriate.

- 4) Your practice staff should have a line manager/supervisor that they can talk to about any issues/concerns openly and honestly as soon as practical.
- 5) To protect staff we suggest that you conduct an assessment of the risk from the premises, equipment, and work to staff and take action accordingly. As part of a risk assessment you may want to consider conducting an assessment of the risk of harassment, bullying, and violence. The Health and Safety Executive has [guidance on conducting risk assessments](#).

We also suggest that you have procedures in place for when staff are subject to violence, bullying or harassment from patients or colleagues.

- 6) We suggest that you make reasonable adjustments to allow staff to perform their role when necessary and appropriate.

Demonstrating compliance

When the CQC is monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to (These are just examples):

- 1) Your induction programme and/or staff handbook/ induction pack;
- 2) Evidence that GPs at your practice take part in the PCT's (or replacement body's) appraisal process/in-house appraisal system and documents;
- 3) Risk assessments relating to violence and any action taken as a result of assessments to protect staff;
- 4) Evidence of reasonable adjustments made so that the staff can perform regulated activities.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in these areas.

Useful information:

BMA's *Appraisal toolkit for GPs*

http://www.bma.org.uk/employmentandcontracts/doctors_performance/1_appraisal/appraisaltoolkit120508.jsp

RCGP's *appraisal* guidance

http://www.rcgp.org.uk/professional_development/appraisal.aspx

BMA's *revalidation* guidance

http://www.bma.org.uk/employmentandcontracts/doctors_performance/professional_regulation/revalidation.jsp

GMC's *revalidation* guidance

<http://www.gmc-uk.org/doctors/7330.asp>

RCGP's *revalidation* guidance

<http://www.rcgp.org.uk/revalidation.aspx>

DH's *Appraisal for general practitioners* guidance

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006979

NHSE guidance for appraisal of Agenda for Change staff

<http://www.nhsemployers.org/PayAndContracts/AgendaForChange/KSF/Pages/Appraisal-and-simplified-KSF.aspx>

RCN's *General practice nurse toolkit*

http://www.rcn.org.uk/development/general_practice_nurse_toolkit

RCN's *Healthcare Assistant toolkit*

http://www.rcn.org.uk/development/health_care_support_workers/learning_and_development/hca_toolkit

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety guidance, Appendix B](#))

- Assuring the Quality of Medical Appraisal July 2005; a report published by the NHS Clinical Governance Support Team
- Secretary of State Directions on work to tackle violence against staff and professionals who work in or provide services to the NHS (DH, 2003)

Quality and Management

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Lead effectively

- 1) We suggest that you collect information about your services for the purpose of quality improvement by:
 - a) having a mechanism for patient feedback/comments (see **outcome 1**);
 - 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 (see **outcome 17**);

- c) conducting clinical audits (such as those required for the Quality and Outcomes Framework- see the [BMA/NHSE OOF 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 OOF guidance](#). A template form for significant event reports can be viewed in **Appendix C11**;
- e) conducting risk assessments as and when appropriate (see **outcomes 8, 10, 11, 14 and 21**). The Health and Safety Executive has [guidance on conducting risk assessments](#);
- f) collecting information related to misconduct investigations of your staff.

We suggest that you review all of the information you gather about the safety and quality of the services you provide. From these reviews you can identify any risks and the action to take to address them; and pinpoint ways to improve your service to patients.

Also during your review of this information if you have concerns about being non-compliant with the CQC standards we suggest you decide how to return your practice to compliance.

As good practice it is suggested that you discuss the information collected at practice team meetings so that learning and development points/changes to working practice are identified if necessary.

However, it should be the case that your staff feel able to raise concerns about risks to patients/staff in a confidential manner at any time.

- 2) You might want to consider showing data about the quality of your practice in some form in your practice reception and/or on your website. For example, you could put up the results of a practice survey or a summary of feedback that you have received via a suggestion box.
- 3) Similarly, for the safety of patients we suggest that you display health and safety information (including information about their own responsibilities for contributing to safety) in the practice reception.
- 4) We suggest that you circulate and act on clinical guidance, medical alerts and safety alerts and any other relevant local or national reports (see **Appendix C5**), so that staff change their working practices, if necessary, for the benefit of patients.

Demonstrating compliance

When the CQC is monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) The systems in place for risk management and clinical governance and any evidence of any change in practice that you have made as a result;
- 2) Examples of how you have improved the safety and quality of the services that you provide at your practice as a result of reviewing information (e.g. complaints etc) gathered;
- 3) Evaluations of changes in practice you have made to ensure that they have improved the service you provide;
- 4) Significant event review/analyses and incident reporting related to controlled drugs and other medicines and any evidence of learning/action taken;

- 5) Any external accreditation process that your practice is involved in;
- 6) Patient feedback.

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in these areas.

Useful information

National Patient Safety Agency's *Significant Event Audit* guidance for primary care teams
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=61500>

RCGP's *Clinical audit in primary care* guidance
http://www.rcgp.org.uk/clinical_and_research/circ/evidence_effectiveness/audit.aspx

BMA/NHSE *QOF guidance for the GMS contract*
http://www.bma.org.uk/employmentandcontracts/independent_contractors/quality_outcomes_framework/qofguidance2011.jsp

Other relevant publications (from CQC's [*Guidance about Compliance: Essential Standards for Quality and Safety*](#) guidance, Appendix B)

- Listening, improving, responding: a guide to better customer care (DH, 2009)

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Your practice should be already compliant with the majority of the below because you already need to comply with the [Local Authority Social Services and National Health Services Complaints \(England\) Regulations 2009; Amendment 2009](#). Your practice should already have a complaints procedure that is publicised on their premises and a person responsible for handling complaints.

Leading effectively

- 1) To ensure that patients, or their representatives, are sure that their complaints and comments are listened to and dealt with effectively we suggest that you:
 - a) have a clear procedure for receiving, handling, considering and responding to complaints and comments that is monitored and reviewed. Your procedure should ensure that:
 - i) the details of the complaint and the desired outcome are understood;
 - ii) advice and advocacy support is available to patients (e.g. the Patient Advice and Liaison Service);
 - iii) it is established what is required to resolve the complaint and the likely timescale of resolution is explained to the patient;

An example of a complaints procedure can be viewed in **Appendix C12**.

- b) have a named individual who is accountable for handling complaints;
 - c) have proportionate and sufficiently thorough investigations into complaints conducted by appropriate staff (preferably someone not involved in the events leading to the complaints) unless the complaint falls outside the remit of your practice's responsibility or cannot be upheld;
 - d) have a documented audit trail of the steps taken and the decisions reached on each investigation;
 - e) have full records of complaints;
 - f) have clear procedures in place for dealing with unreasonably persistent complainants in a fair and consistent manner, whilst still taking into account their points;
 - g) use the information from any complaints to identify any non-compliance with CQC's Essential Standards, and decide what to do to return to compliance;
 - h) produce an annual summary of complaints that you send to your PCT (or replacement body).
- 2) We recommend that to allow patients to make comments you have a mechanism for patients to offer suggestions as well as raise concerns (see **outcome 1**). As good practice it is recommended that you discuss comments with your staff at team meetings.

Promoting rights and choices

So that all patients are able to use your complaints procedure effectively:

- a) your staff should deal with all patients in a fair and equal way, and not discriminate against or negatively change the treatment of patients that have complained;
- b) the procedure should be clearly publicised for patients (e.g. a leaflet/notice), (and include information on how CQC can be contacted if they have concerns about the practice);
- c) patients should be able to make complaints in a variety of ways, including orally, in writing or through a representative;
- d) complainants should be kept informed of progress with the investigation of their complaint and dealt with in the legislative timescales;
- e) patients should be advised of their right to refer a complaint to the Parliamentary and Health Service Ombudsman if they are dissatisfied with the outcome of your investigation.

Demonstrating compliance

When the CQC is monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Your complaints process, complaints log, the outcomes of complaints, evidence of review/learning of complaints (e.g. minutes of team meetings) and any examples of changes to practice that you made as a result;
- 2) Your mechanism for obtaining patient comments/suggestions and any examples of changes to the service you provide that resulted from this feedback;

- 3) Information on display about your complaints process and evidence that there are a variety of ways for a patient to lodge a complaint;

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in these areas.

Useful publications

BMA's *The NHS complaints procedure* guidance

http://www.bma.org.uk/images/NHScomplaintsproc_tcm41-189647.pdf

BMA's *New complaint procedure* FAQs

http://www.bma.org.uk/employmentandcontracts/independent_contractors/managing_your_practice/complaintfaqs.jsp

DH's *Listening, responding, improving: a guide to better customer care* guidance

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_095408

Other relevant publications (from CQC's [Guidance about Compliance: Essential Standards for Quality and Safety](#) guidance, Appendix B)

- NHS Constitution (DH, 2009)
- The Principles of Good Complaint Handling (Parliamentary and Health Service Ombudsman, 2008)
- Listening, improving, responding: a guide to better customer care (DH, 2009)
- NHS Litigation Authority guidance about complaints
- Being open – communicating patient safety incidents with patients and their carers (NPSA, 2009)

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.

The following is a suggestion on how you might meet this outcome and examples of evidence that could help you demonstrate compliance based on CQC guidance. However, you may identify alternative ways of doing both. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does and for considering what you could refer to or use as evidence when you have to demonstrate compliance.

Meeting the outcome

Managing risk

- 1) For the benefit of patients, your staff should continue to:
 - a) update patient records at the same time as the events they are recording or as soon as possible afterwards;
 - b) note information in patient records clearly and accurately;
 - c) make a note of important points from discussions with patients in their records;
 - d) be able to access and contribute to patient records when appropriate.
- 2) Patient and practice records should be stored, shared and disposed of in accordance with the Data Protection Act 1998.

To help you meet your legal obligations under the Data Protection Act we suggest that you use the confidentiality protocol referred to in **outcome 1** (see **Appendix C1**) or have an information governance protocol.

Your confidentiality/information governance protocol should have a section on secure information sharing and stress the importance of storing and handling information received securely. Furthermore in your protocol there should be a requirement for staff to inform the information governance lead or Caldicott guardian when there are data breaches.

We also advise that you observe the [Good Practice Guidelines for general practice electronic records version 4](#).

In addition, you may wish to complete NHS Connecting for Health's [Information Governance Toolkit](#) as this will assist with your compliance.

- 4) Where a patient requests access to their records you should follow the requirements of the Data Protection Act 1998 and Freedom of Information Act 2000. The BMA has [guidance on patients accessing health records](#).
- 5) With regard to the retention and destruction of different types of records we suggest that you follow the Department of Health's [Records Management NHS Code of Practice \(Part 2\)](#). In addition you should keep previous versions of policies and procedures and any notifications to CQC of incidents, events or occurrences for at least three years.

Demonstrating compliance

When CQC are monitoring compliance they will ask through oral discussion, self assessment or site visit what evidence there is that has assured you that you are compliant. Therefore if asked to demonstrate compliance you might use or refer to some of the following (These are just examples):

- 1) Practices that participate in QOF could point to their successful fulfilment of:
 - a) the requirements for Records indicators 8, 9 and 15/18/20 as indications that you are properly managing patient records;
 - b) the requirements for Management indicator 3 as one indication that you are properly managing staff records.
- 2) Your arrangements for information sharing and evidence of when your practice team have learnt from related incidents;
- 3) A summary of requests for access to patient records, disclosures, consent to disclosure and reasons for refusing access;

Your demonstration of compliance could be also assisted by:

- 1) Evidence that you monitor and review relevant policies/protocols/procedures;
- 2) Evidence of relevant local or national guidance having been taken into account;
- 3) Records that show where your staff have had training in these areas.

Useful information

Information Commissioners Office guide to data protection
http://www.ico.gov.uk/for_organisations/data_protection/the_guide.aspx

The Data Protection Act 1998

<http://www.legislation.gov.uk/ukpga/1998/29/contents>

Good Practice Guidelines for general practice electronic records version 3.1

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008657

BMA's *Access to Health Records* guidance

http://www.bma.org.uk/ethics/health_records/AccessHealthRecords.jsp

Joint Guidance on Protecting Electronic Patient Information (BMA and Connecting for Health, 2008)

http://www.bma.org.uk/ethics/health_records/connecting_for_health/protectinginfo.jsp

The Department of Health's *Records Management NHS Code of Practice* (Part 2)

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_093024.pdf

The latest QOF statistics published by the NHS Information Centre:

<http://www.ic.nhs.uk/statistics-and-data-collections/audits-and-performance/the-quality-and-outcomes-framework>

Other relevant publications (from [Guidance about Compliance: Essential Standards for Quality and Safety](#) guidance, Appendix B)

- Confidentiality: NHS code of practice (DH, 2003)
- Caldicott Guardian Manual 2006 (DH, 2006)
- Records management: NHS code of practice (DH, 2006)
- Information security management: NHS code of practice (DH, 2007)

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 that you need to be aware of. You will not need to declare compliance with the regulations relating to these 12 Essential Standards when you apply for registration **but** you are still required to meet these outcomes. These outcomes are only likely to come up if the CQC has concerns about your practice's compliance. In those circumstances they may contact you and undertake further activity. Therefore we recommend that you read all of this section.

The following only describes what will be required from practices during the transitional period 1 October 2011 – 1 April 2012 and does not cover the requirements for new providers that register after 1 April 2012.

Please note: Our use of the word **practice** in this guidance is a replacement for the CQC's word **provider**. We have only done to make the guidance easier to follow.

A provider is the legal entity that provides the regulated activities to patients that must register with the CQC. Therefore provider means GP practice, GP-led health centre, OOH care provider etc. However, a provider can also be the legal entity responsible for more than one practice. A provider can be an individual, a partnership or an organisation.

Therefore you should read references to practice as referring to you our own determined provider status. See **Part 2** for further information on providers.

This is important because, for example, if you are an organisation with more than one location then you will need to provide one statement of purpose that covers both locations.

Outcomes related to your application for registration

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.

Meeting the outcome

This outcome does not apply if you register as an **organisation**.

If you are:

- an **individual** you will need to meet the fitness requirements in the regulations
- a **partnership**, each partner will need to meet the fitness requirements

You will need to have the relevant information available for each of these people if it is requested by CQC.

See **Part 3** of this toolkit for guidance on the information that was required during the application process for dentists.

Demonstrating compliance

If this outcome applies to your practice then it will be covered in your application for registration. If the CQC has concerns about your practice's compliance then they will contact you.

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.

Meeting the outcome

This is only relevant if you apply for registration as an **organisation**. If it does apply to you then it is your responsibility to have checked the relevant information about your nominated individual to ensure they are suitable for this position. You do not need to send this information to the CQC. See **Part 3** of this toolkit for guidance on the application process that took place for dentists.

Demonstrating compliance

If this outcome applies to your practice then it will be covered in your application for registration. If the CQC has concerns about your practice's compliance then they will contact you.

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.

Meeting the outcome

If you register as a **partnership** or an **organisation**, a person who is in charge of the day-to-day running of the regulated activity must also register with the CQC as a **registered manager**.

If you apply for registration as an **individual** then you do not need a registered manager unless you are not in day-to-day charge of the provision of the regulated activities. When you do not have a registered manager then this outcome does not apply.

The appropriateness and fitness of your registered manager will be assessed as part of the application for registration process. See **Part 4** of this toolkit for guidance on the registered manager application process that took place for other registered providers.

Demonstrating compliance

If this outcome applies to your practice then it will be covered in your application for registration. If the CQC has concerns about your practice's compliance then they will contact you.

Outcomes related to notifications to CQC

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

Meeting the outcome

CQC have not yet published their guidance for NHS primary medical services providers.

Demonstrating compliance

You will not have to demonstrate compliance with this outcome as part of a review by CQC. However, if the CQC has concerns that you are not acting in accordance with their notifications policy then they will contact you.

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.

Meeting the outcome

This outcome is **not** applicable to practices.

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.

Meeting the outcome

The CQC has not yet published their guidance for NHS primary medical services providers.

Demonstrating compliance

You will not have to demonstrate compliance with this outcome as part of a review by CQC. However, if CQC has concerns that you are not acting in accordance with their notifications policy then they will contact you.

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.

Meeting the outcome

We will be discussing the requirements of this outcome with the CQC and will update this toolkit in due course.

Demonstrating compliance

You will not have to demonstrate compliance with this outcome as part of a review by the CQC. However, if the CQC has concerns that you are not acting in accordance with their notifications policy then they will contact you.

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.

Meeting the outcome

The CQC has not yet published their guidance for NHS primary medical services providers.

Demonstrating compliance

You will not have to demonstrate compliance with this outcome as part of a review by CQC. However, if the CQC has concerns that you are not acting in accordance with their notifications policy then they will contact you.

Miscellaneous outcomes

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.

The following is a suggestion on how you might meet this outcome. However, you may identify alternative ways of doing this. If you believe that you are already compliant then do not feel obliged to follow our suggestion before declaring compliance.

You can also use our meeting the outcome suggestion as a tool to assess whether you might be compliant by comparing it with what your practice already does.

Meeting the outcome

This outcome is not reviewed regularly by the CQC and you will not be asked to declare compliance with this standard when applying for registration.

However, to be compliant with this standard we suggest as good practice that you be as transparent as possible about fees by displaying information such as when patients are expected to pay fees for services, the methods by which patients can pay for those services and the fee amounts.

Demonstrating compliance

You are unlikely to be asked to demonstrate compliance with this outcome as part of a review by the CQC. However, if you were asked then you should be able to explain how you have information on display about fees including how patients are provided information about fees.

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.

Meeting the outcome

In the statement of purpose you will need to include:

- 1) What you want to achieve in carrying out regulated activities (i.e. aim and objectives);
- 2) The kinds of services you provide for the purpose of carrying out your regulated activities, and the premises (called locations in CQC terminology) from which you provide them.
- 3) The name of your practice and your registered manager (if you have one), along with your practice address, telephone number and, where available, email address.
- 4) The legal status of your practice.
- 5) Details of the locations at which you provide services for the purposes of your regulated activities.

The statement should have enough detail to enable the CQC to have a good understanding about the specific nature of your services in all of your locations and for all of your regulated activities.

The [CQC has a template for the statement of purpose](#) but you do not have to use it.

As the statement is supposed to be an accurate description of the services you provide you are supposed to keep it under review and notify the CQC of any changes.

We believe that the details in your practice leaflet and/or on your website will assist with writing this statement.

The BMA will be discussing this requirement further with the CQC because of our concerns and would advise that you do not start working on this yet.

Demonstrating compliance

The statement of purpose does not need to be submitted with your application for registration but should be available if requested. If the CQC has concerns that your statement is not an accurate reflection of the services you provide then they will contact you.

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.

Meeting the outcome

If you register as an **individual** then you are the registered person. You should ensure that you have appropriate training to carry on the regulated activities effectively and to care for your patients.

If you register as a **partnership** then each partner is a registered person. You should ensure that each partner has appropriate training to carry on the regulated activities effectively and to care for your patients.

If you have a **registered manager**, they are also a registered person. Your registered manager should have adequate training to ensure that they are able to manage the regulated activities.

Demonstrating compliance

You will not have to demonstrate compliance with this outcome as part of a review by the CQC. However, if the CQC has concerns that you are not acting in accordance with this outcome then they will contact you.

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.

Meeting the outcome

To meet this outcome you will need appropriate insurance/indemnity arrangements to cover potential liabilities arising from death, injury, or other causes, loss or damage to property, and other financial risks.

Demonstrating compliance

You will not have to demonstrate compliance with this outcome as part of a review by CQC. However, if the CQC has concerns that you are not acting in accordance with this outcome then they will contact you.

Appendix A

Summaries of regulated activities

When completing a CQC application form, you will need to state which of the 15 regulated activities you conduct in each location. The following is a summary of each regulated activity and guidance on which regulated activities to register for. The legal description of the regulated activities can be viewed in Schedule 1 of the [Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2010](#).

	Regulated activity	Do I need to register my practice for this?
1.	Personal Care: The provision of personal care for people who are unable to provide it for themselves, because of old age, illness or disability, in the place where they are living.	No. This is not relevant to GP practices or other NHS primary medical services providers.
2.	Accommodation for persons who require nursing or personal care: This consists of providing accommodation together with personal care or nursing care.	No. This is not relevant to GP practices or other NHS primary medical services providers.
3.	Accommodation for persons who require treatment for substance misuse: The provision of residential accommodation for a person with treatment for drug or alcohol misuse (where acceptance by the person of such treatment is a condition of the provision of the accommodation).	No. This is not relevant to GP practices or other NHS primary medical services providers.
4.	Accommodation and nursing or personal care in the further education sector: This consists of residential accommodation for people together with treatment for substance misuse.	No. This is not relevant to GP practices or other NHS primary medical services providers.
5.	Treatment of disease, disorder or injury: This is the treatment of a disease, disorder or injury by a healthcare professional. This can be emergency and ongoing treatment.	Yes. This is relevant to GP practices, out-of-hours providers and other NHS primary medical services providers.

	Regulated activity	Do I need to register my practice for this?
6.	<p>Assessment or medical treatment for persons detained under the 1983 Act: Where people are detained or recalled for treatment or assessment under the Mental Health Act 1983 in the hospital setting.</p>	<p>No. This is not relevant to GP practices or other NHS primary medical services providers</p>
7.	<p>Surgical procedures: These are surgical procedures for treating disease, disorder or injury; or cosmetic surgery¹; or for religious observance (e.g. circumcision) carried out by a healthcare professional.</p> <p>Exemptions: Minor surgical procedures that are not included if they are undertaken by a medical practitioner and involve the use of local anaesthesia (or no anaesthesia) are curettage, cautery or cryocautery of warts, verrucae or other skin lesions.</p> <p>Minor surgical procedures that are not included if they are undertaken by any healthcare professional and involve the use of local anaesthesia (or no anaesthesia) are nail surgery and nail bed procedures on the foot.</p>	<p>Maybe. If your practice does any type of surgery except for the exemptions then you should register for this activity.</p> <p>If your practice does a Minor surgery enhanced service or similar then you should register for this activity.</p> <p>If you only do the Minor Surgery additional service and use local or no anaesthesia then our view is that you do not need to register for this activity.</p>
8.	<p>Diagnostic and screening procedures: This covers a wide range of procedures related to diagnostics, screening and physiological measurement.</p> <p>All diagnostic procedures involving the use of any form of radiation, ultrasound or magnetic resonance imaging</p> <p>This also covers the removal of tissues, cells or fluids from the body for the purposes of discovering treatment or for information about a disease, disorder or injury and some endoscopy procedures.</p> <p>The analysis and reporting of the results of the procedures above is also covered.</p> <p>Exemptions These include:</p> <ul style="list-style-type: none"> - taking of pin prick blood samples that are not sent away for analysis; - the taking and analysis of samples of bodily tissues, cells or fluids in for genetic disease research or a national screening programme; - the use of an auroscope. 	<p>Maybe. This is relevant to GP practices and other NHS primary medical services providers.</p> <p>However, out-of-hours care providers would not need to register for this if they only took pin prick blood samples.</p>

¹ Cosmetic surgery does not include the piercing of any part of the human body; tattooing; botox injections to improve a person's appearance and the removal of hair roots or small skin blemishes on by the application of heat using an electric current.

	Regulated activity	Do I need to register my practice for this?
9.	<p>Management of supply of blood and blood derived products etc:</p> <p>This covers the supply of blood, blood components and blood-derived products for transfusion; the supply of tissue or tissue-derived products for transplant, grafting or use in surgery; the matching and allocation of donor organs, stem cells or bone marrow for transplant or transfusion.</p>	<p>No. This is not relevant to GP practices or other NHS primary medical services providers.</p>
10.	<p>Transport services, triage and medical advice provided remotely</p> <p>A. Transport services: Transport services are vehicles which has the transport of people who require treatment as the primary purpose that it is designed for.</p> <p>B. Triage and remote medical advice: This covers responsive, remote advice and where triage is used. Advice is provided over the telephone or by email. It has to be provided by a body established for the purpose of providing remote medical advice.</p>	<p>Our view is that you should register for this activity if you are an out-of-hours care provider.</p> <p>GP practices and other NHS primary medical services providers do not need to register for this regulated activity.</p>
11.	<p>Maternity and midwifery services: This covers maternity and midwifery services where they are carried out by, or under the supervision of, a healthcare professional.</p> <p>There are some exceptions such as it does not include the services if they are done in a patient's own home and it does not include organisations that are not healthcare providers but give out advice and information on pregnancy.</p>	<p>Maybe.</p> <p>If you provide primary medical services to patients who are pregnant as part of routine appointments that are not primarily for the purpose of antenatal or post natal care then our view is that you do not need to register for this regulated activity.</p> <p>We believe you should register for this activity if:</p> <ol style="list-style-type: none"> 1) You provide the Maternity medical services additional service 2) You provide a Maternity-related enhanced service e.g. intrapartum obstetrics 3) You provide appointments to pregnant patients that are primarily for the purpose of antenatal or post natal care.

	Regulated activity	Do I need to register my practice for this?
12.	<p>Termination of pregnancies: The termination of pregnancy, by any method is included in this activity. Advice on termination of pregnancy is not. The “morning after pill” is not a form of termination of pregnancy where it constitutes emergency contraception and has its effect before the earliest stages of implantation. Some medicines used as emergency contraception may however also be used to terminate a pregnancy. Where they are used in that way their use will require registration under this regulated activity.</p>	<p>No. This is not relevant to GP practices or other NHS primary medical services providers.</p>
13.	<p>Services in slimming clinics: These are services provided in a slimming clinic consisting of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of weight reduction.</p> <p>“Clinic” in this activity means a physical location rather than a clinical session or service.</p>	<p>No. This is not relevant to GP practices or other NHS primary medical services providers.</p> <p>This is only applicable to providers that are solely slimming clinics.</p>
14.	<p>Nursing care: This covers nursing care that is not part of another regulated activity. If nursing care is provided as part of another activity, then this activity does not apply.</p>	<p>No. This is not relevant to GP practices or other NHS primary medical services providers.</p> <p>This is because your practice is covered by the other regulated activities.</p>
15.	<p>Family planning services: This solely means the insertion or removal of an intrauterine contraceptive device carried out by, or under the supervision of, a health care professional.</p>	<p>Maybe.</p> <p>Please note that the regulations define ‘Family planning services’ narrowly. If you insert or remove IUCDs then you should register for this regulated activity.</p>

Appendix B

Summaries of service types

When completing a CQC application form, you will need to state which services you conduct in each location. 21 of the service types are listed below, along with our view as to whether they are relevant to general practice. This is not a full list of the service types. Those not included are not considered relevant to general practice. The full description of the service types can be viewed in CQC's [Guidance about Compliance: Essential Standards of Quality and Safety](#).

	Healthcare services	Do I need to register my practice for this service type?
1.	Acute services Medical and/or surgical investigations, diagnosis and treatment for physical illness or condition, injury or disease.	No. This is not relevant to GP practices or other NHS primary medical services providers.
2.	Hyperbaric chamber services These services involve the administration of oxygen to a person in a sealed chamber that is gradually pressurised with compressed air.	No. This is not relevant to GP practices or other NHS primary medical services providers.
3.	Hospice services These provide a range of services for conditions where curative treatment is no longer an option, and people are approaching the end of their life. Care, treatment and support can be provided in accommodation or in the community.	No. This is not relevant to GP practices or other NHS primary medical services providers.
4.	Long-term conditions services These services provide a range of care, treatment and support to people with physical or neurological illnesses, cognitive impairments or injuries that are unlikely to improve. This care, treatment and support is the sole or main purpose of the service.	No. This is not relevant to GP practices or other NHS primary medical services providers.
5.	Hospital services for people with mental health needs, and/or learning disabilities, and/or problems with substance misuse These services are for people with mental health needs or learning disabilities, who are admitted to hospital, involving an overnight stay, for assessment or treatment when there is a need for more intensive support than would typically be provided in the community, or a need for a specialist assessment or intervention.	No. This is not relevant to GP practices or other NHS primary medical services providers.
6.	Prison healthcare services These services offer a primary care type of service in a prison, usually in a health centre or similar setting.	Maybe. This only applies to GP practices that provide services in prisons as part of a NHS contract.
7.	Rehabilitation services These services provide, as their sole or main purpose , treatment to people following an illness or injury that impairs their physical, mental or cognitive wellbeing, but for which	No. This is not relevant to GP practices or other NHS primary medical services providers.

	Healthcare services	Do I need to register my practice for this service type?
	continued rehabilitative care is likely to bring about improvement. The services can be provided on a short or long-term basis, in hospital, residential, day care or domiciliary settings.	
8.	Residential substance misuse treatment/ rehabilitation services These services are provided to adults and children who have problems with misusing drugs and/or alcohol.	No. This is not relevant to GP practices or other NHS primary medical services providers.

COMMUNITY OR INTEGRATED HEALTHCARE

	Community or integrated healthcare service	Do I need to register my practice for this service type?
9.	Community healthcare services These services supply a range of healthcare staff other than doctors, for example nurses or allied health professionals, to people who need healthcare support in their own home, in community settings or in child development units. The care provided may be short or long term, and meet acute or chronic healthcare needs. The services may help people to live independently in the community and they are directly responsible for the quality of the care and support provided by the staff they supply, and do not include employment agencies. For example: District nursing, Nurses agency, Community physiotherapy team, Health visiting team, Support worker team, Children's community nurses, Community paediatric therapies, Community midwifery, School nursing, Family planning and sexual health clinics, Community rehabilitation teams	Maybe. This would be relevant if you were providing these services specifically beyond core contractual work i.e. an enhanced service. A clinic session on family planning and sexual health would not require you registering for this service type.
10.	Doctors consultation services These services involve doctors working in premises, or a room, designated for medical consultation. Often the doctor will complete medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may prescribe medicines for the person to take at home.	Yes. This is relevant to GP practices and other NHS primary medical services providers.
11.	Doctors treatment services These services involve doctors working in premises, or a room, designated for minor medical treatments as well as medical consultation. Often the doctor will complete medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may	Yes. This is relevant to GP practices and other NHS primary medical services providers.

	Community or integrated healthcare service	Do I need to register my practice for this service type?
	<p>prescribe medicines for the person to take at home.</p> <p>They will also undertake minor invasive investigations or procedures, such as conscious endoscopy, in a treatment room designed for this purpose.</p>	
12.	<p>Dental services</p> <p>These services involve registered dentists and dental care professionals usually working in premises designed for consultation and treatments, but can also be provided in a person's place of residence. Treatment is usually provided in a dedicated room and, in consultation with the patient, may be under local anaesthetic or use a laser.</p>	No. This is not relevant to GP practices or other NHS primary medical services providers.
13.	<p>Diagnostic and/or screening services</p> <p>These services provide individual health assessment and/or screening to people, using diagnostic imaging</p> <p>They provide, as the sole or main purpose, diagnosis or screening.</p>	No. This is not relevant to GP practices or other NHS primary medical services providers.
14.	<p>Community-based services for people with a learning disability</p> <p>These services provide care, treatment and support in the community for people with a learning disability.</p>	Maybe. We are seeking clarification on whether this could apply to GP practices providing the Learning Disabilities DES.
15.	<p>Mobile doctors services</p> <p>These services involve doctors working in premises where the person using the service is living (on a long or short-term basis). They may also provide services via an internet website where the initial consultation is with a doctor.</p> <p>The doctors provide medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may prescribe medicines for the person to take at home.</p>	No. This is not relevant to GP practices or other NHS primary medical services providers.
16.	<p>Community-based services for people with mental health needs</p> <p>These services provide care, treatment and support in the community for people with mental health needs. This may include providing care, treatment and support to people subject to supervised community treatment under the Mental Health Act 1983.</p>	No. This is not relevant to GP practices or other NHS primary medical services providers.
17.	<p>Community-based services for people who misuse substances</p> <p>These services are provided in the community for people who misuse drugs and/or alcohol. They provide care, treatment and support, both pharmacological and psychosocial, and help with social and other needs so that people can reintegrate into their communities. They employ a broad</p>	Maybe. This would apply only if you did the activity described to the left under a LES or as part of a shared care scheme.

	Community or integrated healthcare service	Do I need to register my practice for this service type?
	range of health and social care professionals to meet the needs of people who use their services.	
18.	<p>Urgent care services These services are provided in parallel with an emergency department and vary greatly from one service to another. They generally comprise a triage service, run by doctors and nurses.</p> <p>They will not usually screen people whose symptoms require immediate, very urgent or emergency care. Instead, they screen standard cases where time is not of the essence, and where possible refer these for immediate consultation with an on-site primary care provider.</p>	<p>Yes if you are an out-of-Hours care provider, a walk-in centre, or have an urgent care centre.</p> <p>This is not relevant to GP practices</p>

MISCELLANEOUS HEALTHCARE

	Healthcare service	Do I need to register my practice for this service type?
19.	<p>Ambulance services These services include both the provision of emergency response and transport services. They may include patient transport services as well as emergency vehicles used to transport people, including ambulances.</p>	No. This is not relevant to GP practices or other NHS primary medical services providers.
20.	<p>Blood and transplant services The management of the supply of blood, blood-derived products and biologically derived tissues to a healthcare provider for the purposes of administering, grafting or transplantation into a human being</p>	No. This is not relevant to GP practices or other NHS primary medical services providers.
21.	<p>Remote clinical advice services These services provide, as their sole or main purpose, a range of clinical services to people from a distance in an urgent or emergency situation. The initial consultation is usually with a registered nurse. They may provide care, treatment and support to people using:</p> <p>Telephone systems, Digital systems, E-mail.</p> <p>Example of service that fits under this category - NHS Direct</p>	No. This is not relevant to GP practices or other NHS primary medical services providers.