Consultation

Our approach to regulating the:

**Independent healthcare acute sector**

November 2014
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.
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Foreword

In April 2014, I set out our proposed approach towards inspecting and regulating providers of independent healthcare services in our signposting document, *A fresh start for the regulation of independent healthcare*. This document set out the main characteristics of independent acute healthcare services, including the differences from acute health services delivered by the NHS. We also illustrated the diverse nature of the sector in the way that services are delivered through an array of settings and in a number of ways, ranging from the largest corporate hospital provider to individual practitioners working independently as sole traders.

We also set out our priorities for improving how CQC monitors, inspects and regulates these services and confirmed our commitment to developing our new regulatory models in partnership with those who deliver and use the services within them.

We have been working hard over recent months to deliver on this commitment and are now at the stage of having developed a model which we are currently testing in a number of acute independent hospitals. In partnership with stakeholders in this sector we have also developed firm proposals for regulating and inspecting the three main groups:

- Hospitals
- Single specialty services
- Non-hospital acute services.

I am pleased to be able to publish those in this consultation document.

We are also asking for views and suggestions about approaches we want to consider for future development – introducing special measures and ratings for corporate providers – which are part of our wider strategy in other sectors as well as in healthcare.

We know that there is still work for us to do to strengthen how we regulate independent health care services in England. This is particularly to ensure that the approaches we develop are proportionate and appropriate and that we strike the right balance between being mindful of differences in the sector, while still allowing people to make valid comparisons where similar services are provided in different sectors. Getting this right will help us to make sure that we deliver our purpose – ensuring that services provide people with safe, effective, compassionate, high-quality care and to encourage care services to improve.
Please take the time to respond to this consultation. The proposals in this document affect providers of independent healthcare acute services, but I would encourage both independent and NHS providers to respond.

We would like to receive your views by **Friday 23 January 2015**. They are important in helping us to evolve and develop our models for each sector, and to get them right. Thank you.

**Professor Sir Mike Richards**
Chief Inspector of Hospitals
1. Which independent healthcare services does this consultation cover?

The independent healthcare sector is diverse, with providers delivering services from a wide range of settings and in a number of ways. It is important that our new regulatory model assures patients and the public that they will receive the same standards of care in similar services. We also need to ensure that providers experience inspections using methods that proportionately reflect differences and are not a ‘one size fits all’ approach.

To achieve this, we have committed to align as many elements as possible of our new model for the independent healthcare sector with other sectors, including NHS acute services and primary care services. It is important that we treat providers equally when they deliver similar types of services, but at the same time, that we ensure that we tailor our approach to each sector and type of service where there are differences that need to be taken into account. This means we need to be clear about which types of independent healthcare services are similar to NHS acute and primary care services, and those that have specific differences.

We consulted in April 2014 on our handbook for NHS acute trusts and published it in September 2015. The handbook is guidance that describes in detail our approach to regulating, inspecting and rating NHS acute hospitals. We do not plan to have a separate handbook for independent healthcare acute providers, as the approach set out in the handbook for NHS acute trusts would also largely apply to most of the independent healthcare services described below. In section 3, we have set out the aspects of the handbook that we think should remain consistent across NHS and independent acute providers, and those where we think it is appropriate that they should be different. We are seeking views about whether we have judged those correctly.

In our signposting document, we set out the main characteristics of independent acute healthcare services, including the differences from health services delivered by the NHS. Those differences were particularly illustrated in health policy, organisation, staffing and competitive market factors. The document also described in some detail that independent healthcare providers deliver diverse services from an array of settings and in a number of ways. These range from large hospitals that operate under a single corporate body with multiple locations across the country, to single specialties (for example, dialysis centres or refractive eye surgery clinics) and individuals delivering acute healthcare services (under practising privileges or as stand-alone services).

The proposals in this consultation cover independent acute healthcare providers that are private, voluntary or not-for-profit organisations and individuals, which
are not owned or managed by the NHS. They may provide healthcare services that are contracted by the NHS, paid for by individual patients or through healthcare insurance schemes, or a mix of these funding arrangements.

They include:

- All independent acute hospitals, whether corporately-owned or stand-alone, including NHS treatment centres and private patient units located within an NHS acute or specialty trust, where these are run and managed by an independent provider.
- All locations in which cosmetic surgery is undertaken.
- All single-speciality healthcare services.
- Hospitals for people living with long-term conditions.
- All non-hospital acute healthcare services that don’t fall into any of the above categories.

This consultation does not include:

- Independent ambulance, mental health or community services.
- Independent doctors who do not provide acute healthcare services.
- Other independently practising providers, such as dentists and NHS GPs.
- Private patient units or beds in NHS acute or specialty trusts, where these are run and managed by the NHS.
- NHS bodies whose management is contracted out to independent sector organisations.
- Community health hospitals or healthcare at home services.
- Hospices.

In our list of services which are included in this consultation, there are some specific characteristics which apply to certain types of services. We propose to divide the independent acute healthcare sector into three distinct groups to reflect these characteristics, so that we can tailor adaptations of our overall approach to each group (our proposed approach is described in detail in section 2 below).

The three groups are ‘hospitals’, ‘single-specialty services’ and ‘non-hospital acute services’. They are described in more detail below.

**Hospitals**

This group includes independent acute hospitals that are either corporately-owned or stand-alone hospitals. They provide ‘traditional’ hospital services, such as surgical and medical treatment, will have operating theatre and recovery facilities, and day and/or overnight beds. They may provide multiple surgical or medical services, or specialise in usually one or two, such as orthopaedic or ophthalmic surgery. Some will provide complex surgery, some
will have high-dependency or critical care facilities and some will draw patients from other parts of the country or overseas. Most treat only adults, but some provide healthcare services to children and babies.

The hospital group also includes:

- Independent sector treatment centres that provide services solely or mainly to NHS patients under an NHS contract.
- Private patient units located within an NHS acute or specialty trust, where these are run and managed by an independent provider.
- The small number of independent providers of maternity services.
- Independent healthcare practitioners who carry out the surgical procedure of male circumcision for the purposes of religious observance.

We propose that the hospitals group also includes providers of cosmetic surgery, except those that only provide hair transplantation services, which we propose including in the single specialty group (see below). We think it is appropriate that providers of surgical services, other than minor surgery by GPs, are classed together in the hospitals group regardless of whether they are provided for treatment or for religious or cosmetic purposes, on the basis that the risks associated with surgical procedures are similar whatever the underlying main purpose.

Many of the independent acute hospital corporate providers carry out cosmetic surgery procedures as one of the range of surgical services they provide. Our grouping also includes those stand-alone organisations or individuals who specialise in providing only cosmetic surgical procedures. CQC’s guidance document, *The scope of registration*, sets out that cosmetic surgery involves the insertion of instruments or other equipment into the body. As an example, we consider liposuction involving the insertion of instruments into the body to be included as a surgical (cosmetic) procedure, regardless of whether it is carried out under general or local anaesthesia, or whether the procedure involves the administration of a laser via a cannula inserted into the body.

Therefore, to maintain our principle that we treat providers equally when they deliver similar types of services, we propose to include providers of cosmetic surgery within the hospitals group. However, we will look carefully at our approach to inspecting the smaller, stand-alone organisations or individuals who fall into this category, to ensure that we regulate them in a proportionate way.
Single specialty services

We propose that the single specialties group includes the following services where these are the independent provider’s main or sole activity:

- Termination of pregnancy procedures
- Haemodialysis or peritoneal dialysis
- Hyperbaric therapy
- Diagnostic imaging and endoscopy
- Diagnostic laboratory services
- Refractive eye surgery
- Fertility services
- Hair transplantation services
- Specialist inpatient services for long-term conditions.

These services are diverse and different to each other, and may be provided in hospital, clinic or other settings. Several may also be provided by NHS acute trusts and independent acute hospitals as part of the range of services they offer. However, where independent providers specialise in carrying out one of these services as their only or main activity, we propose including them within the single specialties group, which is described in more detail below.

Termination of pregnancy procedures
These can only be carried out where the provider is registered with CQC for that activity, and the place where the provider carries out the termination is licensed by the Department of Health. Surgical or medical terminations are undertaken in a number of settings, including NHS acute trusts, independent acute hospitals, NHS GP surgeries and specialist family planning clinics. However, most terminations are carried out by independent providers who specialise in that service (although they may also offer additional services, such as vasectomy). They may provide services on behalf of the NHS or to private, self-pay patients from the local area or further afield. The single specialty services group includes these types of independent providers only, and includes all the locations where surgical and/or medical terminations are undertaken. Some of these locations will have facilities similar to the hospitals’ grouping, for example overnight or day beds and operating theatre and recovery areas, while others will be clinic-based services, similar to outpatient or NHS GP facilities.

Haemodialysis or peritoneal dialysis
These may be undertaken by NHS acute trusts and in some independent acute hospitals, but services are also delivered by independent providers, on behalf of the NHS. These can be based in a range of settings including within an NHS trust premises, or in stand-alone, purpose-built facilities. The single speciality services group includes these types of independent providers who specialise in the provision of dialysis procedures.
**Hyperbaric treatment**
This is provided by a few NHS acute trusts, as well as by a small number of independent providers. Some of these are based within the premises or grounds of NHS trusts or independent acute hospitals; others may be in stand-alone, purpose-built facilities. They treat a range of medical conditions using hyperbaric therapy, often in emergency situations for acutely ill patients. The single speciality services group includes these types of independent providers who specialise in the provision of hyperbaric treatment. It does not include non-therapeutic hyperbaric services (for example, related to diving at work regulations) or services that do not require supervision by a medical practitioner (for example, hyperbaric chambers where treatment of multiple sclerosis is carried out).

**Diagnostic imaging and endoscopy**
These may be provided in hospital, clinic or other settings. Several may also be provided by NHS acute trusts, independent acute hospitals and NHS GP surgeries as part of the range of services they offer. However, some independent providers carry out these procedures as their main or sole purpose, delivered from a variety of settings including within the premises of an NHS acute trust or independent acute hospital, or in consulting rooms, stand-alone or mobile facilities. They may provide services through a range of funding sources, including under contract to the NHS or to an independent acute hospital provider, or as walk-in, self-pay services to self-referring patients.

Some independent doctors may be required to be registered with CQC because part of their service includes the provision of endoscopy procedures. A few independent providers also carry out invasive cardiac physiology tests as their main or sole purpose under contract to the NHS. We are also proposing to include both these types of providers within the single specialties group.

A small number of services provide ultrasound scanning procedures such as screening for osteoporosis, or baby scanning. These may be provided on a mobile basis, where the provider of the service carries out the scan in the patient’s home, or they may be provided by a company that provides scanning facilities in different parts of the country. We are proposing to include these types of providers in this part of the single specialties group.

**Diagnostic laboratory services**
These may be provided in a hospital, clinic or other settings. Several may also be provided by NHS acute trusts, independent acute hospitals and NHS GP surgeries as part of the range of services they offer. However, some independent providers carry out these services as their main or sole purpose, delivered from a variety of settings, including within the premises of an NHS acute trust or independent acute hospital, or in stand-alone, purpose-built facilities. Most of these providers receive tissue samples for diagnostic testing; a few may take blood samples from patients who attend their premises. Services may be provided for a variety of clients including NHS trusts, independent acute hospitals or independent doctors. The single speciality
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grouping includes these types of independent providers who specialise in the provision of diagnostic laboratory services.

**Refractive eye surgery**
Independent providers of refractive eye surgery procedures are included within the single specialty service group. They specialise in providing vision correction services, carrying out surgical procedures for self-referring, self-pay patients. The service may also be called laser eye surgery or refractive lens surgery. Providers are mostly corporate organisations, providing services in ‘high-street’ clinic locations.

**Fertility services**
Providers of fertility services are primarily regulated by the Human Fertilisation and Embryology Authority (HFEA) for in-vitro fertilisation procedures (IVF). The Care Quality Commission’s regulatory remit extends only to those activities which are not covered by an HFEA licence, and only relates to a very small part of the overall specialised service carried out by such providers. This would include procedures that are related to diagnosing the causes of infertility, or other procedures that are unrelated to fertility treatment or assisted conception that are not covered by the HFEA licence.

Some NHS acute trusts and independent acute hospital providers carry out surgical or diagnostic procedures in order to treat or identify the causes of infertility, such as diagnostic laparoscopy. Some also carry out IVF procedures, licenced and regulated by the HFEA, as part of the wider range of services they offer. Neither of these services is intended to be part of the single specialty group. Most IVF provision is offered in the independent sector, sometimes on behalf of the NHS but mainly to self-paying patients. The single speciality services group only includes those independent IVF providers who also carry out a small range of procedures that are outside the terms of their HFEA licence.

**Hair transplantation services**
These are specialised services offered to treat hair loss for cosmetic purposes. While the underlying outcome is intended to improve the appearance, hair loss may be caused by a number of medical factors, and there are various surgical and non-surgical treatments that can be offered. CQC’s remit extends to the surgical procedure associated with hair transplantation – some procedures are more invasive than others, but all are carried out using local anaesthesia, on a walk-in, walk-out basis, requiring little in the way of recovery. Independent providers of surgical hair transplantation services may offer this as part of a range of cosmetic and aesthetic procedures, or may specialise in surgical and/or non-surgical hair transplantation. Services are mainly provided in ‘high-street’ clinics. The single speciality services group includes only those independent providers that carry out surgical hair transplantation procedures. If they carry out other forms of cosmetic surgical procedures as well as hair transplantation, they will be included with the independent acute hospitals group as a cosmetic surgery provider.
Specialist inpatient services for long-term conditions

A small number of independent hospitals provide highly specialist inpatient services for long-term conditions. They typically provide medical treatment, rehabilitation and care of people with neurological conditions or disabilities, or acquired brain injuries. These hospitals offer very long lengths of stay and are quite different to acute, community or mental health hospitals. Inspections of these hospitals are likely to require the involvement of community and mental health care professionals, as well as acute and specialist practitioners.

Non-hospital acute services

We know that some independent providers that we regulate are healthcare professionals, mainly medical practitioners, who provide healthcare services to private patients. They may also work as consultants for the NHS, or under practising privileges for independent acute hospitals, but may also work independently, or exclusively, in private practice. There are a number of exemptions to the requirement to register, meaning that the majority of NHS GPs and consultants who work for the NHS and/or for independent acute hospitals, and who also provide private healthcare services, are exempt from registration. Full details of the exemptions that apply are published in our document The scope of registration.

Many of the providers who are not exempt will be included within CQC’s new inspection approach being developed for primary medical services. This would be where they provide private medical services such as slimming clinics and vaccinations, online prescribing, private GP or other primary care-type services in consultation rooms or as a visiting service, and remote reporting of diagnostic imaging results. Some of the providers who are not exempt will be included within CQC’s new inspection approach being developed for mental health services, such as independent psychiatrists. These types of services will not be included within the non-hospitals acute services group.

However, some non-exempt independent practitioners provide services of a type that could be considered to be better reflected in the non-hospitals acute services group, because the nature of the services they provide is more aligned to a secondary care setting than a primary care one. These practitioners will typically be secondary care specialists, rather than primary care generalists – for example, consultants.

Some of these providers will be individuals who carry out cosmetic surgery – they will be included with the acute hospital group as a cosmetic surgery provider. Some will be individuals who provide endoscopy or surgical hair transplantation services – they will be included within the single speciality services group under the relevant section.

In cases where a healthcare professional works for the NHS, or under practising privileges with an independent acute hospital, but also independently provides
treatment in a surgery or consulting room under any form of anaesthesia or intravenous sedation (with certain exemptions for very minor procedures), they will be included within the non-hospital acute services group. Where a healthcare professional is not employed by the NHS or working under practising privileges with an independent acute hospital, so is an exclusively private practitioner, they will be included in the non-hospital services group for the provision of any regulated activity, unless it is more appropriate to include them within the primary medical services or mental health services categories.

We appreciate that working out exactly which type of service falls into the non-hospital acute services group is not a precise science, and there may be overlaps with the primary medical and mental health services categories of provider in a few instances. Therefore, we would particularly welcome views in the consultation as to whether we have captured these services in the most appropriate place.

Consultation question

1. Do you agree that our approach to separating independent healthcare providers into three groups as described above is meaningful and appropriate?

If you are an independent healthcare provider, can you readily recognise which of the three groups you fit into?

If not, do you have any suggestions for how the three groups could be otherwise structured or better defined?
2. Our approach to regulating and inspecting independent healthcare acute services

In our signposting document for independent healthcare, we said we would ensure that our regulatory model, while tailored to each sector and type of service, treats providers equally when they deliver similar types of services. To do this, we said we would develop an approach that aligned with, as closely as possible, the assessment framework we have developed for NHS acute trusts.

That model is framed around identifying the ‘core services’ that we will always visit on our inspections and the key lines of enquiry and prompts that guide our inspectors in focusing their attention on the areas that matter most. Using a framework that is as similar as possible to the independent healthcare sector would allow us to make comparisons when similar services are provided, irrespective of the setting. We also said in our signposting document that we would look at single specialty services in the same way wherever they are delivered, and explore how we could work in partnership with other regulatory bodies, use experts within the inspection teams, and make the best use of information to inform our regulatory and inspection processes. We also set out plans to adopt a rating system for independent acute healthcare services similar to NHS acute trusts, in which ratings will only be awarded following an inspection and against our judgements relating to the five key questions that matter most to people who use services – are services:

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

Since we set out these plans, we have been developing our model for regulating and inspecting independent acute providers. At the time of consulting, we are half-way through our first wave of testing the approach, which we have developed with intensive engagement and support from independent healthcare stakeholders and representative groups. We also learned a great deal from how we piloted the NHS acute trust model in late 2013 and the spring of 2014 and took account of the continuing refinement of that approach as we developed the model for testing in the independent healthcare sector.

Our engagement with the sector was particularly helpful, and we are grateful for the time and commitment people have given us in reviewing the NHS model for
its applicability to the independent sector. Stakeholders advised us that, due to the sector’s diversity, it would be preferable for us to start by developing and testing an approach for independent acute hospitals, and to “get it right” for those providers before we looked at other parts of the sector.

We explored that suggestion further and decided that it was the right approach to take, as an approach developed initially for NHS acute trust providers may not necessarily be the most appropriate and proportionate model for some of the smaller or more specialised types of independent healthcare provider. We wanted to have the opportunity to test whether that theory was correct, and to look in more detail at what approaches would be appropriate.

Therefore, having proposed to divide the independent acute healthcare sector into three distinct groups as described above, we are also proposing to make adaptations to the overall approach to regulating them. Although these changes are tailored to each group, they maintain common principles with how we have developed the new approach for the other sectors that we regulate. We have set out details for how we propose to do this for each group below.

**Hospitals**

Main features of the approach:

- The same framework of the five key questions, core services, key lines of enquiry and prompts as for NHS acute trusts, with minor changes.

- *The provider handbook for NHS and independent acute hospitals and single specialty services* will set out the inspection approach and assessment framework.

- An inspection team comprised of our expert hospital inspectors and clinical and other experts, including people with experience of using care (Experts by Experience).

- The size and composition of the team, and duration of the inspection visit, being relevant and appropriate to the size and nature of the service being inspected (this means teams will be significantly smaller than most comprehensive inspection teams for NHS trusts, although with experts continuing to form the majority).

- Using Intelligent Monitoring, including listening to people’s experiences of care, to decide when, where and what to inspect.

- A programme of scheduled, comprehensive inspections, which include an unannounced visit, alongside focused inspections that are responsive to concerns, target particular issues, or update information about services in between comprehensive inspections.
Our approach to regulating the independent healthcare acute sector

- The same principles and characteristics for rating services as for NHS acute trusts, with the overall rating awarded at the level of the location being inspected.
- All acute hospital locations will be rated by April 2016. Thereafter, the frequency of rating will be at least once every three years.

In October 2014, we started to test this approach to inspecting independent acute hospitals. This first wave of testing will run until December 2014. It involves the inspection of eight independent hospitals in different parts of the country of varying size, complexity, facilities, services and ownership, with a mixed patient population of NHS-funded and insured/self-pay, from this country and overseas. Some of the hospitals provide services to children as well as adults.

The approach we are testing was developed jointly with stakeholders. We made relatively minor modifications to the NHS acute trust approach, and retained all the core elements of that model. We know through widespread feedback and evaluation that the model is working well in NHS acute trusts, although further review will continue as the approach becomes embedded. Therefore, to achieve as much parity as possible between NHS and independent acute hospitals, we think the adaptations we are testing are proportionate and appropriate, while still allowing for people to make comparisons where similar services are provided in different sectors.

However, our signposting document noted the lack of consistent, comparable, nationally available data in most of the independent sector, and described the challenges in improving our access to accurate, complete and meaningful data and information about services. This is an important factor for us to consider in our aim to ensure that similar services in different sectors can be fairly compared and rated. We have reviewed the indicators we use in acute NHS trusts to inform which areas of care we will want to look at during an inspection, and have adjusted them in our independent healthcare ‘provider information request’ to reflect the differences in the availability of data. The absence of national data sets for independent acute healthcare means that the provider information request is lengthier than that for the NHS. We continue to consider this an unsatisfactory situation and while we are testing the information request during our pilots, we will continue to work with independent healthcare providers, the Private Healthcare Information Network (PHIN), insurers and commissioners to explore ways in which they can develop nationally comparative data sets, in line with statutory requirements on this sector from the Competition and Markets Authority.

In common with the two-stage piloting process we have used in all the sectors we regulate, we will formally evaluate how well this inspection approach has worked, from the pre-inspection period right through to publication of the final report. We will use a variety of methods to evaluate this with our inspection teams and the providers involved in the testing. We will use the learning from
Our approach to regulating the independent healthcare acute sector

our first wave to make adjustments, which will be further tested in our second wave of pilot inspections, starting in January 2015. These will take place in another eight independent acute hospitals, selected using the same criteria as above, so that we can test the model in as wide a range of services as possible. We will make final adjustments at the end of our second wave of testing in March following further evaluation. We intend to roll out the approach for all independent acute hospitals (those services described in the Hospitals section on pages 7 to 8) from April 2015.

We will not rate independent acute hospitals in our first wave of testing, but intend to publish indicative ‘shadow’ ratings for those included in the second wave. From April 2015, we will publish formal ratings using the same principles we apply to acute NHS trusts.

We have adjusted a number of aspects of the model for NHS acute trusts in order to reflect the differences between NHS and independent acute hospitals, and are testing these changes in our pilot inspections. We would particularly welcome views about whether it is appropriate that these aspects, described below, are different to those for NHS acute trusts.

We have introduced a core service of ‘termination of pregnancy’, which will apply mainly to the ‘single specialty services’ providers, but will be used in those independent acute hospitals that are licensed by the Department of Health to provide terminations. Where providers offer gynaecology services, we will look at this under the core service of surgery, rather than under the maternity and gynaecology core service.

We do not plan to run a listening event before the inspection, as there is often no specific catchment area to the same extent as for NHS acute trusts, but we will look for other ways to seek people’s views of the service being inspected. Quality summits will not be a standard feature of our inspections in the independent sector and will be replaced with a feedback session after the inspection. However, we are testing the situations in which a quality summit might be appropriate during our pilot inspections. For example, in certain cases we believe it may be useful to involve corporate teams, members of the Medical Advisory Committee, patient groups, or commissioners and other public bodies in a quality summit; but in many cases this would be disproportionate.

Consultation question

2. Do you agree with the approach we are proposing for regulating independent acute hospitals?

Do you have any suggestions for other things we could take into account?
Single specialty services

Main features of the approach:

- The same framework of the five key questions, core services, key lines of enquiry and prompts as for NHS and independent acute hospitals, with minor changes to reflect service specific guidance.

- The provider handbook for NHS and independent acute hospitals and single specialty services will set out the inspection approach and assessment framework.

- An inspection team comprised of our expert hospital inspectors and clinical and other experts, including people with experience of using care (Experts by Experience).

- The size and composition of the team, and duration of the inspection visit, being relevant and appropriate to the size and nature of the service being inspected (this means teams will be significantly smaller than comprehensive inspection teams for NHS trusts and often only one inspector plus one to two experts).

- Using Intelligent Monitoring, including listening to people’s experiences of care, to decide when, where and what to inspect.

- A programme of scheduled, comprehensive inspections, which may include an unannounced visit, alongside focused inspections that are responsive to concerns, target particular issues, or update information about services in between comprehensive inspections.

- The same principles and characteristics to rate services in NHS and independent acute hospitals, with the overall rating awarded at the level of the location being inspected.

- We will start to rate single specialty locations from October 2015, with the end date for rating all locations to be decided. Thereafter, the frequency of rating will be at least once every three years.

- Scheduling of comprehensive inspections for each of the single specialties within a reasonable ‘window’, as far as is practicable, to enable training for inspectors in each specialist service and enable a reasonably contemporaneous national commentary in our State of Care reports on all providers in each specialty.

We will have completed our pilot inspections using our new approach for inspecting independent acute hospitals by the end of March 2015 and intend to roll out the model for all independent acute hospitals from April 2015. At the same time that we run our second wave of testing for hospitals, we will be developing the approach that we want to take for the single specialty services (described on pages 9 to 12). We will do this jointly with relevant stakeholders for those service areas, using the learning from developing the acute hospitals approach, so that we can start to pilot the approach for single specialty services.
in two waves between April and September 2015. We intend to roll out the new approach for all single specialty services from October 2015.

The approach for single specialties will include the same core elements as for hospitals, with certain modifications, described below. We will select a range of different types of locations in which to widely test our approaches in the same way as we have done for acute hospitals. Our approach to evaluating our pilot inspections will be the same, and we will rate locations from the start of our second wave, taking specific account of the issues about comparability and availability of data, and will not run listening events or quality summits as part of the inspection approach.

We expect that the main differences in the approach to inspecting single specialty providers will be in some of the prompts and service-specific guidance within our overall assessment framework, and the way we schedule inspections and report on the services at national level. These are described below, and we would particularly welcome your views about whether these differences are appropriate and proportionate.

**Prompts and service-specific guidance:**

*Termination of pregnancy procedures*

We have introduced a new core service of termination of pregnancy and have already carried out co-production work with the sector to develop specific prompts and guidance that are tailored to this sector. We are planning to test this initially in one of the locations selected for our second wave of pilot inspections of acute hospitals. After reviewing, we plan to run further testing during the wave pilot inspections for the single specialty services during April and September 2015. It is likely that other core services, such as surgery, will apply to these providers and we will assess before and during our pilot inspections whether additional prompts are needed.

*Haemodialysis or peritoneal dialysis*

The core service of medical care is likely to apply to these services and the generic acute prompts will fit most aspects of care and treatment. However, to fully reflect the specific risks associated with these services and nationally accepted good practice standards, we will work with stakeholders to develop prompts and service specific guidance within our assessment framework. We will do this in our development phase between January and March 2015, so that the approach is ready to be tested from April.

*Hyperbaric therapy*

The core services of medical care, critical care and, possibly, urgent and emergency care are likely to apply to these services and the generic acute prompts will fit most aspects of care and treatment. However, to fully reflect the specific risks associated with these services and nationally accepted good
practice standards, we will work with stakeholders to develop prompts and service-specific guidance within our assessment framework. We will do this in our development phase between January and March 2015, so that the approach is ready to be tested from April.

**Diagnostic imaging and endoscopy and diagnostic laboratories**

The core service of outpatients and diagnostic imaging is likely to apply to these services. We think that the existing prompts will not need to be extended to more specific ones, but welcome views about this in this consultation.

**Refractive eye surgery, fertility services and hair transplantation services**

The core service of surgery is likely to apply to these services. We think that the existing prompts will not need to be extended to more specific ones, but welcome views about this in this consultation.

**Scheduling and reporting**

We are considering scheduling each type of single specialty service in a block, which would involve inspecting all providers of a certain type over a set period. To be practicable, this period might range from a few weeks for the smallest groups of providers (such as hyperbaric therapy services), to up to 18 months for the largest (such as termination of pregnancy services). This would enable us to provide a national commentary on the entire service type and help to maximise the comparability of ratings for the public. We are also considering whether the inspections could be carried out by a cohort of inspectors, who have specific training for each specialised service.

If we did schedule inspections over a defined period, we would need to prioritise how we would do that in order to maximise the benefit to the public and people using the services, and to target our resources in the most effective way. It may be that block inspections would be scheduled to run concurrently or consecutively. Block scheduling would have an impact on the date by which we will have rated all services in that sector, meaning we may have to have a phased approach to achieving our commitment to rating all services.

Our priorities for scheduling would most likely be:

- Termination of pregnancy
- Dialysis services
- Specialist inpatient services for long-term conditions.
- Hyperbaric therapy
- Diagnostic imaging and endoscopy and diagnostic laboratory services (to run concurrently)
- Refractive eye surgery
- Hair transplantation services
These priorities for scheduling are based on a number of factors, including access to the service where patient choice may be limited, provision of urgent care, clinical risk, and the relevance to or interest of the public in the service.

We are proposing to treat fertility services differently to other single specialties in two ways. The rationale for this is that the HFEA is the specialist regulator for this sector, and our remit usually only covers a very limited part of their services. Therefore, we propose to:

- Publish narrative reports on the aspects of the service that we have inspected, describing performance against regulations. We will not publish any ratings for these clinics or providers – full, comprehensive reports on these services are already provided by the HFEA.

- As far as possible, schedule inspections of these services by coordinating with the HFEA, so that we will normally carry out joint or parallel inspections to coincide with the HFEA’s schedule.

**Focused inspections**

In any single specialty, we may carry out focused inspections (which focus on specific areas of potential concern) in advance of block scheduling comprehensive inspections (which consider key lines of enquiry for all five key questions and produce a rating). Just as proposed above for inspections of fertility clinics, these early focused inspections will result in a narrative report describing performance in relation to regulations, taking account of CQC’s guidance on meeting the fundamental standards regulations (to be published in March 2015). As in the NHS, focused inspections will be based on key lines of enquiry and will not change any previously awarded rating, as ratings can only be changed after we have carried out a comprehensive inspection.

**Consultation question**

3. Do you agree with the approach we are proposing for regulating single specialty services?

Do you have any suggestions for other things we could take into account?
Non-hospital acute services

Main features of the approach:

- The same five key questions.
- The fundamental standards regulations mapped against the five key questions.
- High level prompts for each key question.
- The provider handbook for NHS and independent acute hospitals and single specialty services will not apply to these services.
- An inspection team comprised of our expert hospital inspectors and clinical and other experts as appropriate, possibly including people with experience of using care (Experts by Experience).
- The size and composition of the team, and duration of the inspection visit, being relevant and appropriate to the size and nature of the service being inspected (this means teams will be significantly smaller than comprehensive inspection teams for NHS trusts and often only one inspector usually plus one to two experts).
- The use of Intelligent Monitoring, including listening to people’s experiences of care, to decide when, where and what to inspect.
- A programme of scheduled, comprehensive inspections where we will look at all fundamental standards regulations.
- Focused inspections that are responsive to concerns, target particular issues or regulations, or update information about services in between comprehensive inspections.
- We will not rate non-hospital acute services at the present time, although this will be kept under a rolling programme of review for introduction at an appropriate date.
- Inspection reports will present narrative findings.
- Comprehensive inspections will be carried out over three years, randomly inspecting a third of providers (approximately 100) each year, using risk and intelligence in the criteria for selection.

As we set out in our description of non-hospital acute services on pages 12 to 13, the providers in this group are a diverse range of mainly single-handed practitioners providing specialist, rather than generalist or primary care services, in consulting rooms. We do not yet know whether it is feasible to rate these non-hospital providers in a meaningfully comparative way, given the diversity of services they provide and the small number of providers. We also think that the comprehensive inspection approach we have developed for the other independent healthcare services, hospitals and single speciality services, which is based on the approach for NHS acute trusts, may not be appropriate as a method for regulating these small providers.
We have looked across the sectors that we regulate to identify if there are other, more relevant models that we could test for this sector, and suggest that the approach being developed for inspecting primary care dentists may provide a useful framework on which to build and test an approach for inspecting non-hospital acute providers. We are simultaneously consulting on our approach to regulating the dental sector and the full document is available on our website here.

There are clear differences between the dental sector and the non-hospital acute providers, not least in terms of volume of providers. However, 90% of the dental sector comprises single location, small providers, which is comparable to the organisational arrangements in the non-hospitals acute sector. The dental consultation also sets out that there are currently no plans to rate dental providers (although we welcome views from stakeholders on whether we should in future) – this again is comparable to our thinking for non-hospital acute services at the present time.

We will be developing the approach that we want to take for the non-hospital acute services between January and March 2015 and will do this jointly with relevant stakeholders. At the same time, we will be running our pilot inspections of our new approach for inspecting dental providers and will use the learning from those pilots to inform our planning for the non-hospitals acute approach, wherever relevant. We will start to pilot the approach for non-hospital acute providers in two waves between April and September 2015 and intend to roll out the new approach for these services from October 2015.

The approach for non-hospital acute services will have some key differences to the other two groups in the independent healthcare acute sector. These are:

- Instead of assessment against core services, key lines of enquiry and prompts, there will be a focus on assessment against the fundamental standards regulations. However, we will report on these under the five key questions.
- There will be no commitment to rate services at the present time.
- Comprehensive inspections will mean assessment against all of the regulations.
- We are considering scheduling comprehensive inspections over a three year period, randomly inspecting a third of the providers in each year.

Where possible, we will select a range of different types of locations in which to test our approaches in the same way as we have done for the other two independent healthcare groups. Our approach to evaluating our pilots will be the same.
Our longer-term plans for this part of the sector will consider whether and when we might rate services. For the moment, we are considering how this might be done to answer questions such as:

- What would the benefits of rating these types of services be for the public, patients, commissioners and providers?
- Would introducing ratings increase the provider’s accountability to these groups?
- Would ratings help people (including relatives and carers) to choose services, and help commissioners of publicly-funded services to choose providers (possibly not relevant in this part of the sector)?
- Would they help to improve the performance of providers?
- Would they help to identify and prevent failures in the quality of care?
- How could they provide public reassurance as to the quality of care?

We would value your views about potential answers to these questions, which we anticipate revisiting in October 2015 as part of our rolling review of the approach for non-hospital acute services.

**Consultation question**

4. Do you agree with the approach we are proposing for regulating non-hospital acute services?

Do you have any suggestions for other things we could take into account?

Do you agree that we should continue to engage with non-hospital acute providers before deciding on ratings?

What sort of guidance would be useful for this sector in the meantime?
3. The provider handbook for NHS and independent acute hospitals and single specialty services

We consulted in April 2014 on our handbook for NHS acute hospital trusts and published it in September 2015. The handbook is guidance that describes in detail our approach to regulating, inspecting and rating NHS acute hospitals. It includes what we mean by the different core services we will inspect, our key lines of enquiry that will direct the focus of the inspections, and the characteristics of care at the four rating levels as they apply to NHS acute hospital services.

We encouraged independent healthcare providers to take part in the consultation as it was intended that the approach set out in the handbook for NHS acute trusts would also, largely, apply to independent healthcare acute providers when its methods were developed.

We do not plan to have a separate handbook for independent healthcare acute providers so are not consulting again on the entire inspection methodology and assessment framework. The handbook was supported by the respondents to the initial consultation, and will form the approach to independent healthcare acute hospitals and single specialty services. Our changes to the approach we are building for those services are such that we consider only minor adjustments to the handbook will be needed. However, we have set out below the aspects of the handbook that we think should remain consistent across NHS and independent acute providers, and those we where we think it is appropriate that they should be different, and are seeking views about whether we have judged those correctly.

We will re-issue the handbook in April 2015. At that point it will have been revised to take into account the new fundamental standards which come into effect from 1 April, and will incorporate any changes as necessary that stem from the responses to this consultation. We will re-badge it then as our handbook for all (NHS and independent) acute hospitals and single specialty services.

As we are proposing to adopt a different approach for non-hospital acute providers, as set out earlier in this consultation, the acute hospitals and single specialty handbook will not apply to those services. We will continue to engage with non-hospital acute providers on our approach to inspection, and this will include issuing guidance as appropriate, with the potential to refresh the handbook in the future if we propose to rate these services. In the meantime,
we would also encourage providers from that part of the independent sector to send us their views on the handbook.

We think the following aspects will remain the same in the handbook:

- The high level methodology of comprehensive and focused inspections
- The key lines of enquiry
- The characteristics of ratings
- The ratings principles, although some will not apply to independent healthcare
- The frequency of rating at least once every three years, and the use of focused inspection to update information about services in between comprehensive inspections.

We would value your views about whether these aspects should remain consistent between the NHS and independent acute hospitals and single specialty sectors.

We think the following aspects need to reflect the differences between NHS and independent acute hospitals and single specialty sectors.

- Core services – the main difference is the introduction of a “termination of pregnancy” core service. We are not intending to introduce a core service of cosmetic surgery on the basis that the surgery core service can already sufficiently cover surgical standards. We are working with the Royal College of Surgeons Cosmetic Surgery Interspeciality Committee to ensure that our prompts are in alignment with their published standards.
- Adjusting the model to tailor the size and composition of the inspection teams, and the time needed on site during the visit.
- No listening event as there is usually no specific catchment area. This is not unique to independent healthcare providers as it applies similarly to NHS specialist trusts. We will work with providers to access their patient networks and appropriate surveys to obtain as much information about peoples’ views as possible, in as many ways as needed, before the inspection.
- Our approach to the provider information request and use of data to reflect the difference in the availability of data.
- Quality summits will not be a standard feature of our inspections and will be replaced with a feedback session.

We would value your views about whether it is appropriate that these aspects are different.
Consultation question

5. Do you agree that the changes we propose to the acute provider handbook will help our inspectors to assure the public on how safe, effective, caring, responsive and well-led independent acute hospital and single specialty providers are?

If not, what is missing?
4. Special measures in the independent healthcare sector

Special measures apply to NHS trusts and foundation trusts that have serious failures in the quality of care and where there are concerns that the existing leadership cannot make the necessary improvements without support. It is not appropriate simply to close these services if they fall below our quality standards, since the local population depends on them, and so the special measures regime seeks ways of exerting maximum pressure for improvement while maintaining continuity of service. A specific process is in place between the NHS Trust Development Authority (NHS TDA), Monitor and CQC, which details the circumstances when a trust might be put into special measures and the subsequent areas of responsibility for securing improvement. Special measures regimes are also being put in place for care home providers and NHS GP services.

We are also considering introducing special measures regimes for the independent acute providers who will be rated – acute hospitals and single specialty providers – as an additional option to the ability that we already have to use our range of enforcement powers. We appreciate that the approach will not be the same as for NHS trusts and foundation trusts, as there is no equivalent body to Monitor and the NHS TDA, but we are keen to explore how we might introduce this to the independent sector. We are using the same term of ‘special measures’ in the context of the levers for improvement we might introduce alongside our powers of enforcement but recognise that it will have a different application and meaning in different sectors.

Our ratings of providers will provide a more rounded and in-depth diagnosis of both quality and organisational capability, through the assessment of the key question, “is the service well-led?” Ratings will help us to be clearer about the need for improvement in particular services and the areas where support is needed. A rating of ‘inadequate’ will be a clear indication that radical steps are needed to secure improvement.

Where patients depend on a service (for example, a haemodialysis service for NHS patients, provided by an independent provider) it is therefore more desirable to improve it than to close it. Other than in urgent situations, we believe it will add more value to require a time-limited period in which action must be taken to address the causes of the issue as well as the presenting symptoms of the failure. While we already have powers of enforcement, if we only relied on using those powers, rather than seeking to secure improvement, it would tend to address only the presenting symptoms rather than the root cause.
We are seeking views in this consultation about how we might introduce a form of special measures to independent acute hospitals and single specialty providers, and what criteria respondents think should apply to the circumstances in which they would be taken, either alongside, or instead of, our powers of enforcement. For example, should the criteria for allowing a ‘last chance to improve’ through a special measures regime be wholly or partly based on the extent to which people depend on a service, or have a choice of alternative providers? Where there is less dependency on using a particular service provider, should we go straight to enforcement rather than offering a time-limited ‘last chance’? How should we ensure a fair playing field with the NHS for ‘one last chance to improve’?

It may be worth noting that we have recently consulted on a new enforcement policy which, from April 2015, would position CQC as the main prosecuting authority for the sector (rather than the Health and Safety Executive) in relation to harm to people who use services. It also signalled a greater willingness to restrict or close services that fail to comply with regulations.

Consultation question

6. Do you have any suggestions for how we could develop our approach to special measures in the independent acute sector?
5. Rating independent healthcare corporate providers

When we apply ratings to NHS acute trusts, we can apply those at the level of the locations we have inspected, and aggregate them up to trust-wide level. The trust is the legal entity providing the services we regulate, and is registered with CQC as the registered provider. In the independent sector, the same registration requirement applies to corporate providers – they are registered with CQC as the legal entity. However, their locations arrangements are different to NHS acute trusts, where those are mainly based in a defined, fairly local area, are identifiable to the public as ‘belonging to’ the trust, and are all inspected at the same time. Independent healthcare corporate providers’ locations are often spread across different parts of the country and cannot easily be inspected at the same time, or within a limited timescale as the number of locations makes this an unrealistic prospect.

In order to achieve parity and comparability across the sectors, we are considering how we might aggregate ratings to provider level in the independent healthcare sector. We want to explore whether assessing corporate systems for quality governance would add value and encourage improvement. We are aware that corporate systems for quality governance have a key influence on quality governance at individual locations, and that involvement of the corporate level can be a significant lever for ensuring improvement where there are problems locally.

However, feedback from independent healthcare providers on how we could engage with the corporate level has been very mixed. Some feel that rating at this level adds little value and is of no interest to the public. Others feel that a rating only on well-led could be useful (focused on quality governance). Others feel that a corporate rating overall and for each key question is necessary for equal treatment with the NHS. Most providers recognise that some form of corporate engagement is needed to avoid duplicating assessment at each location. But there is no consensus on what form this engagement should take, how or when it should happen, whether CQC’s past policy is appropriate of only engaging at corporate level if a provider has more than 20 locations, and whether this engagement should lead to a corporate rating.

This is an issue for CQC to consider across all independent sector providers, not just in the acute sector. We are interested in seeking your views about how we might take account of provider level quality governance, leadership and overall performance in the independent sector, and whether that should be in the form of an overall provider rating. The feedback from this consultation will contribute to our future approach to this sector, and for other independent providers in other sectors, where we are also considering the same thing.
Consultation question

7. Do you have any suggestions for how we should or should not develop our approach to corporate provider assessment in the independent acute sector?
6. Regulatory impact assessment and equality and human rights

As part of this consultation, we have also published a regulatory impact assessment. We would like to receive your comments on this.

We will publish an equality and human rights duties impact analysis in due course.

7. Conclusion

We have been working hard to develop the new regulatory approaches for the independent healthcare sector and take forward the ideas we set out in our earlier signposting document.

We know there is much more to do and we are grateful for the help and support that providers and numerous people have given us in co-producing each new approach.

Whether you’ve helped us get this far or not, we are interested in hearing everyone’s views. Please do take the time to respond.
How to respond to this consultation

You can respond to our consultation in the following ways. Please send us your views and comments by Friday 23 January 2015.

**Online**
Use our online form

You can also find the form and more information at: [www.cqc.org.uk/consultation-dental-independenthealthcare-ambulance](http://www.cqc.org.uk/consultation-dental-independenthealthcare-ambulance)

**By email**
Email your response to: CQCchanges.tellus@cqc.org.uk

**By post**
Write to us at:

CQC consultation: How we inspect, regulate and rate
CQC National Customer Service Centre
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

**On Twitter**
Use #tellcqc for your feedback and mention @carequalitycomm

**Consultation questions**

1. Do you agree that our approach to separating independent healthcare providers into three groups as described above is meaningful and appropriate?

   If you are an independent healthcare provider, can you readily recognise which of the three groups you fit into?

   If not, do you have any suggestions for how the three groups could be otherwise structured or better defined?
2. Do you agree with the approach we are proposing for regulating independent acute hospitals?
   Do you have any suggestions for other things we could take into account?

3. Do you agree with the approach we are proposing for regulating single specialty services?
   Do you have any suggestions for other things we could take into account?

4. Do you agree with the approach we are proposing for regulating non-hospital acute services?
   Do you have any suggestions for other things we could take into account?
   Do you agree that we should continue to engage with non-hospital acute providers before deciding on ratings?
   What sort of guidance would be useful for this sector in the meantime?

5. Do you feel confident that the changes we propose to the acute provider handbook will help our inspectors to assure the public on how safe, effective, caring, responsive and well-led independent acute hospital and single specialty providers are?
   If not, what is missing?

6. Do you have any suggestions for how we could develop our approach to special measures in the independent acute sector?

7. Do you have any suggestions for how we should or should not develop our approach to corporate provider assessment in the independent acute sector?

8. As part of this consultation we have published a Regulatory impact assessment. We would also like your comments on this.
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