# Consultation

# Our approach to regulating:

## Independent doctor services

August 2015

## The Care Quality Commission is the independent regulator of health and adult social care in England

### Our purpose

We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

### Our role

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

### Our values

Excellence – being a high-performing organisation

Caring – treating everyone with dignity and respect

Integrity – doing the right thing

Teamwork – learning from each other to be the best we can

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# Foreword

CQC is responsible for regulating the small number of independent doctor services which come within the scope of its regulatory remit.

In October 2014, we published our provider handbook for NHS GP practices and GP out-of-hours services, and we have recently consulted on our approach to inspecting independent healthcare acute services and dentists. This document sets out our approach to regulating and inspecting independent doctor services.

We have worked closely with providers and stakeholders to develop this guidance, and we will continue to do so while we test it during our inspections.

This consultation asks a number of specific questions and we urge you to respond to these and any other issues relating to our proposed approach.

Your views are important and matter to us. Thank you for responding.

# Introduction

In this document we are consulting on our proposed new approach to regulating and inspecting independent doctor services.

This consultation will run from 24 August 2015 to 19 October 2015 – details on how to respond are at the end of this document. The detail of the consultation is set out in this draft handbook for providers.

We will publish an update of this guidance along with our final approach in November 2015 and we will roll out our new approach from late November 2015.

## What are independent doctor services?

The private healthcare sector is diverse, with providers delivering services from an array of settings and in a number of ways. These range from single handed individuals to private organisations. They may operate for one or more days a week in private practice. Patients using independent doctor services may move between private and NHS funded care or stay completely in the private sector for their care. Independent doctor services have varying characteristics that will inform the changes we need to make to the way we monitor, regulate and inspect providers. These include the:

- Complexity and range of services offered.
- Type of services offered. For example, private GP services, specialist consultation and treatment, slimming clinics, online consulting and prescribing.
- Level of risk to patient safety.
- The safety, effectiveness and quality of care and treatment.

It is not appropriate to undertake some types of treatment outside of a hospital, for example, administering general anaesthesia, intravenous sedation and some regional anaesthesia. Patients must not be put at risk because of inadequate premises, equipment or other resources, policies or systems.

| Type of main service provided |
| --- |
| Specialists providing consultation and/or treatment, who are on the specialist register at the GMC or have completed further Royal College Certificate of Completion of Training (CCT) and who are **not** exempt from CQC registration, and who would ordinarily provide the same or similar services in an acute/community or mental health hospital. |
| Specialists providing consultation and/or treatment remotely, for example via the telephone or internet (including FaceTime or SKYPE), who are on the specialist register at the GMC or have completed further Royal College CCT training and who would ordinarily provide the same or similar services in an acute/community or mental health hospital. |
| Travel vaccination clinics (Note: it is possible that some of these services may not be operated by an independent doctor but if travel vaccination is the main purpose of the service it will come under this approach). |
| Slimming clinics where the regulated activity of 'services in slimming clinics' is main purpose. |
| Vasectomy carried out under local anaesthesia. |
| Private GP services, including medical agencies that carry out visits to people in their homes or other places that they are staying such as hotels or care homes, non NHS primary medical type services, including online consultation with or without prescribing. |
| Private GPs or Registered Medical Practitioners providing consultation and/or treatment remotely, for example via the telephone or internet (including FaceTime or SKYPE). |
| Endoscopy restricted to nasopharyngoscopy, colposcopy and use of auroscope etc. |
| Health screening (only if undertaken in a primary care service). |
| Gynaecology, dermatology, cardiology or other healthcare or diagnostic services that does not involve any treatment that falls under the acute or single specialty category. |
| Family planning services – only if operated by a medical practitioner and where the regulated activity of family planning is the main purpose. |

Note**:** independent doctor providers who provide solely or mainly NHS funded primary care at a location will be inspected under the model for NHS GPs.

Services are mainly provided in consulting rooms, patient's own homes or other mobile settings.

Not all medical practitioners in independent practice are required to be registered with CQC. Some providers are exempt from regulation and further

information about the exemptions can be found in our Scope of Registration (March 2015). This applies mainly to NHS GPs and consultants who work for the NHS and/or independent acute hospitals, and who also provide private healthcare services. There are approximately 60,000 medical practitioners in private practice but CQC only directly regulates less than one per cent of that number.

This consultation does not include:

- Private independent healthcare providers of hospital services (secondary and tertiary care) or single specialty services such as termination of pregnancy or In Vitro Fertilisation (IVF).
- Any residential services.
- Independent community services.
- NHS GP and GP out-of-hours services even though these are often provided by independent organisations.
- Private dentists.

## Why we are consulting

It is important that our new regulatory model assures patients and the public that they will receive the same standards of care across all services. We also need to ensure that our inspection methods proportionately reflect the differences between different types of providers, so that they do not experience a 'one size fits all' approach.

To achieve this, we have committed to align as many elements as possible of our new model for independent doctor services with our model for other sectors, including dentists. It is important that we treat providers equally when they deliver similar types of services but, at the same time, we must ensure that we tailor our approach to each sector and type of service where there are differences that we need to take into account.

The CQC is the regulator of health and adult social care services provided by individuals, partnerships or companies. The GMC is the professional and primary regulator of individual independent doctors. We have a mutual interest to ensure that patients receive safe, effective, high-quality and evidence based care and treatment.

Although CQC currently regulates independent doctors, we know that the government periodically reviews the scope of regulation in relation to small businesses such as those operated by independent doctor services. Independent doctors are also subject to regulation by their professional regulator the GMC so there is some overlap with CQC. It is always possible that independent doctors could come out of regulation by CQC and as such their practice could be solely regulated by their professional regulator. We are also seeking views on what people think of this.

# Our approach to regulating and inspecting independent doctor services

Our consultation, *A New Start,* set out the principles that guide how CQC will inspect and regulate all care services. It set out our new overall operating model, which includes:

- Registering those that apply to CQC to provide services.
- Intelligent use of data, evidence and information to monitor services.
- Using feedback from patients and the public to inform our judgments about services.
- Inspections carried out by experts.
- Information for the public on our judgments about care quality, including a rating to help people chose services.
- The action we take to require improvements and, where necessary, the action we take to make sure those responsible for poor care are held accountable for it.

When we monitor, inspect and regulate care we want to make sure that we look at the things that matter to the people who use them and that their interests are at the heart of the five key questions we ask about quality and safety – are services:

- Safe?
- Effective?
- Caring?
- Responsive to people's needs?
- Well-led?

Unlike most other sectors we regulate, we will not be giving a rating to independent doctor services in 2015/16. However, we are interested in people's thoughts about rating in the future.

For independent doctor services, our approach to inspecting and regulating will assess whether or not a provider is meeting the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, which include the fundamental standards and the Care Quality Commission (Registration) Regulations 2009. We will carry out an assessment of the quality of independent doctor services leading to a judgment about whether they provide people with safe, effective, caring, responsive and well-led care, based on whether the regulations are being met.

# 1. Our framework

## Our operating model

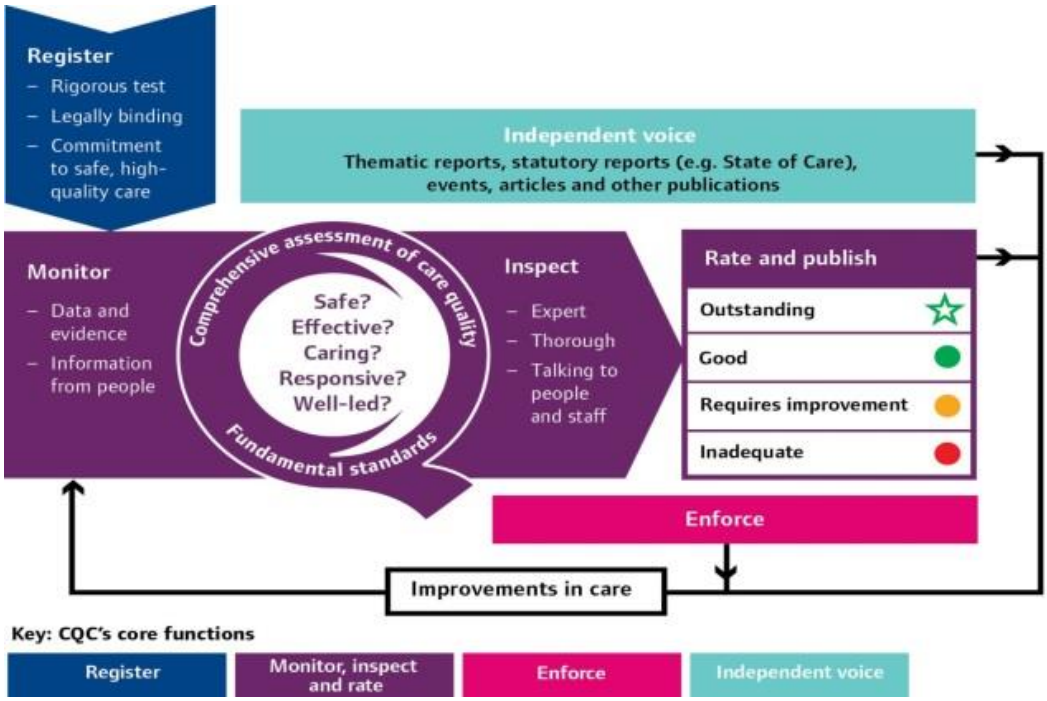
Although CQC inspects and regulates different services in different ways, there are some key elements that guide our operating model across all our work. These include:

- Registering those that apply to CQC to provide services.
- Continuous monitoring of information, shared intelligence and risk assessment.
- Taking action against those who provide services but fail to secure registration before doing so.
- Involving specialist advisors to accompany our inspectors, for example where services are more complex, higher risk or we identify specific concerns.
- Using feedback from people who use services and the public to inform our judgments about services.
- Providing information for the public on our judgments about care quality.
- The action we take to require improvements and, where necessary, the action we take to make sure those responsible for poor care are held accountable for it.
- Using our independent voice to speak about what we find on behalf of people who use services.

Our model is underpinned by the new fundamental standards that came into force on 1 April 2015. We have published guidance for providers on meeting the regulations to help providers understand how they can meet the new regulations.

The following diagram shows an overview of our overall operating model. It covers all the steps in the process. Although we are not currently proposing that we rate independent doctor services, we are seeking views as to whether we rate in the future.

**Figure 1: Overview of CQC's operating model**




Please note that this is the overall CQC operating model but unlike some sectors that CQC regulates we will not be rating independent doctor services, although we may do so in the future.

## Applying the operating model to independent doctor services

We will carry out an assessment of the quality and safety of independent doctor services leading to a judgment about whether they provide people with care that is safe, effective, caring, responsive and well-led, based on whether the regulations are being met.

Although we are adopting the principles and many of the key elements of the overall operating model in our new approach to inspecting primary care dental services, some of the detail will be different to the methods we use when regulating other sectors.

We will look for notable practice to promote learning and encourage improvement as well as make sure that independent doctor services meet the requirements set out in the regulations, including the new fundamental standards of care. In accordance with CQC's operating model, we will ask if practices are safe, effective, caring, responsive and well-led, and will report our findings under the five key questions.

To support this we will use the key lines of enquiry (KLOEs) and provide examples of what we would expect to see to demonstrate that no regulations have been breached and, therefore, that services are safe, effective, caring, responsive and well led, based on the regulations. To enable this, the KLOEs

map to the regulations to ensure that we can identify breaches of the fundamental standards.

The KLOEs are set out in appendix 2 of this draft handbook.

Having a standard set of KLOEs ensures consistency of what we look at under each of the five key questions and that we focus on those areas that matter most. This is vital for reaching a credible assessment of independent doctor services. To enable inspection teams to reach a judgment, they gather and record evidence in order to answer each KLOE.

### Consultation question 1

- Do you agree that the KLOEs will enable us to comment on independent doctor services under the five key questions?

  Yes/No

- Is there anything else we should include?
- We have provided examples of the evidence we may look for during our inspections. Do you agree that this will identify any areas of poor quality care?

  Yes/No

## Registering those that apply to CQC to provide services

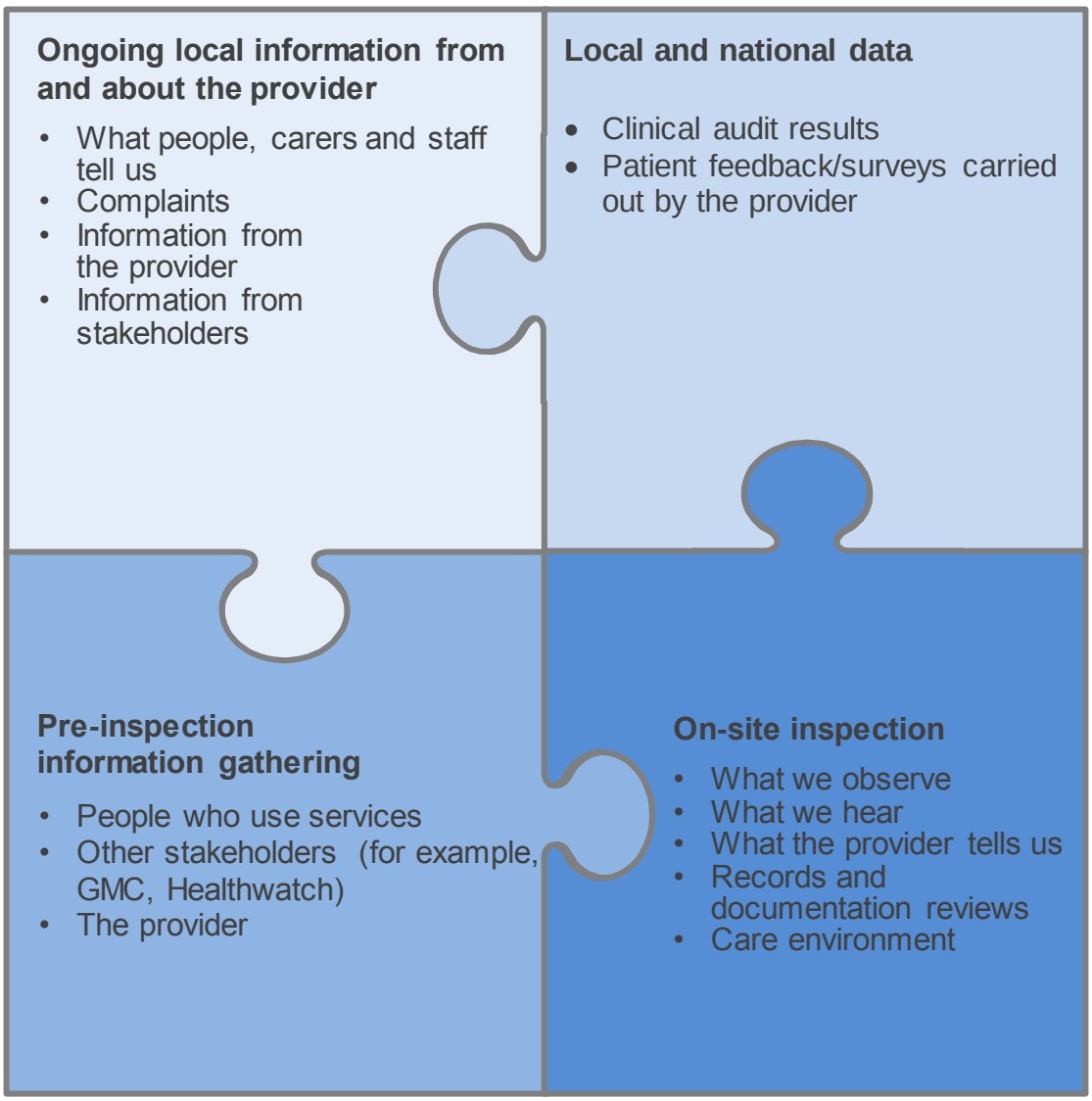
Before independent doctor services can begin to provide services, they must apply to CQC and secure registration for the regulated activities they intend to deliver. Providers must satisfy CQC that they will be able to meet a number of registration requirements.

Registration assesses whether all new providers, whether they are organisations, individuals or partnerships, have the capability, capacity, resources and leadership skills to meet relevant legal requirements, and are therefore likely to demonstrate that they will provide people with safe, effective, caring, responsive and high-quality care.

## Intelligent use of data, evidence and information to monitor services

To make the most of the time that we are on site for an inspection, we must make sure we have the right information to help us focus on what matters most to people. This will influence what we look at, who we will talk to and how we will configure our team. We will collect and analyse data about independent doctor services from a range of sources including information from people who use services, other regulators and oversight bodies, local organisations, other stakeholders and service providers. The information we gather is also used as evidence when we make our judgments against the fundamental standards of care.

## The main sources of evidence we may use




Some examples of the information that may indicate whether services are safe, effective, caring, responsive and well-led are set out in the table below.

We would use this information to give our inspectors more detailed knowledge of the areas that may need to be followed up on inspection and to help them determine when to inspect.

Table 1: Examples of intelligence to inform independent doctor service inspections.

| Information from the provider | Information from patients and the public | Information from and about staff |
|---|---|---|
| • Patient safety incidents<br>• Safe prescribing<br>• Completed clinical audit cycles/ independent peer review<br>• Detailed information from the provider about services offered and systems and processes in place<br>• Safeguarding referrals and alerts<br>• Patient feedback/surveys carried out by the provider | • Responses from 'Share your experience' (people's experiences shared with CQC)<br>• Comment cards and feedback during inspections<br>• Feedback left on other websites<br>• Complaints<br>• Feedback from local stakeholders, including Local HealthWatch, private hospital or NHS trust<br>• Information from national stakeholders, such as the GMC and royal colleges | • Concerns raised by staff to CQC<br>• Qualifications, skills and experience<br>• Staff training and appraisal<br>• Revalidation arrangements in place |

## Consultation question 2

- Do you agree that the examples of intelligence we plan to look at will identify both good practice and risks of poor quality care?

  Yes/No

## The five key questions we ask

To get to the heart of people's experience of care, the focus of our inspections is on the quality and safety of services, based on the things that matter to people. We always ask the following five questions of services.

For all health and social care services, we have defined these five questions as follows. Are services:

| | |
|---|---|
| **Safe?** | By safe, we mean that people are protected from abuse and avoidable harm. |
| **Effective?** | By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence. |
| **Caring?** | By caring, we mean that staff involve and treat people with compassion, kindness, dignity and respect. |
| **Responsive?** | By responsive, we mean that services are organised so that they meet people's needs. |
| **Well-led?** | By well-led, we mean that the leadership, management and governance of the organisation assures the delivery of high-quality person-centred care, supports learning and innovation, and promotes an open and fair culture. |

## Rating

The government introduced new legislation in 2014 to enable CQC to rate most of the providers it regulates, however, it did not include certain services such as dentists and independent doctor services. Although we have introduced ratings as an important element of our new approach to inspection and regulation of other sectors, we do not intend to rate independent doctor services but we may be granted the power to rate independent doctor services in the future.

Our model for rating services regulated by CQC is to provide a rating against each of the five key questions. We currently rate each key question as either outstanding, good, requires improvement or inadequate.

If CQC were given powers to rate independent doctor services we could still rate services in line with our current approach or we could inspect services against each of the five key questions (safe, effective, caring, responsive, well-led) but we do not necessarily have to rate each key question or use all of the rating scales we currently use for other services.

Given the diversity of services provided by independent doctors, should we be given the powers to rate, we would need to consult further on our KLOEs and ratings descriptors. As part of this current consultation we would like to get your views on whether you think our model for rating services could be applied to independent doctor services or whether a different approach, such as rating some rather than all of the key questions, would be preferable.

### Consultation question 3

- Should CQC rate independent doctor services?

  Yes/No

- If CQC are granted the powers to rate independent doctor services in the future, which of the approaches below should we take?
  - Inspect and rate across all of the five key questions in line with our current model for other services we rate.
  - Inspect against all of the five key questions but only rate against certain key questions.
- If you think we should only rate against some of the key questions, which key questions should we rate against?
  - Safe
  - Effective
  - Caring
  - Responsive
  - Well-led
- If you think we should consider other options, please tell us what these are.

## Scope of regulation

Although CQC currently regulates independent doctors, we know that the government periodically reviews the scope of regulation in relation to small businesses such as those operated by independent doctor services. All independent doctors registered with CQC (as with any other healthcare professional) are also regulated by their professional regulator, the GMC, who are responsible for their fitness to practise.

Independent doctors will also be subject to revalidation. All medical practitioners who carry out practice that requires a licence to practise must also be revalidated every five years. Revalidation is led by the GMC and is a way of providing reassurance that a doctor holding a licence to practise remains fit to practise. Revalidation of a medical practitioner can only be recommended to the GMC by the medical practitioner's Responsible Officer whose role is set out in statute. Providers who are individual medical practitioners, partnerships or employ medical practitioners (including under practising privileges arrangements or otherwise) must have systems in place that provide evidence that those medical practitioners are complying with GMC guidance for appraisal and revalidation requirements. CQC checks this on inspection.

CQC currently regulate independent doctor services but there is overlap with their professional regulator, the GMC. We are therefore asking a question about whether they should remain in the scope of our regulation. We would welcome your views on this.

### Consultation question 4

- Do you agree that independent doctors should remain within the scope of regulation by CQC?

  Yes/No
- If yes, please tell us why you think it should be CQC.

## Inspection

Our inspections are at the heart of our regulatory model and are focused on the things that matter to people. Within our new approach, we have two types of inspection:

| Type of inspection | Description |
|---|---|
| **Comprehensive** | • Takes a good look at a service, encompassing all the fundamental standards applicable to independent doctor services.<br>• Addresses all five key questions CQC asks of services (safe, effective, caring, responsive, well-led).<br>• Usually takes half to one day at a service.<br>• May include a specialist advisor.<br>• Usually announced four weeks before the inspection. |
| **Focused** | • Follow-up to a previous inspection, or to respond to a particular issue or concern.<br>• Does not look at all the fundamental standards.<br>• Will not address all five key questions CQC asks of services (safe, effective, caring, responsive, well-led).<br>• Team composition and size will depend on the concern(s).<br>• May be unannounced. |

## Making judgments

Our statutory objective is to protect and promote the health, safety and welfare of people who use health and social care services.

We will make judgments using all the available evidence gathered from three main sources:

- Information from the ongoing relationship with the independent doctor service.
- Information gathered in the weeks before the inspection.
- Information from the inspection visit.

To help inspection teams carry out their role and to ensure consistency in our inspection approach, we have developed a set of KLOEs, which are listed in appendix 2. These also include examples of what we would expect to see to demonstrate that no regulations have been breached and therefore that services are safe, effective, caring, responsive and well-led based on the regulations. Providers should read this appendix in conjunction with our guidance for providers on meeting the regulations.

The inspection KLOEs and examples of evidence are not an exhaustive list, or a 'checklist'. We will take into account the context of the service when we look for evidence. We will consider the amount and depth of evidence that we need to assess and will gather sufficient evidence to be able to reach a robust judgment.

When making our judgments we consider the weight of each piece of relevant evidence. In most cases we need to verify our evidence with other sources to support our findings. When we have conflicting evidence, we will consider its source, how robust it is and which is the strongest. We may conclude that we need to seek additional evidence or specialist advice in order to make a judgment.

## Enforcement

Where we have identified concerns, we will decide what action is appropriate to take. The action we take is proportionate to the impact or risk of impact that the concern has on the people who use the service and how serious it is. Where the concern is linked to a breach in fundamental standards, we have a wide range of enforcement powers given to us by the Health and Social Care Act 2008.

Our enforcement policy describes our powers in detail and our general approach to using them.

## Encouraging improvement

Our approach is to carry out an assessment of the quality of independent doctor services leading to a judgment about whether they provide people with care which is safe, effective, caring, responsive and well-led based on whether the regulations are being met. This is part of our role in encouraging services to

improve. We will be clear about our expectations of practices through our guidance that underpins the regulations, including the fundamental standards of care.

Additionally, our role in encouraging improvement in the independent doctor services sector will be to share and promote learning between providers. During inspections, we will look at what providers do over and above the fundamental standards to assure themselves that patients receive good outcomes. We will ask the provider at the start of an inspection to tell us about this. We may also wish to identify and share 'notable practice'.

Given the diversity of the independent doctor sector, please tell us how we could best recognise and encourage notable practice.

### Consultation question 5

- How can CQC recognise and encourage notable practice for independent doctor services?

## Equality and human rights

One of CQC's principles is to promote equality, diversity and human rights. This is a means to an end and not an end in itself. The end is good quality care for all. Respecting diversity, promoting equality and ensuring human rights will mean that everyone using health and social care services receives good quality care.

We have developed a human rights approach to regulation. This looks at a set of human rights principles in relation to the five key questions CQC asks of services. These principles are: fairness, respect, equality, dignity, autonomy, right to life and rights for staff. We have developed definitions of these principles through public consultation and linked these to the Human Rights Act 1998 and the Equality Act 2010.

People who use services have told us that these principles are very important to them. Using a human rights approach that is based on the rights that people hold, rather than what services should deliver, also helps us to look at care from the perspective of people who use services.

Our human rights approach is integrated into our approach to inspecting and regulating independent doctor services, as this is the best method to make sure we promote equality and human rights in our work. We have identified the most important fundamental standards relating to equality and human rights and have integrated the human rights principles into our inspection prompts, inspection methods, learning and development for inspection teams and into our policies around making judgments and enforcement.

## Monitoring the use of the Mental Capacity Act

The Mental Capacity Act (2005) is a crucial safeguard for the human rights of people who might (or might be assumed to) lack mental capacity to make decisions, in particular about consenting to proposed care or treatment interventions. The Mental Capacity Act provides the essential framework for balancing autonomy and protection when staff are assessing whether people aged 16 and over have the mental capacity to make specific decisions at the time they need to be made. This refers specifically to the capacity to consent to, or refuse, proposed care or treatment.

We will look at how and when mental capacity is assessed and, where people lack mental capacity for a decision, how that decision is made and recorded in compliance with the Mental Capacity Act.

Independent doctor services are unlikely to be responsible for seeking authorisation of a deprivation of liberty. However, independent doctors and their staff must be aware that if they are providing care or treatment to a person who is subject to an authorisation for deprivation of liberty, this authorisation does not authorise specific treatment, which must be given using the wider provisions of the Mental Capacity Act. Where it is likely that a person is deprived of their liberty to enable them to receive essential care or treatment, we will look for evidence that efforts have been made to reduce any restriction so that the person is not deprived of their liberty. Where this is not possible, we will check that the deprivation of liberty has been authorised as appropriate, by use of the Deprivation of Liberty Safeguards, the Mental Health Act 1983, or by an order of the Court of Protection.

The importance of this is reflected in our inspections. We have a specific KLOE about consent, which takes account of the requirements of the Mental Capacity Act and other relevant legislation, such as the Children Acts 1989 and 2004.

## Concerns, complaints and whistleblowing

Concerns raised by people using services, those close to them and staff working in services provide vital information that helps us understand the quality of care. We will gather this information in three main ways:

- Encouraging people who use services and staff to contact us directly through our website and by telephone, and providing opportunities to share concerns with inspectors when they visit a service.
- Asking national and local partners (for example, the GMC and Healthwatch) to share with us concerns, complaints and whistleblowing information that they hold.
- Requesting information about concerns, complaints and whistleblowing from providers themselves.

We will draw on different sources of evidence to understand how well providers encourage, listen to, respond to and learn from concerns. Evidence sources may include complaints and whistleblowing policies and procedures, reviewing

indicators, such as a backlog of complaints, and speaking with people who use services, carers, families and staff.

# 2. How we work with others

Good relationships with stakeholders are vital to our inspection approach. These relationships allow CQC better access to qualitative as well as quantitative information about services, particularly local evidence about people's experience of care. Local relationships also provide opportunities to identify notable practice and to work with others to raise standards. Our inspection managers will be responsible for maintaining local relationships with stakeholders.

## Working with people who use services

People's experiences of care are vital to our work; they help to inform when, where and what we inspect. We want people to tell us about their care at any time through our website, helpline and social media. We are committed to engaging with the public to encourage people to share their views and experiences with us. This includes people who use services and those close to them, carers and advocates. We do this through raising awareness among the public, working with local Healthwatch organisations, healthcare professionals, providers, Experts by Experience and through public events.

## Working with other regulators and oversight bodies

We also work closely with other regulators and oversight bodies at both a local and national level, such as:

- Nursing and Midwifery Council
- Health and Care Professions Council
- General Medical Council
- Royal Colleges
- Parliamentary and Health Service Ombudsman
- NHS England
- Local medical committees
- Local education and training boards
- Health and Safety Executive

We may contact these organisations as part of our information gathering before an inspection visit or to ensure that they take action on any concerns that we have identified, where that is more proportionate or likely to be more effective than CQC acting on its own.

## Working with local organisations

CQC has a statutory duty to have regard to the views of local Healthwatch organisations as part of our wider statutory responsibility to involve people who use services in our work. Each local Healthwatch organisation acts as a voice for any member of the public in its area who wants to influence the commissioning, provision or delivery of care services. As part of our inspection planning, we will write to local Healthwatch organisations and local overview and scrutiny committees to ask them to share with us any issues or concerns they wish to raise about individual services. The information they provide will help direct the focus of our inspection.

## Working with providers

Each registered provider location of an independent doctor service will have a member of CQC's inspection staff as their 'relationship owner'. Their role will include reviewing any information received from or about the provider obtained from a number of sources and stakeholders. They will be supported by our intelligence teams, who may analyse some of the information.

# 3. Planning the inspection

To make the most of the time that we are on site for an inspection, we must make sure we have the right information to help us focus on what matters most to people. This will influence what we look at, who we will talk to and how we will configure our team. The information we gather during this time before the inspection is also used as evidence when we make our judgments. We will analyse data from a range of sources, including information from people who use services, information from other stakeholders and information that providers send to us.

## Gathering people's views in advance of our inspections

A key principle of our approach to inspecting is to seek out and listen to the experiences of the public, people who use services and those close to them, including the views of people who are in vulnerable circumstances or who are less likely to be heard. The purpose of this is to better understand the issues that are of most concern to people to guide our inspection.

We will gather information from people who use services in advance of the site visit in the following ways:

- We continually invite people who use the service and their carers to tell us about the care they have received through our website, social media, our helpline, and where appropriate, at public meetings run either by CQC or our partners.
- Patients can ask to speak to an inspector or fill in a comment card, which we will ask you to publicise by displaying our posters and information in your service reception area or you could email patients if you prefer to do that.

We are continuing to explore the best ways to gather the views of people who use services in advance of our inspections.

## Gathering information from the provider

Before we start the inspection, we will ask independent doctor services to complete a pre inspection provider information request by using an online form.

The form will evolve over time but initially will include questions that will help us understand more about the service, including arrangements the service has in place for monitoring the quality of treatment it provides as well as arrangements for revalidation of doctors working in the service. We may also use a two stage approach whereby we have the initial information request followed by one requesting certain documentation but we will work with the sector to develop our approach on this.

We may ask for documents and examples of information that will provide us with helpful pre inspection insight. Services will then have 10 working days to respond to our request. The letter will make it clear how to complete the online form, what information to send, where to send information and who to contact with any queries or questions.

The information we will request is likely to include:

- The range of services provided (we will also look at provider websites for this information).
- Arrangements in place for revalidation.
- Results from patient feedback/surveys and associated action plans.
- A summary of any complaints received in the last 12 months, any action taken and how learning was implemented.
- A summary of any serious adverse events for the last 12 months, any action taken and how learning was implemented.
- Evidence of monitoring the quality of services provided (including completed clinical audits and action taken on results/engagement in any independent peer review). You can also share with us the data you used for revalidation if this is recent).
- Information about any supplying of urgent/emergency medicines or prescribing medicines outside of their product licence.

This list is not exhaustive.

## Gathering information from stakeholders

Many national partner organisations we work with hold information about people's experiences and we want to make the best use of their evidence. This includes, for example:

- The General Medical Council
- Nursing and Midwifery Council
- Medical Royal Colleges

## Announced inspections

Inspections are usually announced. We feel that this is the most appropriate way to make sure our inspections do not disrupt the care provided to people.

When we announce inspections, we will give four weeks' notice to providers. The inspector will phone the service to announce the inspection, which will then be followed up in a letter. After announcing the inspection and throughout the inspection process, the lead inspector and inspection planner will support and communicate with the service by letter, email and telephone to help them prepare for the day and know what to expect. We also provide guidance about what to expect on an inspection, which is available on our website.

## Unannounced inspections

We may also carry out unannounced inspections, for example if we have concerns about a service or if we are responding to a particular issue or concern. This may be something identified at a previous inspection that we are following up or be due to new information.

At the start of these visits, the team will meet with the most senior person in charge at the time and will feed back to them at the end of the inspection – particularly if there are any immediate safety concerns.

When we are following up concerns from a previous inspection, we will usually carry out an unannounced focused inspection.

# 4. The inspection visit

Inspection visits are a key part of our regulatory framework, giving us an opportunity to talk to people who use services, staff and other professionals to find out their experiences. They allow us to observe the physical premises as well as how the service implements systems and processes in delivering the regulated activities. They also enable us to observe care, if appropriate and necessary, and to review records where appropriate, to see how their needs are identified and managed.

Inspections will be led by an inspector. Inspectors visiting independent doctor services may include a specialist advisor.

We anticipate that most of our comprehensive inspections will be carried out on one day by a CQC inspector with support from a specialist advisor. This support may include attendance at the inspection or providing advice remotely.

To ensure that we gather sufficient and robust evidence to support our judgments, in some circumstances, an inspection may be supported by any or all of the following:

- A larger inspection team.
- Team members with specific skills or experience.
- Spending more time in the service

The lead inspector is the main point of contact during the inspection and the inspection team will vary in size, to reflect the size of the service. The lead inspector will contact you before the inspection to discuss the arrangements for the inspection and provide a brief outline of the plan.

We will announce which services we intend to inspect, usually four weeks before the date of the inspection. We will write to the provider notifying them that we will be inspecting and what information we require before the inspection.

## The start of the visit

At the start of the site visit, the inspector will meet with the registered manager, if there is one and/or with the provider or their nominated representative. This introductory session will be short and will explain:

- How CQC regulates independent doctor services.
- Who the inspection team are.
- The scope and purpose of the inspection, including our relevant powers and the plan for the day.
- How we will escalate any concerns identified during the inspection.
- How we will communicate our findings.

We will ask the practice to share with us any concerns they have identified themselves in their ability to meet the fundamental standards and what they are doing about it. We will also ask them to share with us any notable practice that they think goes beyond the requirements of the fundamental standards.

There is no specified format or presentation/media template for this briefing; the provider can choose whichever format suits them. This should take no longer than 30 minutes.

We want providers to be open and share their views with us about where they are providing good care and what they are doing to improve in those areas they know are not so good.

## Gathering evidence

We will gather the views of patients by:

- Asking them if they would like to speak to us individually.
- Using comment cards placed in your reception areas and other busy areas to gather feedback from people who use services, their family and carers.
- Using posters to advertise the inspection and give an opportunity to speak to the inspection team. We would be grateful if you could display them in areas where patients will see them.
- Exploring options for using other digital routes for people to share their experience, through text messaging, social media such as Twitter and through apps.
- Using the information gathered from our work, for example, direct feedback to CQC or looking at patient complaints and concerns.

Other ways of gathering evidence may include:

- Pathway tracking patients through their care
- Reviewing records
- Reviewing policies and documents
- Observation.

The inspection team timetable will have the following stages:

- Planning for the inspection (including following up on any outstanding compliance or enforcement actions)
- Inspection of independent doctor services (we will also provide high level feedback at the end of the inspection)
- Draft report
- Final report
- Publication of report.

### Consultation question 6

- During our inspections of independent doctor services, we will use a number of methods to gather information from providers, the public and others about their views of the services provided. Do you agree that the proposed methods of doing this are the right ones to use?

  Yes/No

- Will they enable us to gather views from all of the people we need to hear from?

  Yes/No

## Feedback on the visit

At the end of the inspection visit, the inspector will provide high level feedback to the provider. This would usually include:

- Thanking the provider for their support and contribution.
- Explaining findings to date, but noting that further analysis of the evidence will be needed before final assessment can be reached on all of the issues.
- Whether we need additional evidence or are likely to seek further specialist advice in order to make a judgment.
- Any issues that were escalated during the visit.
- Any plans for follow-up or additional visits (unless they are unannounced).
- Explaining how we will make our assessment against regulations.
- Explaining the next steps, including challenging factual accuracy in the report, final report sign-off and publication. Including an indication of when you can expect your draft report.
- Answering any questions from the provider.

# 5. Focused inspection

Focused inspections do not usually look at all the fundamental standards of care; they focus on the areas indicated by the information that triggers the focused inspection.

## Areas of concern

We will undertake a focused inspection when we are following up on areas of concern, including:

- Concerns that were originally identified during a comprehensive inspection.
- Concerns that have been raised with us through other sources, such as information from our stakeholders, members of the public or staff.

## Change of service provider

When there is a change in the legal entity of the service provider, such as a sale, merger or an acquisition of a service, we may undertake a focused inspection depending on the level of risk to patients and the safety and quality of care.

## The focused inspection process

Although they are smaller in scope, focused inspections broadly follow the same process as a comprehensive inspection. The reason for the inspection determines many aspects, such as the scale of the inspection, when to visit, what evidence needs to be gathered, the size of the team and which specialist advisors to involve. These visits may be announced or unannounced, depending on the focus of the inspection.

As a focused inspection is not an inspection of the whole of a provider, we will not necessarily address all the five key questions; safe, effective, caring, responsive and well-led.

When a focused inspection identifies significant concerns, it may trigger a comprehensive inspection.

# 6. Reporting, quality control and action planning

## Reporting

After each inspection we produce a report on what we found. To do so is a legal obligation under section 61(3) of the Health and Social Care Act 2008. The report is drafted in collaboration with members of the inspection team (where applicable) and is written in clear, accessible, plain English.

Our reports focus on our judgments about whether services are providing people with care that is safe, effective, caring, responsive and well-led, based on whether regulations are being met. We want to help providers to continually improve, so our reports will include information about any improvement we think the provider could make, even if they meet the fundamental standards of care. If we identify any breaches in the fundamental standards we will clearly set out the evidence about the breach.

## Quality control

We engaged widely with stakeholders and independent doctor providers when developing this handbook and heard that there were some concerns about our ability to be consistent in making judgments. Consistency is one of the core principles that underpin all our work. We have put in place an overall approach across CQC to embed consistency in everything we do. The key elements of this are:

- A strong and agreed core purpose for CQC.
- A clear statement of our role in achieving that purpose.
- Consistent systems and processes to underpin all our work.
- High-quality and consistent training for our staff.
- Strong and consistent quality assurance processes.

Following quality checks, we send the draft report to the provider to comment in relation to its factual accuracy. The report is published following any necessary changes.

## Action planning

We expect practices to respond to areas of concern that we have identified and to make the recommended improvements. This is their responsibility and includes developing an action plan to address any concerns raised.

## Publication

CQC will publish the inspection reports on our website after the end of the inspection. We encourage independent doctor providers to publish their report, including any action plans, on their own website.

# 7. Enforcement and actions

## Types of action and enforcement

From April 2015, new regulations including the 'fundamental standards' came into force. These are more focused and clear than the previous regulations about the care that people should expect to receive.

Where we have identified concerns, we decide what action is appropriate to take. The action we take is proportionate to the impact or risk of impact that the concern has on the people who use the service and how serious it is. Where the concern is linked to a breach in fundamental standards, we have a wide range of enforcement powers given to us by the Health and Social Care Act 2008.

Where appropriate, if the provider is able to improve the service on its own and the risks to people who use the service are not immediate, we will expect the provider to make improvements. We will do this as part of our powers under Regulation 17(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This will be reflected in our inspection report and judgment of the five key questions that CQC asks of services.

Our enforcement policy describes our powers in detail and our general approach to using them.

We include in our report any concerns, recommended improvements or enforcement action taken, and expect the provider to take appropriate action.

We follow up any concerns or enforcement action we take. If the necessary changes and improvements are not made, we can escalate our response, gathering further information through a focused inspection. However, we always consider each case on its own merit and we do not rigidly apply the enforcement rules when another action may be more appropriate.

## New regulations: fit and proper person requirement and the duty of candour

Two new regulations, Regulation 5: Fit and proper persons: Directors and Regulation 20: Duty of candour, apply to all providers from 1 April 2015.

The intention of Regulation 5 is to ensure that people who have director level responsibility for the quality and safety of care, and for meeting the fundamental standards, are fit and proper to carry out this important role. It applies to all providers that are not individuals or partnerships. Organisations retain full responsibility for appointing directors and board members (or their equivalents). CQC may intervene where it has evidence that a provider has not met the requirement to appoint and have in place fit and proper directors, using the full range of enforcement powers.

The intention of Regulation 20 is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It

also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong. This statutory duty on organisations supplements the existing professional duty of candour on individuals.

We have published guidance for providers on meeting the regulations, which provides information on how we look at these regulations to make judgments at registration and on inspection.

## Responding to inadequate care

We will intervene if people are at risk of harm or providers appear not to be meeting the fundamental standards. We will start with whatever level of intervention will achieve our purpose of protecting people who use the service, or holding providers and individuals to account, or both.

In addition to our statutory powers, we also work with other regulatory and oversight organisations to ensure that they take action on any concerns that we have identified, where that is more proportionate or likely to be more effective than CQC acting on its own.

As well as using our enforcement powers, CQC will also work with other regulators and oversight bodies, such as the General Medical Council and NHS England (where independent doctor services provide NHS funded care), to ensure that action is taken to address concerns that we identify.

## Challenging the evidence

We want to ensure that providers can raise legitimate concerns about the way we apply our judgments, and have a fair and open way of resolving them.

Providers can challenge the factual accuracy of reports and make representations about the evidence in Warning Notices. Independent doctor services can challenge our judgments in the following ways.

## Factual accuracy check

When we send a copy of the draft report to providers, we invite them to provide feedback on the factual accuracy. Providers can challenge the accuracy and completeness of the evidence. Providers have 10 working days to review draft reports for factual accuracy and submit their comments to CQC.

## Warning Notice representations

If we serve a Warning Notice, we give registered persons the opportunity to make representations about the matters in the Notice. The content of the Notice will be informed by evidence about the breach that is in the inspection report.

Under our process for factual accuracy checks and Warning Notice representations, unresolved issues can be escalated to managers in CQC who were not involved in the inspection.

## Complaints about CQC

We aim to deal promptly and efficiently with all complaints about how we carry out our work, including complaints about members of our staff or people working for us.

Providers should make complaints to the person that they have been dealing with because they will usually be the best person to resolve the matter. If the complainant feels unable to do this, or they have tried and were unsuccessful, they can call, email or write to us. Our contact details are on our website.

We will write back within three working days to say who will handle the complaint.

We will try to resolve the complaint. The complainant will receive a response from us in writing within 15 working days saying what we have done, or plan to do, to put things right.

If the complainant is not happy with how we responded to the complaint, they must contact our Corporate Complaints Team within 20 days and tell us why they were unhappy with our response and what outcome they would like. They can call, email or write to our Corporate Complaints Team. The contact details are on our website.

The team will review the information about the complaint and the way we have handled it. In some cases we may ask another member of CQC staff or someone who is independent of CQC to investigate it further. If there is a more appropriate way to resolve the complaint, we will discuss and agree it with the complainant.

We will send the outcome of the review within 20 working days. If we need more time, we will write to explain the reason for the delay.

If the complainant is still unhappy with the outcome of the complaint, they can contact the Parliamentary and Health Service Ombudsman. Details of how to do this are on the Parliamentary and Health Service Ombudsman's website.

# How to respond to this consultation

There is further work to do on our proposed new model and approach but we very much welcome hearing your views and any ideas you want to put forward.

Whether you have commented on past consultations or not, please do take the time to respond.

Please send us your views and comments **by midnight on Monday 19th October 2015.** We will be unable to accept any responses after this date.

You can respond to our consultation in the following ways.

## Online

This is the quickest way to respond - use our online form at:

http://www.cqc.org.uk/independentdoctorsconsultation

## By email

Email your response to:

CQCchanges.tellus@cqc.org.uk

Responses sent to alternative CQC email addresses will not be considered as part of this consultation.

## By post

Write to us at:

CQC consultation: How we inspect, regulate and rate
Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

On the next page, we repeat the consultation questions we have asked throughout this document.

# Consultation questions

## Consultation question 1

- Do you agree that the KLOEs will enable us to comment on independent doctor services under the five key questions?

  Yes/No

- Is there anything else we should include?
- We have provided examples of the evidence we may look for during our inspections. Do you agree that this will identify any areas of poor quality care?

  Yes/No

## Consultation question 2

- Do you agree that the examples of intelligence we plan to look at will identify both good practice and risks of poor quality care?

  Yes/No

## Consultation question 3

- Should CQC rate independent doctor services?

  Yes/No

- If CQC are granted the powers to rate independent doctor services in the future, which of the approaches below should we take?
  - Inspect and rate across all of the five key questions in line with our current model for other services we rate?
  - Inspect against all of the five key questions but only rate against certain key questions?
- If you think we should only rate against some of the key questions, which key questions should we rate?
  - Safe
  - Effective
  - Caring
  - Responsive
  - Well-led

- If you think we should consider other options, please tell us what these are.

## Consultation question 4

- Do you agree that independent doctors should remain within the scope of regulation by CQC?

  Yes/No

- If yes, please tell us why you think it should be CQC.

## Consultation question 5

- How can CQC recognise and encourage notable practice for independent doctor services?

## Consultation question 6

- During our inspections of independent doctor services, we will use a number of methods to gather information from providers, the public and others about their views of the services provided. Do you agree that the proposed methods of doing this are the right ones to use?

  Yes/No

- Will they enable us to gather views from all of the people we need to hear from?

  Yes/No

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