

Consultation 2

Our next phase of regulation

A more targeted, responsive and collaborative approach to regulating in a changing landscape of health and social care

Cross-sector Primary medical services Adult social care services







June 2017

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Foreword

As a result of CQC's inspections, England has, for the first time, a comprehensive baseline of information about quality in every NHS trust, primary care and adult social care provider. We know that many services are good and outstanding and we have evidence that, with the right leadership and support, services can improve.

Now that we have established this quality baseline we want to focus more on understanding how services improve and using our insight and regulatory approach to strengthen how we encourage improvement. We know that some services struggle to improve and this can be a particular problem for some of the adult social care services that we have repeatedly rated as requires improvement. We want to develop a consistent approach across all sectors and make sure that our approach to registration enables us to always hold the right people to account.

Our strategy for 2016 to 2021, published in May 2016, set out an ambitious vision for a more targeted, responsive and collaborative approach to regulation, so that more people get high-quality care. Using the principles set out in our strategy and the learning from our inspections, we want to continue the discussion about how we should develop our approach further and move into the next phase of our regulatory model.

We want your views on how we should respond to our changing society and the care environment in a way that supports improvement and sustainability, and that continues to make sure people have access to safe, effective, compassionate, high-quality care.

We started these detailed discussions about our regulatory model in December 2016, when we published *Our next phase of regulation*. This proposed principles for how we will regulate new models of care and complex providers, and changes to our assessment frameworks for health and social care and how we register services for people with a learning disability. It also detailed changes to our approach to regulating NHS trusts.

This second consultation also has proposals that apply to all regulated sectors, including how we register, monitor, inspect and rate new models of care and large or complex providers; how we use our unique knowledge and capability to encourage improvements in the quality of care in local areas; and how we carry out our role in relation to the fit and proper persons requirement.

Our other proposals focus on changes to how we regulate primary medical care services and adult social care services.

Throughout the development of our regulatory approach, we want to keep the elements that we know people value and to improve what people tell us we can do better. We will continue to work with people who use services, providers, professionals and our other local and national partners to co-produce what we do.

Thank you for giving us your views on how we can continue to develop a more targeted, responsive and collaborative approach to regulating in a changing landscape of health and social care.

Sir David Behan CBE Chief Executive

Introduction

CQC's purpose is to make sure health and social care services provide people with safe, effective, compassionate high-quality care and to encourage care services to improve. Our strategy, *Shaping the future*, set out a vision for a more targeted, responsive and collaborative approach to regulation, and outlined four strategic priorities, which are to:

- 1. Encourage improvement, innovation and sustainability in care.
- 2. Deliver an intelligence-driven approach to regulation.
- 3. Promote a single shared view of quality.
- 4. Improve our efficiency and effectiveness.

In December 2016, we published a consultation *Our next phase of regulation*. It proposed principles for how we will regulate new models of care and complex providers, changes to consolidate our assessment frameworks for health and social care, our approach to regulating NHS trusts, and how we register services for people with a learning disability. Our response is published alongside this new consultation. We also published a joint consultation with NHS Improvement about our approach to assessing leadership and use of resources in NHS trusts.

In this second consultation, we continue to describe how we are developing our regulatory approach in line with the direction set out in our five-year strategy. We provide further information about how we are adapting to a changing landscape of care and how we propose to regulate providers that deliver care across sectors. We seek your views on specific proposals for how we will:

- register, monitor, inspect and rate new models of care and large or complex providers
- use our unique knowledge and capability to encourage improvements in the quality of care in local areas
- regulate primary medical care services and adult social care services
- carry out our role in relation to the fit and proper persons requirement.

These proposals have been informed by what we have learned during the past four years and the feedback we have received from the public, people using services, providers and other stakeholders, including feedback from our December consultation. The proposals build on our knowledge of specific sectors and our specialist expertise, and enable a more flexible and joined-up approach.

The *Next steps on the NHS Five Year Forward View* sends a clear signal about the increasing importance of system-based transformation of care built around local populations. In July 2016, we outlined our own intention to support innovation in health and social care, and we have spent much of the past year listening to, and learning alongside, those providers who have been developing new models of care within and across the NHS, and in primary care and

adult social care. We have worked with our partners to consider how we need to respond to changes in the way care is provided and to support improvement in a time of financial constraint. We will continue to develop our relationships with providers and other stakeholders so that our knowledge about service provision and the quality of care across the country is up to date. We will also continue to share good practice and to use our independent voice to encourage improvement.

In our December consultation, we asked for feedback on our principles for regulating in a complex, changing landscape. A summary of this feedback and our response is published alongside this consultation, and we have updated the principles in light of this. We will now use these principles to support a more targeted, responsive and collaborative approach to regulation, with greater emphasis on integration and leadership. They are:

- **1.** We will always take *action* to protect and promote the health and wellbeing of people using services.
- **2.** We will hold to *account* those responsible for the quality and safety of care.
- **3.** We will be *transparent* about our approach, our regulatory decisions and how our actions support improvement.
- **4.** We will work closely with our *partners* so that we take a coordinated approach to quality assessment, assurance and improvement.
- **5.** We will be *proportionate* by using information about an organisation's structure and track record to determine when and how to inspect.
- **6.** We will *simplify* our inspection process, where possible, to minimise complexity for providers that deliver more than one type of service.
- **7.** We will deliver a *comparable* assessment for each type of service, regardless of whether it is inspected on its own or as part of a complex provider.
- **8.** We will rate and report in a way that is *timely* and *meaningful* to the public, people using services, carers, providers and commissioners.
- **9.** We will be *fair* to providers by not penalising them when they have taken on a service in order to improve it.
- **10.** We will bring together inspectors who have *specialist* knowledge of different sectors to inspect jointly, where this is most appropriate for the provider.

These principles underpin the proposals that we describe throughout this consultation.

We are grateful for your feedback on this consultation, which closes on **Tuesday 8 August 2017**. See page 58 to find out how to respond.

PART 1: REGULATING IN A COMPLEX CHANGING LANDSCAPE

1.1 Clarifying how we define providers and improving the structure of registration

Introduction

In this section we set out our proposals for how we will develop our approach to registration and how we will change the CQC register in the future.

CQC has a statutory duty to maintain a register of who is legally able to deliver regulated activities. This register shows the public what services are available, who they are for and where to find them. The register also provides information that supports our regulatory functions to monitor, inspect and report on what we know about the quality of these services, and to take enforcement action where necessary.

In our five year strategy we proposed moving towards registering all organisations that are accountable for the quality of services to make sure that we can monitor quality across an organisation and hold the right people to account. By 'accountability', we mean:

Accountability (either directly or through other legal entities or contractual arrangements) for the carrying on of regulated activities, where that direction or control has the effect of rendering the organisation accountable for the quality and safety of those activities, even where responsibility for delivering care sits with others.

We also propose changes to the way we structure the information we hold on our register of services to give the public a more accurate reflection of how care is delivered now, and to make sure that we can identify and adapt to future changes.

Summary of proposals

We propose to:

- develop our register so that it properly informs the public about ownership of providers, what services are provided, to whom and where to find these services
- clarify who is required to register with us so that we can hold to account all of those who are accountable for quality and make sure they improve quality across their services
- improve our understanding of large and complex organisations so that we can take a more targeted and responsive approach to regulation

• re-structure our approach to registration so that we hold more information about different types of services and so that we can make it easier to register new organisational forms and innovative types of services.

The changes we propose for registration

The scope of registration

Limitations of our current approach

Section 10 of the Health and Social Care Act (2008) requires that any person 'carrying on' a regulated activity must be registered with CQC. Until now we have interpreted this as meaning the legal entity that has ongoing direction and control of the regulated activity and which delivers the service day-to-day.

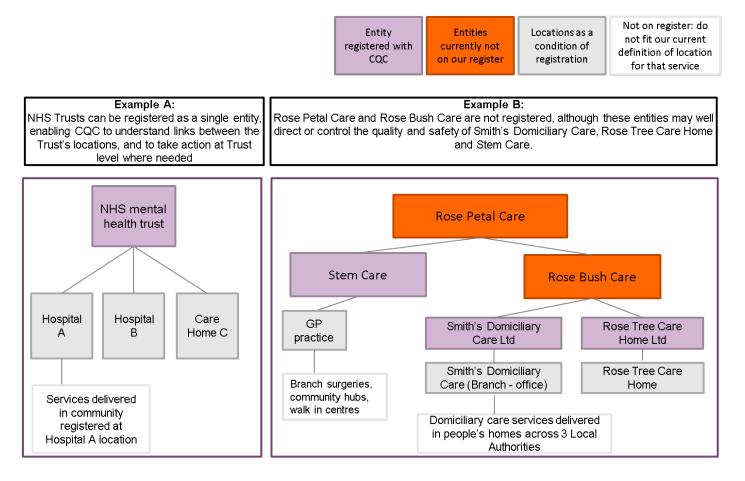
Where care providers are subsidiaries within wider groups, this means rather than registering the group as a whole, we have in most cases registered:

- the entity that is directly above the location (where regulated activities are provided or managed) in an organisational structure, and
- each provider individually.

At the beginning of June 2017, there were 30,868 providers registered with CQC delivering services across 49,394 locations. We estimate that 2,300 of these providers are part of around 350 wider groups, for example 'corporate providers' (including approximately 50 that are subject to Market Oversight Regulations). These wider groups run services from approximately 11,300 locations and own around a third of all care homes in England. We do not currently register at the corporate or group level for the majority of these services.

Here are two hypothetical examples of how this currently works in practice (figure 1).

Figure 1: Hypothetical examples of how CQC currently registers providers



We know that good leadership and accountability are crucial in ensuring that people receive safe, high-quality care in a way that is sustainable. This is not just about leadership at the local level but about recognising that leaders at the top of organisations also play a vital role in ensuring the quality of care. Our current approach to registration means that we have not been able to fully take account of this influence on quality, or to reflect the ways that many providers structure themselves and run their businesses.

Our new approach

Any providers that are currently registered with us will remain registered. We will also register any related organisations, such as parent companies, that also have accountability for quality. This means that these organisations will also appear on the CQC register, and the public will be given information about who is accountable for the care being provided.

By making changes to who is required to register, we will be able to monitor and inspect at provider level and, if necessary, require organisations to take action to improve quality using our enforcement powers (see the following table). These changes will mean that we can take action against those that are accountable for the failings. This may be the providers already registered with us, or it might be other related organisations, such as those owning and directing the provider. In the example in figure 1, this means that if there are failings in Stem

Care or Rose Bush Care we could take action against each provider. However, we could also take action against Rose Petal Care if this company was accountable for the poor quality of care across the two providers.

We want people to be able to see the history of a service where they come under new ownership, new contracting arrangements or if there is an administrative change such as change of address. In making decisions about registering providers we intend to take more account of this history.

When a person checks the register using our website to look at an individual care service, they will see a list of all the providers that are involved in delivering and are accountable for regulated care.

	Current approach to registration	New approach to registration
Register	 The CQC register shows the organisation directly delivering care day to day, but not other organisations that have some accountability for that care We may know when separate providers are linked by common ownership and/or management, but legislation does not require registered providers to tell us about these links The registered provider is as close as possible to delivering day-to-day services Where services change owners, or where existing owners change the legal entity of the provider, the regulatory history and previous rating and enforcement actions do not continue, and are not displayed on our website. 	 The CQC register will show all organisations based in England that are accountable for care being provided We will have oversight of how providers fit into wider organisations and who is influencing or directing the quality of that care We will continue to register the entity that is as close as possible to delivering day-to-day services, but we will also register organisations that are accountable for delivering these services above this level Where services change owners, or where existing owners change the legal entity of the provider, the regulatory history stays with a service. This includes the ratings and any enforcement action. The information will be displayed on our website and will remain part of the CQC register
Monitor	• We can see a provider's strengths and weaknesses but cannot always identify systemic issues across	• We will know about the quality of care across the full range of a group's services sharing common ownership or

	providers, which may be linked by ownership or management	management. This will allow us to make much more informed decisions about how to respond to poor care and where to appropriately target our engagement or regulatory action to improve services
Inspect and rate	 We can target inspection activity but have limited scope to make the links where we have concerns across different services. This can delay inspections and duplicate effort both for our inspection teams and for providers We have limited ability to carry out focused inspections at the overall leadership level for all health and social care providers, or to rate them; we can currently only do this in NHS trusts We cannot use our findings to encourage improvement by recommending or requiring a provider to take action across all of its services We are not able to inspect at relevant headquarters for organisations owning multiple providers 	 We will retain the ability to inspect and rate at local service level We will have a much more joined-up approach to providers that share common links. This will enable us to target inspections more effectively, with the option of assessing and rating the overall leadership of the organisation We will be able to use inspection findings as a basis for more effective interaction with leadership, drawing together all we know and setting out what action we want the provider to take We will be able to undertake inspection at relevant headquarters for organisations owning multiple providers where this is appropriate
Enforce	 We cannot always hold to account those ultimately responsible for care, as we can only carry out enforcement against legal entities that are registered with us We risk having to hold lower levels of provider organisations to account even though true accountability does not sit at that level (for example, the fit and proper persons requirement for directors) 	 We will still be able to focus enforcement action at any level of a group or organisation, but will also be able to hold overall leadership to account We will have an enhanced ability to identify those ultimately accountable for delivering care

Independent voice	 We can't be fully confident that the information we publish in the register and in inspection reports and national publications reflects all the facts about the provider's structure and the health and care market People choosing and using care services will not know that their local service is owned or operated by a company other than that shown on our website 	 We will have a definitive register and greater confidence in the findings that we report We will be transparent about the links between local services and organisations that are responsible for the quality of care. We will be able to report on the quality of care across these groups and organisations to enable people to make more informed judgements and choices
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Defining who is accountable for the quality of care

Our proposal brings all those accountable for care onto our register. We know that different organisations are structured and run in a variety of ways and we will need to consider each provider individually. However, we believe we can define some criteria that will help us determine when an entity has responsibility for quality and so should be registered with us. These criteria would include whether the entity:

- Manages and delivers assurance and auditing systems or processes that assess, monitor and drive improvement in the quality and safety of the delivery of regulated activity and to which entities delivering that activity are accountable.
- Has the right to require providers of regulated activity to submit consolidated annual budgets in advance for approval.
- Has the right of veto such that entities providing regulated activity will only be entitled to carry on their business in accordance with financial plans that have been signed off.
- Directly develops and enforces common policies on matters such as staffing levels, clinical policy, governance, health and safety, pay levels and procuring supplies that must be adhered to by entities providing regulated activity.
- Has the right to make employment decisions concerning:
 - People who work or are seeking to work in support of the delivery of regulated activity
 - People who run or who seek to run individual care settings that deliver regulated activity
 - Board membership where the board is responsible for holding to account services or entities delivering regulated activity.

In all cases, we will only be interested in those parts of an organisation that exert significant influence over the quality and safety of services. Organisations such as hedge funds and other

types of investors that do not exert this influence will not be required to register with us and will not appear on the register on our website.

CQC was established to regulate health and social care in England, and cannot carry out enforcement action against companies that are not based in England. Therefore, we will not seek to register those that are not based in England. However, we will require providers to inform us of owners that are not based in England and will use this information to link together what we know about providers with common ownership and publish this on our website.

Figure 2 shows how this would look in practice. In this hypothetical example, we would bring four additional entities into registration as they meet the test for having sufficient direction and control over the delivery of regulated activities. In other words, they meet the definition of a 'service provider'. This would mean that when somebody used our website to look up Provider A on the register, they would also see that Target Care and the Archer Group have an influence on the quality of care provided by Provider A. If we needed to take enforcement action, we could take this against whichever organisation was accountable for the regulatory breaches.

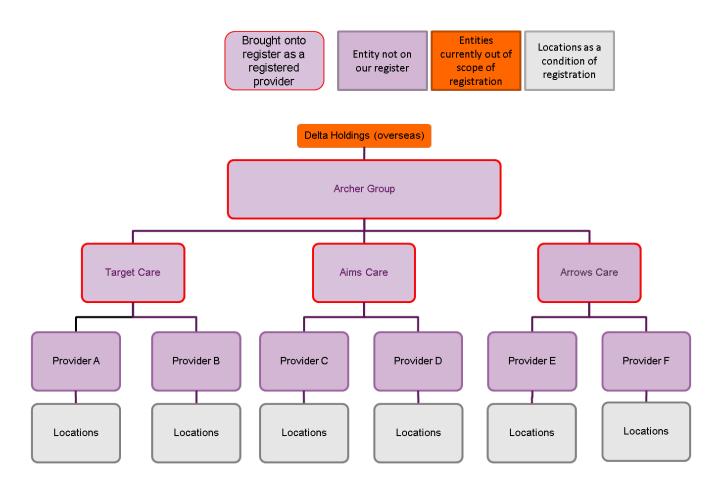


Figure 2: Hypothetical example of the effects of our registration proposals

Consultation questions

- 1a What are your views on our proposal that the register should include all those with accountability for care as well as those that directly deliver services?
- 1b What are your views on our proposed criteria for identifying organisations that have accountability for care (see page 12)?

Changing the structure of the register

Limitations of our current approach

The CQC register currently displays the provider, the regulated activities and the locations from which the provider can carry on those regulated activities. The way our register is currently organised restricts providers to deliver specific regulated activities only at, or from, specific buildings defined by our 'location rules'. This means providers need to apply to us before they can change the address of buildings they manage or deliver care from (as well as to change or add regulated activities). This works where a service is delivered in a single building (such as a care home), but is less effective when services are delivered across multiple sites, in communities, in people's homes, or digitally, such as through online GP services.

We propose to change how the register is structured so that it provides a more useful record of not only who is providing care, but also how, to whom, where and when.

A new structure

We propose to use the information that providers record in their statement of purpose so that the register will include **what** type of services are provided, **who** the service is for, **what** type of setting it is provided in, **where** the service can be found and, where relevant, **how much** care is provided. Figure 3 illustrates this with some examples.

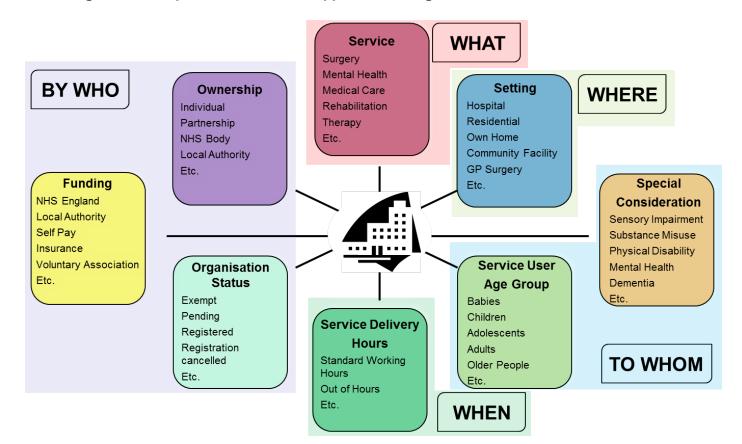


Figure 3: Example information to support a new register structure

By collecting this more detailed information we will be able to describe services in a way that is meaningful to the people who use them and to providers themselves. It will also enable us to be more responsive to innovation, as this approach will allow us to register new types of services in line with changes in health and social care.

Current structure of the register	New structure of the register
• The CQC register shows a provider, their regulated activities and the locations from which they are registered to carry these on	 The CQC register will give more detailed information about what services are provided, including the type of service, who it is for and the type of setting
• We register providers and registered managers for the regulated activities they deliver	 We will continue to register providers and managers against the same set of regulated activities
• Records the locations at which a provider carries on regulated activities, based on specific buildings and our location rules	• We will retain buildings as a core feature where appropriate (for example, care homes or hospitals) and continue to record where services are located. However, we

- Places limits on how much care a provider can deliver on the basis of the number of buildings it operates from
- Does not reflect the size of services, where the public can access them, and where they are provided (online, in communities or people's homes). This is because the provider may register one office (a location), but deliver care in a different area or across the country. This is particularly relevant when care is delivered in the community or in people's homes
- Does not make enough use of information in a provider's statement of purpose because of the limitations of our current systems and processes
- Applies the location rules differently for each type of service. This makes it more confusing when services are being combined in new ways, such as in new models of care

will have a wider set of criteria to describe a service. Location will be only one attribute of that description

- We will have a wider set of criteria that we can use to set the limits within which a provider can operate (for example, the geographical area a domiciliary care agency can cover)
- We will have a more accurate picture of what the service delivers, where, to whom and when

- We will make more use of the valuable information in statements of purpose by developing our systems and processes
- We will understand a provider in terms of the description of its services, and reflect this in the register

Consultation question

2 We have suggested that our register show more detailed descriptions of services and the information we collect. What specific information about providers should be displayed on our register?

Implications for our fees policy

From 2017/18, we will receive around 90% of our funding from providers. We define our fees as a charge for entering and remaining within a regulated market, and we then adapt this to account for provider type and size. We do not intend to change this approach, but changes to

the level at which we register providers and the structure of the register will have implications for our fees scheme and income. This will provide better information and enable us to be clearer with providers about how we calculate their fees using information in the register. The overall cost of regulation will not increase as a result of this work. We will ensure that the fees scheme aligns to this work so that our fees remain proportionate.

We are required to consult on any changes to our fees scheme, and any proposals to charge a fee for registration applications. We will ensure that the registration timetable aligns with our fees timetable, taking into account our duty to consult providers and seek the approval of the Secretary of State.

Timetable for implementation

We recognise the importance of a phased, well-managed transition for providers. We also need to allow sufficient time to develop and test new information systems, policies and procedures.

We will engage with providers whose registration will expand to include other companies within their wider group in order to identify the appropriate level to register.

Any changes to the way we record services on the register will affect all providers. We plan to test the core dataset for registration using provider information collections before applying it to providers' registrations.

April 2017 to March 2018:

• Develop, plan and assess the impact of our proposed changes.

April 2018 to March 2019:

• Start live testing, continue to engage with stakeholders and begin phased implementation.

April 2019 to March 2021:

• Continue phased implementation and engagement with stakeholders.

1.2 Monitoring and inspecting new and complex providers

Introduction

Since we introduced our new approach to regulation three years ago, we have seen an increasing number of providers operating across multiple sectors, and we expect to see many more new and complex models of care emerging over the coming years, including accountable care organisations and systems.

In this section, we describe our approach to monitoring and inspecting 'complex providers', by which we mean:

Organisations that deliver services across more than one sector. For example, NHS trusts that provide GP services or care homes, independent community health providers that deliver NHS 111 services, or 'new models' and 'accountable care organisations (ACOs)', such as fully integrated multi-specialty community providers (MCPs) and integrated primary and acute care systems (PACS).

We also describe how we will combine our regulatory approaches for NHS trusts, primary medical services and adult social care and how we will build on our experience of regulating existing complex providers to monitor and inspect services in a more streamlined and coordinated way.

Summary of proposals

We propose to:

- identify a single CQC relationship-holder for each complex provider, who will work alongside named leads for each type of service to coordinate our regulatory activity for that provider
- align the way we collect information from providers and combine our monitoring information to inform a single regulatory plan
- coordinate our inspection activity within a defined period, except for any focused inspections in response to concerns about quality in individual services
- assess leadership and governance across all services when we assess the well-led key question in NHS trusts, and in any future provider-level assessments in other sectors (see section 1.3)
- test this approach, including with a small number of accountable care organisations and systems.

The changes we propose to monitoring and inspecting complex providers

Monitor

In our proposals for NHS trusts, GP and adult social care services, we describe how we will place more emphasis on monitoring to enable a more intelligence-driven approach to regulation. We commit to working closely with providers and other stakeholders and making better use of information throughout the year.

For complex providers, we will coordinate our monitoring activities and combine information about their services. We will identify a single CQC relationship-holder who will be the main point of contact between CQC and the provider. They will have responsibility for coordinating and planning all aspects of the provider's regulation, and will work alongside the named CQC lead for each type of service. In most cases the relationship holder will be from the CQC directorate that inspects the majority of the provider's services. For example, if an NHS trust is operating a number of care homes, the relationship holder will be from our Hospitals directorate, and they will work with our inspectors from the Adult Social Care directorate.

We want to make sure that we continue to collect the information we need about individual services but that we do not place additional burden on providers by sending multiple requests for information. We will build on our experience of regulating existing complex providers and will develop an approach to collecting information that also helps us understand any changes they are making or propose to make in the future. We will review how we engage with local partners, the public and other stakeholders, to make sure that we can capture their views on all services and, where relevant, the organisation as a whole. This will include speaking to people using services about how well care is coordinated to meet their needs.

We will strengthen our internal cross-sector risk and planning arrangements to improve how we coordinate our regulatory activity for these types of providers. Each year we will hold an internal regulatory planning meeting where we will review the information we hold about a provider and its services, and agree an appropriate inspection schedule. This will inform which services we need to inspect, when and how.

As well as this annual regulatory review, we will continue to respond to alerts and concerns about individual services in line with the approach set out for NHS trusts, primary medical care and adult social care services. When inspectors identify the need to carry out a focused inspection in addition to the planned inspection schedule, they will liaise with the relationship holder.

Current approach to monitoring	New approach to monitoring
• A separate approach to Intelligent Monitoring for each sector	 Coordinated approach brings together monitoring information for all services
• Different approaches to provider information collection in each sector	Provider information collections are aligned across sectors
• Stakeholder engagement before inspection for each type of service	 Single relationship holder for each provider with named CQC leads for each type of
 Named inspectors for each service but no overall relationship holder 	 service Annual internal regulatory planning meeting involving all CQC sector leads

Inspect and report

The relationship holder will work with the named leads for each of the services to develop a single regulatory plan, with inspections scheduled, wherever possible, within a defined period. This will help to avoid multiple inspections and help to simplify our inspection process. The plan will take into account the range of services provided, the inspection frequencies set out for each sector, and the risks identified through monitoring. Inspections will be conducted by one or more sub-teams, as needed, with expertise that reflects the scope and configuration of services. We will use the relevant key lines of enquiry from the assessment frameworks for health care and social care services.

When assessing the well-led key question at NHS trust level, we will look at how well the trust is working with its partners and how well it is integrating services across the sectors, where this is relevant. CQC staff from all inspection directorates will be involved in the quality assurance process. In section 1.3 we discuss how we might assess quality at provider level for other types of organisation, subject to the changes to registration described in section 1.1.

We will improve our website to make it easier for people to see the links between services and the overall provider.

Current approach to inspection	New approach to inspection
• Separate inspections for different services and sectors	Coordinated schedule of inspectionsAssessment of well-led key question at a
Single provider-level assessment for combined trusts only	provider level reflects leadership across all the services that the provider delivers
	 Inspections will be carried out by teams of hospital, primary care and adult social care

Integrated health and care systems

We are also seeing an increasing number of organisations developing partnerships to deliver care as part of more integrated health and care systems. These include accountable care systems (ACS) that receive more control and freedom over a local health economy in order to provide joined-up, better coordinated care that keeps people in their local population healthier for longer.

In most of these cases, given that there is no change to the legal responsibilities of each organisation working as part of the ACS, we expect to continue to register and regulate each organisation as a separate legal entity. This means that we can hold the right people to account for the quality of care they provide. However, we recognise that there could be benefits in taking a coordinated approach to monitoring and inspecting these services, in a similar way to that described above. This would help us understand the structure and aims of the model, and enable us to provide an independent assessment of how well the individual providers and services are working together to meet people's needs.

This could include a single relationship holder for a group of providers, a coordinated planning review and inspection schedule, and potentially an assessment of leadership, governance and integration across the whole model or system. We propose to test this in a small number of areas during 2017/18. Our approach will be shaped through discussion with local providers and stakeholders, as well as with our system partners, such as NHS England, NHS Improvement and the Local Government Association.

Timetable for implementation

April 2017 to March 2018:

- test a coordinated approach to monitoring, inspecting, rating and reporting on health and social care services in a sample of areas, with a focus on evolving accountable care organisations and systems.
- identify relationship holders and introduce joint regulatory planning meetings and joint inspections for existing complex providers
- begin using provider information collections to identify complex providers and links between services.

April 2018 to March 2019:

- continue using provider information collections to identify complex providers and links between services
- test approach with independent health and social care led organisations, alongside live testing of provider-level registration

- test approach to provider-level assessment and, if appropriate, ratings for complex providers, in line with proposals set out in the next section
- agree approach to regulating accountable care organisations and groups of organisations in accountable care systems.

Consultation questions

3a Do you agree with our proposals to monitor and inspect complex providers that deliver services across traditional hospital, primary care and adult social care sectors?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

3b Please explain the reasons for your response.

1.3 Provider-level assessment and rating

Introduction

In this section we set out proposals to assess the quality of care at provider level and consider options for how this might work across health and social care sectors, including where providers deliver more than one type of service. By provider level, we mean:

The highest level at which we register any organisation that delivers more than one service. This would include the board level of an NHS trust or independent sector provider, or the management level of a GP federation or care home group.

We explain how we will develop and test our approach with different types of organisation alongside the proposed changes to the scope of registration discussed in section 1.1.

Summary of proposed changes

We propose to introduce a provider-level assessment and/or rating for providers across all the sectors we regulate, subject to the proposed changes to registration.

We will:

- continue to rate NHS trusts at provider level in 2017/18 based on our assessment of the well-led key question and use our aggregation principles and professional judgement to rate the other four key questions
- develop a new provider-level assessment for NHS trusts, corporate providers of health and social care services, large-scale general practices and other complex providers
- work with providers and other stakeholders from across the sectors that we regulate to develop and test the assessment
- introduce our assessment in phases to reflect the organisational context of providers, including where registration changes are needed.

What we propose for assessing and rating at provider level

Provider-level assessment in all sectors

During our first phase of comprehensive inspections, the only type of provider that we registered and rated for the quality of care at provider level was NHS trusts. This year, we will continue to rate NHS trusts at provider level for all five key questions. The rating for well-led

at trust level will be determined through our assessment of the well-led key question. Provider-level ratings for the other four key questions will be determined using our ratings aggregation principles and the professional judgement of our inspection teams, as outlined in our guidance for NHS trusts, published alongside this consultation.

Where trusts deliver services across sectors, for example GP services or care homes, these services will be inspected and rated in line with the approach described in Part 2 of this consultation document, and will be coordinated in line with our approach to complex providers described in section 1.2. The quality of these services will be considered in the trust-level assessment of well-led, and our inspection teams will work together to agree how their ratings should be reflected in the trust-level rating.

To ensure that we make consistent decisions, we follow a set of 16 ratings principles when rating core services, locations and providers. We may use professional judgement and deviate from the principles when aggregating ratings to ensure they are proportionate to all available evidence and the specific facts and circumstances. This includes when a provider has taken on new services or where a service or location significantly differs from the other services – for example in the type and mix of service (including other than hospital care), or the size of a service, its type of setting, or the population groups it serves. We will consider any concerns we have identified, such as the potential impact on people who use services and the risks to quality and safety. We will then consider how confident we are in the service's ability to address these concerns.

We can already comment on the overall quality of care in large provider groups in other sectors, using the findings of our service-level inspections. However, we propose to develop a provider-level assessment for all sectors, including NHS trusts, corporate providers of health and social care services, large-scale general practices and other complex organisational forms. This will enable us to hold them to account more effectively at this level, including when we have rated several of their services as requires improvement or inadequate.

We will introduce provider-level assessments as we start to change the way we register providers, in line with our approach to registration described in section 1.1. We will test this with providers that are already registered at this level, for example some corporate providers of independent healthcare. This assessment will be in addition to our inspection and rating at service level, which will continue as set out in our proposals for regulating hospitals, primary medical services and adult social care.

Rating at provider level

Since the introduction of our ratings approach, we have seen that ratings can have different purposes for different audiences at provider and service level (summarised in figure 4).

In taking forward our proposals, we need to make sure that we continue to give people the information they need and that we can continue to encourage improvement. We will need to consider whether we should rate providers of health and social care at the highest level, as we

already do for NHS trusts, and whether this would be effective in encouraging improvement and providing accountability to the public, people who use services, and commissioners of care. We may introduce provider-level rating across some or all sectors.

As new models of care evolve, we will also need to consider how we can develop a more consistent approach across different types of organisation, including NHS trusts and providers in the independent sector.

Purpose of ratings	Audience
Help people to choose services	Commissioners, people who use services , the public (but limited at provider level)
An incentive to improve performance in delivering safe, high-quality care	Health and care providers and their staff
Increase accountability and transparency about quality of care	Commissioners, public, people who use services
Enable comparisons of performance over time and between organisations	Commissioners, public, providers, national bodies including CQC, NHS Improvement, NHS England

Figure 4: Purposes of CQC ratings for different audiences

Developing our approach

We plan to involve providers and stakeholders from across all sectors in developing our approach to an assessment at provider level. We will consider the scope of the assessment and the benefits of rating, and will test and evaluate the effectiveness and affordability of our proposals with different types of organisation.

We have been exploring a number of possible options for our provider-level approach, including:

- 1. Developing a new provider-level assessment framework, where the scope of the assessment would reflect those elements of the existing five key questions which are most relevant at the provider level.
 - Bespoke assessment framework
 - KLOEs reflecting what good looks like at provider level; these would combine parts of the five key questions with other factors which influence care at this level
 - A provider inspection team would undertake the provider-level assessment

- It would result in a narrative report, and potentially a single rating for quality and safety could be awarded for some or all provider types.
- **2. Assessing well-led only at the provider level**, using a single well-led assessment framework, based on the existing frameworks. The other four key questions would not be assessed or rated at provider level.
 - A single well-led assessment framework, based on the existing healthcare framework
 - A provider inspection team would undertake an assessment of well-led using the existing framework
 - Outcome would be a narrative report, and potentially a rating for well-led could be awarded for some or all provider types
 - No ratings for the other four key questions at this level.
- **3. Assessing up to five key questions at provider level,** using a single well-led assessment framework, based on the existing healthcare framework, plus assessment frameworks for some or all of the other key questions applied at provider level.
 - A well-led assessment framework, based on the existing healthcare framework.
 - Bespoke assessment frameworks for four key questions to ensure they can be applied at provider level.
 - A provider inspection team would undertake an assessment of all five key questions at provider level
 - Outcome would be a narrative report, and potentially a rating for all five key questions could be awarded for some or all provider types
 - Where five ratings are awarded, these could be aggregated into a single provider level rating for some or all provider types.
- **4.** Adopting the current approach in NHS trusts for other types of provider, with an assessment and rating for the well-led key question at provider level, and rating of the other four questions based on aggregation and professional judgement.
 - A well-led assessment framework, based on the existing healthcare framework
 - A provider inspection team would undertake an assessment of well-led using the existing framework
 - Outcome would be a narrative report. A rating for well-led would be based on the assessment, and the provider rating for the other four key questions would be based on aggregation and professional judgement for some or all provider types
 - Where five ratings are awarded, these could be aggregated into a single provider level rating for some or all provider types.

Option	Assessment framework	New or existing framework?	Ratings	Assessment or aggregation?
1	Provider level assessment	New	One provider rating	Assessment
2	Provider well-led	Existing	One well-led rating	Assessment
3	Provider five key questions	New	Five key questions and overall ratings	Assessment, with aggregation for overall rating
4	Provider well-led	Existing	Five key questions and overall ratings	Assessment for well- led/aggregation and professional judgement

Figure 5: Options for our provider-level approach

With NHS Improvement, we plan to introduce an assessment of an NHS trust's use of resources. This is for acute trusts initially and then for all NHS trusts. We will develop and test options for combining use of resources and quality ratings, and will consult on options later this year.

We will develop our provider-level assessment approach in parallel with our approach to assessing use of resources, and the development and testing will continue as we make changes to the scope of registration.

Current approach to provider-level assessment	New approach to provider-level assessment
NHS trusts only	 A wider range of providers including corporate providers, NHS trusts, large-scale GP services, new care models
 Includes an assessment of well-led and rating at provider level Ratings for other four questions aggregated using professional judgement 	 Assessment likely to include well-led Could go beyond well-led to reflect other aspects of quality and safety. May include an assessment or aggregated rating for other questions Will include a use of resources rating for NHS trusts
• Core services and hospital ratings based on aggregation	 Core services and hospital level ratings continue to be determined through aggregation

Timetable for implementation

April 2017 to March 2018:

- Consultation on more detailed proposal, informed by the current consultation, (Winter 2017/18)
- Development of operational approach (Spring 2018).

April 2018 to March 2019:

- Pilot assessments alongside live testing of registration approach
- Publish final assessment approach
- Begin provider-level assessment in line with registration timetable.

Consultation questions

- 4a Do you agree that a provider-level assessment in all sectors will encourage improvement and accountability in the quality and safety of care? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 4b What factors should we consider when developing and testing an assessment at this level?

1.4 Encouraging improvements in the quality of care in a place

Introduction

As the regulator for the quality of health and adult social care in England, we are responsible for the regulation of providers. This helps ensure that people receive safe, effective, compassionate and high-quality care. But we know that people's experiences are also affected by how well services work together and that quality can be influenced by factors that are outside a provider's direct control.

We need to make sure that we are able to understand and assess quality in a way that remains meaningful to the public, that we can always tell who is accountable for quality locally, and that we offer a proportionate approach that supports providers and commissioners to deliver the aims of the Five Year Forward View.

In this section we describe how we will use our unique knowledge and influence across the health and social care sector to work with our national and local partners, to encourage improvement, innovation and sustainability beyond the boundaries of individual providers, in line with the direction set out in our five-year strategy.

When we refer to quality of care in a place, we mean:

The quality of health and social care services within a geographical area and their collective impact on people's experiences and outcomes. For example, the quality of care provided within local clinical commissioning group or local authority commissioning areas, within sustainability and transformation plan areas, or nationally in England.

Summary of proposals

We propose to:

- use our monitoring and inspections of individual providers to assess how well services are working together and to understand the impact on people's experiences
- use our insight about quality in a place to help us understand the context in which providers are working
- use our independent voice and relationships with national, regional and local partners to share our view of quality across health and social care and to highlight cross-system issues
- undertake a small number of targeted reviews that look at how health and social care work together and identify improvements that benefit people that use services

 work with local providers and commissioners, and national oversight bodies – such as NHS England and NHS Improvement – to coordinate what we do to make best use of our respective powers in order to overcome barriers to improvement.

Understanding how providers work together to improve quality

In our December consultation we proposed aligning our assessment frameworks for health care and social care and strengthening our focus on leadership, partnership working and integration. This will help us to look more closely at the ways in which providers are working together in a local area and the experiences of people moving within and between services. This may include, for example, looking at how:

- GPs refer people to acute or mental health services and support people living in care homes
- acute services liaise with GP, social care and community care teams and discharge people out of hospital
- adult social care staff assess and support people's healthcare needs and coordinate care with healthcare services.

We propose to:

- develop CQC Insight our new approach to monitoring data in each sector to include information about quality in local areas and, where relevant, about the quality of a provider's different services, so that our inspectors have a better understanding of the context in which services are working
- use our new cross-sector risk and planning and scheduling arrangements (described in Section 1.2) to identify, share and follow up information about quality in the area, including the views of people using services, their families and carers, about their experiences across different services
- develop inspection prompts for hospital, primary medical care and adult social care services that enable us to assess the interactions between providers and the impact on people using services
- report our findings about local partnership working and integration in our provider inspection reports and share with local partners and other stakeholders (as set out below).

Using our independent voice to encourage improvement, innovation and sustainability

We will make more effective use of our knowledge and our independent voice to encourage improvements and inform sustainability and transformation plans (STPs). We will bring together the information we hold about quality in a local area, highlight changes in quality and priorities for improvement, and share examples of good practice and innovation. We will continue to provide a national view of quality across the health and social care system and the development of integrated models of care.

We propose to:

- develop CQC Insight products that draw on the information we hold, including information about people's experiences of care, our inspection findings and local knowledge, to provide a view of quality across national, STP and local commissioning area footprints
- share information with our national partners, local commissioners and other stakeholders, including Quality Surveillance Groups, to help them identify priorities for improvement and agree where further monitoring, inspection or other activity may be required by CQC or others
- use our independent voice, including our national State of Care report, to comment on the changing landscape of care provision, how providers are working together, and the quality of care for local populations.

Helping local partners identify opportunities for improvement

In recent years we have tested different ways of looking at the quality of care across a place. We have provided views of quality in Salford, North Lincolnshire and Tameside, and we have looked at urgent and emergency care networks in the Bradford and Airedale area and in South Warwickshire. This work has developed our understanding of quality across a system. We have built on this learning to test a more targeted approach to place-based activity in Cornwall and the London Borough of Sutton. In 2017, the Secretary of State for Health also asked CQC to carry out targeted reviews across a small number of areas to look at how health and social care work together and what improvements could be made to benefit people who use services.

We will develop a framework that supports local inspection teams to identify and respond to system-wide issues that we identify as part of our internal cross-sector conversations and risk meetings. This may inform what we look at when we carry out our routine inspection activity. In more exceptional circumstances, we may agree with our partners about the benefit in using our review powers to help local stakeholders understand the issues affecting quality and to identify opportunities for improvement.

We propose to:

- develop a framework to enable us to assess quality across a local system, with a focus on leadership, governance and collaboration between providers and commissioners across sectors
- work with our system partners, NHS Improvement, NHS England and locally with Quality and Surveillance Groups, to ensure that we are making the best use of our respective powers, coordinating our activity and sharing what we find in a way that is meaningful to people using services and local stakeholders.

Timetable for implementation

April 2017 to March 2018:

- publish findings from our work in Cornwall and the London Borough of Sutton (Summer 2017)
- develop and test prompts to assess integration as part of our service-level inspections
- continue to develop and test area data profiles and engage with partners to shape the data that we can offer for external use
- carry out targeted reviews in a small number of areas, as requested by the Secretary of State.

April 2018 to March 2019:

- continue to develop our approach to sharing insight and agreeing action with our national and local partners
- agree a programme of reviews using our section 48 powers, as required.

Consultation questions

- 5a Do you think our proposals will help to encourage improvement in the quality of care across a local area?
 [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 5b How could we regulate the quality of care services in a place more effectively?

PART 2: NEXT PHASE OF REGULATION

2.1 Primary medical services

Introduction

In this section we describe how we propose to develop our approach to regulating primary medical services in the context of a changing landscape of care and in line with the direction set out in our new five-year strategy. We describe how we will monitor, inspect, rate and take action to encourage improvement in GP services. We highlight key aspects of our approach to regulating independent sector primary care services, NHS 111, GP out-of-hours and urgent care services, primary medical care delivered online, and large scale models of primary care provision such as GP federations, super practices and multi-speciality community providers.

The majority of GP practices are currently rated good or outstanding (91%), based on inspections we have undertaken since October 2014. We have also seen that, with the right support, practices found to be providing poor care have improved significantly. This means that we can build on the aspects of our current approach that have worked well and have encouraged improvement, and can also take a more proportionate, targeted and responsive approach. One aspect of our approach that we want to review in light of experience is the way that we inspect and rate against the six population groups.

We are reviewing our approach to dental regulation and will consult in autumn 2017 if any substantive changes are proposed. We are not proposing to change our approach to regulating health and justice services at this time.

Summary of proposals

Information will be at the centre of our approach and we will strengthen how we manage our relationships to support more responsive and targeted inspections.

We propose to:

- implement a more consistent approach to working with providers and other stakeholders to understand the quality of care and to encourage improvement
- introduce an annual online provider information collection to allow providers to tell us about the quality of care they provide
- introduce a new Insight model to alert our inspectors to changes in the quality of care

- explore information about the quality of care in local areas or within large-scale models of primary care
- focus our inspections on the issues highlighted through our monitoring or identified as part of our cross-sector planning
- increase the period between inspections for services rated as good or outstanding
- continue to carry out comprehensive inspections for new providers and for practices that have been rated as requires improvement or inadequate
- review how we assess and rate the quality of care for different population groups, to focus on how effective and responsive practices are to the different groups.

We will continue to develop our approach in response to changes in the primary care landscape, and in line with the changes to registration and regulating complex providers outlined in Part 1.

The changes we propose for general practices

Monitor

Our monitoring function will play a greater role in how we regulate. Our new CQC Insight model, strengthened relationship management, and online provider information collection will enable us to monitor potential changes in the quality of care. We will use this intelligence to target our activity and encourage improvement.

Provider information collection

We will replace the existing provider information return with an annual online information collection. We will ask providers for information every year rather than as part of the preparation for an inspection, and will encourage them to keep it up to date. This is one way that providers can demonstrate an open culture and that they are taking responsibility for assuring the quality of care they provide.

We will ask providers for information including:

- what has changed about the quality of care provided over the last year and what plans they have to improve
- examples of good practice
- how they provide effective and responsive care to each of the population groups.

Over time, the annual information collection will be aligned with requests from other organisations to reduce duplication and the burden on providers. For example, we are working with the General Medical Council and NHS England to streamline and align our requests (including the Annual Electronic Declaration – eDEC). We will work with our

regulatory partners to ensure that practices only need to provide a single description of their quality, based on the five key questions.

CQC Insight

CQC Insight is a tool that presents practice-level data against national comparators and identifies potential changes in the quality of care. In time, it will include more information about quality within a clinical commissioning group, including outcome indicators that can provide a better measure of effectiveness within the area than we can accurately measure at practice level. If a practice is part of a GP federation or other organisation, CQC Insight will include information about the performance of other services in the group.

Our analyses will be updated throughout the year and will provide our inspectors with more timely information. We will use this information to plan when and what to inspect and include it as part of the evidence in our inspection reports. We will continue to develop the model and work with stakeholders on future updates. Analyses from CQC Insight will include information from people who use services and national and local partners, as well as from the new provider information collection.

Strengthened relationship management

We already work closely with providers and national, regional and local partners. We will continue to strengthen these relationships to share information, reduce duplication and coordinate action where support is needed to improve, for example from the Royal Colleges and professional regulators, NHS England, the GP Regulatory Programme Board, local and national Healthwatch, clinical commissioning groups or local medical committees. Our inspectors will also work with colleagues in CQC's Hospital and Adult Social Care directorates to review information about quality across the local system and to share this with quality surveillance groups and those developing sustainability and transformation plans.

Our inspection teams will communicate with local stakeholders and gather information about the providers in their area throughout the year, rather than focusing their engagement activity around an inspection. This will help us understand how the delivery and quality of care is changing and make decisions about what, if any, action to take.

Planning our regulatory response

Every year we will formally review all of the information we have about a provider. This will ensure that our monitoring and planning decisions are made clearly, consistently and transparently.

Our inspectors will consider whether there have been any changes to the quality of a provider's care since our last inspection or if the available evidence still supports the rating. This will include reviewing the annual provider information collection, CQC Insight and information from stakeholders.

During this review, we may need to contact the provider to clarify an issue. If information indicates that the quality of care has improved or deteriorated since the last rating, we may decide to inspect. If we don't need to take any action, we will tell the practice that we have carried out the review.

Current approach to monitoring	New approach to monitoring
 Intelligent Monitoring indicators used as part of a wider approach to gathering information before an inspection Indicators updated periodically Provider information request sent when inspection announced Short turnaround time for providers 	 Ongoing monitoring will identify potential changes in the quality of care CQC Insight indicators will be updated frequently. Insight will focus on changes since the previous rating (improvements and areas of risk) and include data about quality in the area Every year providers will tell us about changes to the quality of care provided, improvement plans, and examples of good practice Providers can update at any point during the year

Where a service is provided by an NHS trust or other complex provider, our inspectors will work with our hospital and/or adult social care inspectors to plan a joint inspection schedule, as set out in Part 1.

Consultation questions

6a Do you agree with our proposed approach to monitoring quality in GP practices?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

6b Please give reasons for your response.

Inspection

Scope of inspections

Inspection remains an important part of our regulatory approach. It enables us to gain an indepth understanding of the quality of care and to identify and encourage improvement. In all sectors we ask five key questions: is care safe, effective, caring, responsive and well-led? In general practices we also assess quality for six population groups: older people; people with long-term conditions; families, children and young people; working age people; people whose circumstances might make them vulnerable; and people experiencing poor mental health.

Comprehensive inspections will continue to address all five key questions and all six population groups. We will always carry out a comprehensive inspection for providers rated as inadequate or requires improvement, or that have not been inspected before. However, we propose to change our approach to assessing care for population groups (see the ratings section below).

We will carry out more focused inspections for providers rated as good and outstanding. These will follow up any potential changes in the quality of care indicated by our monitoring activity, or will focus on a specific population group or care pathway when this is highlighted in the data for the local area. We will develop criteria to help our inspectors decide which key questions or issues to focus on. We will always inspect the leadership, governance and culture of the practice under the well-led key question.

All of our inspections will include a site visit. Our inspection teams will still involve specialist advisors and, where appropriate, people who have personal experience of using services. The size and composition of our inspection teams will depend on whether it is a comprehensive or focused inspection and the type of services being inspected, and will include hospital or adult social care inspectors where services are provided in an integrated or complex model.

Inspection scheduling

If we have concerns about services, we will inspect them more frequently than those where we receive assurance that they are maintaining a good quality of care.

We will continue to inspect providers with an overall rating of inadequate every six months and those rated as requires improvement every 12 months, until they improve. For providers rated as good or outstanding overall, we will move to an inspection interval of up to five years, in line with our commitment in our strategy and NHS England's General Practice Forward View.

We may bring forward an inspection when:

- our monitoring information indicates a potential improvement or deterioration in the quality of care
- practices are part of a larger or complex provider and we have chosen to carry out a coordinated inspection, for example alongside our hospital and adult social care inspectors
- we are undertaking a place-based review, as described in section 1.4.

Every year a proportion of the providers rated good or outstanding will be inspected to make sure that they are all inspected at least once every five years.

We may inspect any service at any time, irrespective of rating, where this is appropriate.

There will be greater flexibility around inspection notice periods. For example, inspectors may give longer notice periods where we are focusing on specific themes or carrying out an areabased or complex provider inspection. Or we may carry out short notice or unannounced inspections where we have concerns.

Current approach to inspection	New approach to inspection
• All providers inspected at least once during our first programme of inspections	• Maximum inspection intervals determined by rating and monitoring information
Inspections usually announcedFixed notice periods for inspection	 Greater flexibility to use announced, short notice and unannounced inspections
 All providers receive at least a 'baseline' comprehensive inspection (all key questions) 	 Inspections alongside our adult social care and hospitals colleagues when we inspect more complex models
Focused inspections for follow-up of concerns or risks	 Focused inspections based on CQC Insight for providers rated as good and outstanding – may focus on key questions, population groups or care pathways

Reporting

Our inspection reports enable us to give the public a better understanding of what they should be expecting from their local care services. They also encourage improvement by sharing examples of outstanding and innovative practice and highlighting areas that need to improve.

Our reports will be shorter and less repetitive, and will use language that is more accessible for the public. They will include a summary report and a more detailed 'evidence table' – which will set out in more detail the evidence we have used to make our judgements. Both sections will be structured around the key lines of enquiry (KLOEs). We will streamline our internal quality control and assurance processes to speed up the publication of reports. We are committed to publishing 90% of reports within 50 days of the inspection taking place.

Current approach to reporting

- Report includes all evidence, findings, ratings, contextual information and any enforcement action we have taken
- Presented in a narrative style

New approach to reporting

- Report includes summary of findings, contextual information and ratings
- Appendix includes all the evidence presented factually

Rating

Ratings are an important indicator of quality for patients and the public, enabling people to make choices. They increase accountability and transparency and help services and others compare performance between organisations, to identify good practice and incentivise improvement.

We will only change a rating on the basis of evidence from data and inspections. Currently we do not update overall ratings following focused inspections carried out more than six months after a comprehensive inspection. However, in future we propose to remove this rule and to update ratings any time following an inspection.

Ratings for population groups

We currently inspect and rate the quality of care for each of the six population groups against each key question and provide aggregated ratings for each population group, each key question, and for the practice overall. This results in 43 separate ratings for each practice, and means that where practices have developed specific initiatives for particular populations, their achievements are not always discernible in their overall rating. For example, a practice could be rated as outstanding for providing responsive and effective care for people experiencing poor mental health, but not have this recognised because their overall performance on safety or well-led is not good. We want to simplify this by reducing the overall number of ratings we give.

During our full programme of inspections in general practice over the last three years, we have learned that the most significant differences in quality between the population groups are in the effective and responsive key questions. We find that our ratings for caring, safety and well-led are broadly consistent for each of the population groups and at overall practice level.

We want to make our judgements on the quality of care provided to population groups more transparent and easy to understand. We could achieve this by only rating population groups using the effective and responsive key questions. If we make this change, we would instead assess caring, safety and well-led at practice level, highlighting any population-specific issues that we find. In addition, we would continue to inspect a practice's safeguarding arrangements for children and adults as a key line of enquiry under the safety question and

report this at practice level. These changes would not affect the way we look at safeguarding issues or the way we calculate overall ratings for the practice. We would continue to give each of the key questions equal weighting.

The grid below sets out the ratings we give for a practice on a comprehensive inspection. The shading shows the ratings we are proposing to no longer provide.

Figure 6: Proposed ratings grid for a comprehensive inspection of a GP practice

Level 1: Two key questions fo	Dr	Safe	Effective	Caring	Respon- sive	Well-led	Overall	Level 2: Aggregated rating for
	Older people							every population group
	People with long-term conditions	•						-
	Families, children and young people							
	Working age people (including those recently retired and students)							
	People whose circumstances make them vulnerable							
	People with poor mental health (including people with dementia)							
Level 3: Rating for every key question	Overall							Level 4: Overall rating for the

Current approach to rating

- An overall rating and a rating for all key questions at practice level
- An overall population group rating and ratings for each key question across all population groups
- Focused inspections more than six months after a comprehensive inspection do not update the overall rating

New approach to rating

- Continue to give an overall rating and a rating for all key questions at practice level
- Ratings for effectiveness and responsiveness for all population groups
- Ratings can be changed after a focused inspection at any time

Consultation questions

- 7a Do you agree with our proposed approach to inspection and reporting in GP practices?
 [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 7b Please give reasons for your response.
- Ba Do you agree with our proposal to rate population groups using only the effective and responsive key questions? (Safe, caring, and well-led would only be rated at practice level.)
 [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 8b Please give reasons for your response.
- 9a Do you agree with our proposal that the majority of our inspections will be focused rather than comprehensive?
 [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 9b Please give reasons for your response.

Taking action to improve care

Services that repeatedly require improvement

In general practice, we have found that the majority of services rated as requires improvement take timely action and improve. Our regulatory response will therefore always take into account whether a service has breached any regulations, its track record on quality and plans for improvement.

We will continue to engage with partners to highlight examples of improvement, and promote good practice and available sources of support. We will also monitor services more closely to identify any changes or deterioration in quality, so that we can respond more quickly if necessary.

There are occasions when services are unable to demonstrate that they have the necessary leadership or governance processes to assure and improve quality, and this may represent a breach of Regulation 17 (good governance). We will always consider this when a provider has received an overall rating of requires improvement more than once, and we may ask the provider for a written report to set out how they will assess, monitor and improve the quality and safety of their services. This improvement action plan will need to be agreed with their commissioners. If they are rated as requires improvement for a third time, we will hold a formal management review meeting (MRM) to consider the next steps and the potential use of our enforcement powers. As with the current framework, if one or more key questions is rated as inadequate in two consecutive inspections, the provider will enter special measures.

Where we register larger primary care providers, we will monitor quality across all their services. Where there are concerns across the group, we may consider taking action to hold the provider to account, for example by using our enforcement powers.

More effective and consistent enforcement

We cannot currently publish information about enforcement activity in inspection reports until the period in which providers may submit representations and appeals has closed and the outcome of these has been decided. In future, we want to be more transparent with the public when we are taking enforcement action by publishing the details sooner. We are working with the Department of Health on this issue.

Independent sector primary care – overview of proposed approach

In 2015, we consulted on our approach to regulating and inspecting primary care services in the independent sector and we tested our approach in pilot inspections of 40 independent doctor services. Feedback from providers and those involved in the pilots was positive, and has informed our next phase approach.

We propose to no longer separately categorise services provided in the NHS or independent sector. Independent sector services will instead be categorised in line with similar types of services provided in the NHS. The majority of the services will be categorised as primary medical services. In some cases providers may also deliver services that are not defined as regulated activities and therefore fall outside the scope of regulation. Where this is the case, we will make this clear on our website so that the public can understand what we are unable to inspect.

We will assess independent sector primary care services using the approach set out for general practice. For providers offering private GP services, we may also consider how they care for population groups. Where necessary, we will develop sector-specific guidance and inspection prompts. The size and composition of our inspection teams will depend on the kind of services being inspected, and will involve specialist advisors with relevant experience.

We are looking to include these services in the scope of our ratings powers but, in the meantime, we will make judgements about whether care is safe, effective, caring, responsive and well-led, based on whether the relevant regulations are being met.

NHS 111, GP out-of-hours and urgent care services – overview of proposed approach

We face two challenges when regulating NHS 111, GP out-of-hours and urgent care services – by which we mean walk-in centres, minor injury units and urgent care centres:

- 1. These services can be provided, or hosted, by primary care providers, as well as secondary care providers (including acute and ambulance trusts, and community providers).
- 2. There is no national data available for urgent care services.

We recognise that, regardless of commissioning arrangements or whether it is a primary care location or part of a trust, these services are doing the same things. Therefore, we will be consistent in our assessment of these services, across the different sectors, regardless of who is providing or hosting these services.

For NHS and foundation trusts that provide NHS 111, GP out-of-hours and urgent care services, we will tailor how we inspect and report on these providers, while being consistent in the assessment we use. This will enable us to take account of the complexity, scale and scope of these providers, and be responsive to the different provider arrangements that we are seeing in the sector.

The key changes we make to our approach for those services provided by primary care providers will be consistent with the model for general practice, as set out above. In summary, we will:

• Strengthen our relationships with providers and our partners (including commissioners) to help us understand service provision, accountabilities and responsibilities. This will help ensure we involve the right people with the right expertise on our inspections.

- Align the provider information collection with requests from other bodies, including NHS England – the collection will tell us about the services being provided, and any changes happening within providers.
- Align our CQC Insight model with NHS England's Integrated Urgent Care Key Performance Indicators.
- Continue to carry out comprehensive inspections of these services, with an increased focus on issues highlighted through our monitoring, or identified as part of our cross-sector planning arrangements.
- Where possible, try to inspect NHS 111, GP out-of-hours and urgent care services at the same time, where a provider is delivering these services across an area.

We are aware that providers of NHS 111, GP out-of-hours and urgent care services are working within the context of greater integration, under new commissioning arrangements and new care models. For example, urgent and emergency care services are working together under 'alliances' to provide more coordinated care and support across local areas. We will improve how we coordinate our regulatory activity across local providers so that we may conduct a series of inspections, across a range of providers within a local area at the same time – sometimes as part of a place-based review of care. We will also use the new assessment framework to strengthen our focus on how these services are working with each other, and other providers, to share information and coordinate care.

Primary care delivered online

In March 2017, we published information to clarify how we propose to regulate digital primary healthcare providers. These are services that provide a regulated activity online. Examples include providers prescribing medications or delivering GP consultations over the internet. Our methodology will include the standard key lines of enquiry, supplemented by sector-specific prompts.

We do not currently have the legal powers to rate most digital healthcare services due to the type of provider and the contracts they hold but we are looking to bring them into the scope of rating. Until then, we will make judgements about whether the care provided is safe, effective, caring, responsive and well-led, based on whether the relevant regulations are being met. We will take action where care is not safe.

Where GP practices also offer online consultations, inspection teams will use the specific digital healthcare prompts, together with the standard KLOEs and prompts in the assessment framework for health care services. Our aim is to ensure that the same safeguards are in place during those consultations as we would expect in exclusively online providers.

Primary care at scale – overview of our proposed approach

Primary care is evolving and the way care is organised is changing. Many GP practices are joining federations, super-partnerships, multi-site practice organisations or other new models of care, including GP-led multi-speciality community providers (MCPs) which we refer to as large-scale general practice. We anticipate that we will continue to inspect the majority of GP services as part of our GP inspection programme. This will include practices that have retained their independent status, as well as practices that are fully integrated within a larger organisation. Our new KLOEs will enable us to assess how well these services are integrating with other parts of the health and social care system.

The pace and scale of change is different around the country, so we need a flexible and responsive approach. We will inspect some practices as part of a coordinated complex provider or area inspection and, in time, we may move towards also inspecting at the highest level of accountability for quality, in line with our proposals set out in Part 1 of this consultation. If and when we introduce a provider-level assessment, we may consider using our CQC Insight model to select a sample of locations for practice-level inspection and rating.

During 2017/18, we will work with a number of areas to pilot our approach to how we regulate evolving models of primary care.

Consultation questions

- 10a Do you agree with our proposed approach for regulating the following services?
 - i. Independent sector primary care [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
 - ii. NHS 111, GP out-of-hours and urgent care services[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
 - iii. Primary care delivered online [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
 - iv. Primary care at scale [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 10b Please give reasons for your response (naming the type of service you are commenting on).

Timetable for implementation

April 2017 to March 2018:

- consult on proposed changes to primary medical services
- refine and test our new methodology, including for rating population groups
- CQC Insight published for general practice providers (June)
- introduce provider information collection (non-digital collection up to April 2018) and implement regulatory review process (November)
- start inspections using the new approach (November)
- remove the six-month limit on focused inspections changing overall ratings.

April 2018 to March 2019:

- introduce provider information collection for GP federations and super practices
- develop and test provider-level assessment alongside live-testing of registration changes.

April 2019 to March 2021:

• phased implementation of provider-level assessments, subject to registration changes for some providers.

2.2 Adult social care services

Introduction

In this section, we describe how we propose to develop our approach to regulating adult social care providers, in line with the direction set out in our new five-year strategy. We describe our approach to monitoring, inspecting and rating and using our enforcement powers to require providers to take action when they need to improve.

Since October 2014, we have found the quality of care in adult social services to be variable. At the beginning of May 2017, 77% of services were rated as good and just 2% rated as outstanding. We have also found that our ability to influence improvement has been mixed. Over three-quarters of services rated inadequate improved on re-inspection, but for services that require improvement the picture is less encouraging, with 38% remaining unchanged on re-inspection and 5% getting worse.

Summary of proposals

We will strengthen our use of information and relationship management to support a more responsive and targeted approach to inspection. We will focus more on providers that are unable to sustain improvement, and on recognising providers that have improved but have not yet managed to achieve a better rating.

We propose to:

- implement a more consistent approach to working with providers and other stakeholders to understand the quality of care and encourage improvement
- introduce an online provider information collection and share information with key stakeholders
- develop a new CQC Insight model that brings together information about all the locations of a provider to help inspectors see the broader context for performance
- increase the period between comprehensive inspections for services rated as good and outstanding, as our monitoring improves
- make more use of focused inspections, which will always include an assessment of the well-led key question
- remove the 'six month limit', which only allows us to change an overall rating if a focused inspection is carried out within six months of the last comprehensive inspection
- extend the time in which to gather views about the quality of services that provide care to people in their own homes
- increase our focus on services rated as requires improvement to drive improvement.

The changes we propose for adult social care

Monitor

Our monitoring function will play a greater role in how we regulate. Our new Insight model and online provider information collection will enable us to monitor potential changes in the quality of care, and we will monitor more closely services that repeatedly fail to achieve a good standard of care. This will help us to target our responses to these services to encourage them to improve.

Provider information collection

We will introduce a new approach to collecting information from providers. This will be a live online process, rather than a form to collect information in the run-up to an inspection. We will ask providers to provide a statement of quality in relation to the five key questions and to describe what they are doing to support continuous improvement. The process will facilitate regular, ongoing engagement with providers.

Providers will need to complete the information collection once a year as a minimum. However, by keeping the information up-to-date, a provider can demonstrate an open culture and show that they are committed to continual learning. We will continue to work with health and local authority commissioners, providers and other stakeholders, to explore how we might develop and share the information as the basis of a single core dataset – information that is collected once and shared many times.

CQC Insight

CQC Insight is a tool that presents information about services and, where possible, compares performance over time or in relation to other providers. We hope that the new provider information collection will help to provide a dataset that we can use across the adult social care sector to monitor quality and compare performance between services and over time.

CQC Insight can also help inspectors to understand the broader context, by setting out how a provider is performing across all of its services. Changing the level of registration – as recommended in Part 1 – would make it much easier to bring together information about services run by corporate provider groups.

Strengthened relationship management

We will be clearer and more consistent about how we engage with the leaders of provider organisations and other stakeholders, such as local authority commissioners and clinical commissioning groups (CCGs) – for example:

- when we find recurring themes across a provider's services
- where services fail to sustain a good standard of care
- where ratings of inadequate and requires improvement are predominant across a provider.

Current approach to monitoring	New approach to monitoring
 Intelligent Monitoring Provider information return issued before an inspection 	 Clearer and more consistent engagement with leaders in organisations and other stakeholders, such as local authority commissioners and CCGs Provider information collection will be an online
 Engagement with providers and partners variable Data collected by many different 	 Provider information conection will be all online process, containing a 'statement of quality' in relation to the five key questions and activities supporting continuous improvement
 Data collected by many different organisations 	 Provider information shared with key stakeholders as a single shared view of quality

Planning our regulatory response

We will continuously monitor all available information to inform when we will inspect and the issues we may look at. For example, where information does not flag up risks or concerns, we may maintain our comprehensive inspection schedule. We may bring forward comprehensive inspections in response to a wide range of concerns, or conduct a focused inspection where concerns are more limited. We will have the flexibility to expand the scope of focused inspections where additional or different concerns are identified before the inspection or during the site visit.

Where an adult social care service is provided alongside hospital or primary care services within a complex provider, we will monitor quality and plan a coordinated inspection schedule as set out in Part 1. Where we identify a pattern of concerns across services within a larger provider, we may also plan a coordinated approach to inspection, and in future may decide to undertake a provider-level assessment, subject to the proposed registration changes.

Consultation questions

- 11a Do you agree with our proposed approach to monitoring quality in adult social care services, including our proposal to develop and share the new provider information collection as a single shared view of quality? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 11b Please give reasons for your response.

Inspection

Scope of inspections

We want to introduce a more proportionate, targeted and responsive approach to inspection, with a better balance between monitoring, comprehensive inspections and focused inspections. Every service will have a comprehensive inspection, which will address all five key questions. Focused inspections are more targeted. They focus on specific risks or concerns identified through monitoring activity or from a comprehensive inspection. They may not address all five key questions but will always address the well-led question. We may also use focused inspections to inform reports that examine particular themes or aspects of care, such as pathways of care or how people with specific conditions are cared for.

Inspection scheduling

As our monitoring improves, we believe it would be more proportionate to increase the maximum timescales between planned comprehensive inspections:

- from two to two and a half years for services rated as good
- from two to three years for services rated as outstanding.

We will continue to monitor quality in these services and will respond to risks by bringing forward a comprehensive inspection or carrying out a focused inspection. We may also bring forward an inspection where we have information that indicates that a provider has improved or deteriorated.

We will continue to re-inspect services that are rated as requires improvement overall every year. However, we will address inconsistencies in our approach to regulating services that are consistently rated as requires improvement. Our proposed approach is described on page 52.

We have found that on re-inspection, over three-quarters of services rated as inadequate have improved, so we will continue to re-inspect these services every six months until they are able to achieve a better rating.

Wherever possible we will inspect adult social care services delivered by a complex provider as part of a coordinated scheduled of inspections, as set out in Part 1.

We may inspect any service at any time, irrespective of rating, where this is appropriate.

Inspecting services providing care to people in their own homes

It can be harder to assess the quality of care when people are cared for in their own homes by domiciliary care, supported living and extra care housing services. Unannounced and short notice inspections can make it difficult to discuss experiences with people who need time and support to participate and share their experiences, such as those with cognitive impairment.

We are therefore developing a more extensive 'toolkit' for inspectors that will include new methods for gathering additional information from providers, people using services and their families, and other stakeholders:

- 1. An announced inspection: we may not specify the actual day and time of an inspection, but we could point to a period when it will happen, retaining an unannounced element in certain circumstances.
- **2.** Extended time for additional fieldwork: this could involve activity after an unannounced or short notice first visit.

Rating

Ratings are an important indicator of quality. They help people using services, their families and carers to make choices about the services they use. They increase accountability and transparency and incentivise improvement. They also help providers and others to compare performance over time and between organisations, and to identify good practice.

We will continue to rate services against each of the five key questions. Ratings will be changed on the basis of evidence from data and inspections and we will be able to change an overall rating on the basis of a comprehensive or focused inspection. We also propose removing the current 'six month limit', which only allows us to change an overall rating if a focused inspection is carried out within six months of the last comprehensive inspection.

Current approach to inspection and rating	New approach to inspection and rating
 All key questions inspected and rated as part of comprehensive inspection programme Comprehensive inspection carried out within two years for good and outstanding services No requirement to inspect any area or key question as a minimum when carrying out a focused inspection Inspection only at location level Focused inspection can only change overall rating if within six months of a comprehensive inspection 'One size fits all' for inspecting the quality of care delivered to people in their own homes 	 Using registration, risk and rating information to target when, what and how we inspect Comprehensive inspection carried out within 2.5 years for good services and within three years for outstanding services Focused inspections will always include an assessment of the well-led key question Will be able to change an overall rating on the basis of a focused inspection, removing the 'six-month limit' that we currently apply More flexible approach for inspecting care delivered to people in their own homes, supported by a 'toolkit' of methods to support evidence gathering

Reporting

Our inspection reports will be shorter, clearer and more informative. We will include the inspection history of the individual service and will explore how we can also include a picture of quality of all the services operated by the provider. As we develop our use of data over time, we will consider introducing an evidence table, setting out the facts and figures that support our judgements, in line with our proposals for other sectors.

Consultation questions

12a Do you agree with our proposed approach to inspecting and rating adult social care services?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

- 12b Please give reasons for your response.
- 13a Do you agree with our proposed approach for gathering more information about the quality of care delivered to people in their own homes, including in certain circumstances announcing inspections and carrying out additional fieldwork?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

13b Please give reasons for your response.

Taking action to improve care

Services that repeatedly require improvement

When a service is rated as requires improvement, our regulatory response will take into account whether it has breached any regulations, its track record on quality and plans for improvement.

We will engage with partners to highlight good practice, examples of improvement, and available sources of support. We will also monitor services more closely to identify any changes or deterioration in quality, so that we can respond more quickly if necessary.

In some circumstances, for example where services are unable to demonstrate that they have the leadership or governance processes in place to assure and improve quality, this may represent a breach of Regulation 17 (good governance). We will always consider this when a provider has received an overall rating of requires improvement more than once, and we may ask them for a written report that sets out how they will assess, monitor and improve the quality and safety of their services. This action plan will need to be agreed with the provider's commissioners. If they are rated as requires improvement for a third time, we will hold a formal management review meeting (MRM) to consider the next steps and the potential use of our enforcement powers.

We will also monitor quality across all of a provider's services and, where more than half are rated as requires improvement or inadequate, we will hold an MRM to decide the best course of action. We will engage directly with the provider's leadership and, in future, may consider enforcement action against the provider, subject to the changes in the level of registration proposed in Part 1.

More effective and consistent enforcement

Our proposed change to the level of registration for corporate provider groups will mean that we can hold the corporate-level leadership to account when we have concerns about poor care. We want to explore the use of provider-level conditions, which would include setting out the actions that the provider must take to deal with systemic failings across its services. This will support a more consistent approach and will encourage providers to monitor the quality of care across all their services and to respond when it falls below acceptable standards.

We cannot currently publish information about enforcement activity in inspection reports until the period in which providers may submit representations and appeals has closed and the outcome of these have been decided. In future, we want to be more transparent with the public when we are taking enforcement action by publishing the details sooner. We are working with the Department of Health to take this forward.

Current approach to enforcement	New approach to enforcement
 Enforcement action taken in response to issues at individual services Potential for repeated requires improvement ratings with no enforcement 	 More action taken at provider level (including corporate head office level) where issues affect more than one service More consistent approach to repeated ratings of requires improvement, including potential breach of Regulation 17

Consultation questions

- 14a Do you agree with our proposed approach for services which have been repeatedly rated as requires improvement? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 14b Please give reasons for your response.

Timetable for implementation

April 2017 to March 2018:

- refine and test new methodology
- implement online provider information collection and new inspection methodology
- start using the revised assessment framework (inspections in the first six weeks will use the existing PIR)
- start using the revised methodology for services providing care to people in their own homes
- removal of six-month limit on focused inspections changing overall ratings.

April 2018 to March 2019:

• pilot provider-level assessments alongside live testing of registration changes.

April 2019 to March 2021:

 phased implementation of provider-level assessments, subject to registration changes for some providers.

PART 3: FIT AND PROPER PERSONS REQUIREMENT

This section sets out our proposed changes to the way CQC will carry out our role in relation to the fit and proper persons requirement (Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014), including the way we will share information with providers when we receive information of concern from a third party. We also provide additional guidance for providers on interpreting "serious misconduct and serious mismanagement".

The fit and proper persons requirement

The fit and proper persons requirement (FPPR) was introduced in November 2014 for NHS hospitals and in April 2015 for providers in all other sectors. This was in response to concerns raised following investigations into Mid Staffordshire NHS Foundation Trust and Winterbourne View Hospital. It requires all providers registered with CQC to assure themselves that all directors (or those in equivalent roles) are fit to carry out their responsibility for the quality and safety of care.

CQC's role is to make sure that providers have appropriate recruitment and performance management processes in place, and to take action against a provider if we believe they are failing to meet the requirement. It is not our role to regulate individuals or to assure that any individual is fit or proper. We will continue to check this when a provider applies to register, or to vary its registration, and when we carry out inspections using the well-led key question.

Following up concerns

When we receive concerns from the public or health and social care staff about the fitness of directors, our current approach is to assess the information and to ask the provider to consider and respond only to the information that we believe is relevant.

In future, we propose to continue to notify providers of all concerns relating to their directors, but will ask them to assess all the information we receive. We will ask the person providing the information for their consent to do this, and will seek to protect their anonymity if necessary. In some exceptional cases, we will need to progress without consent when we are concerned about the potential risk to people using services. We will also inform the director to whom the case refers, but we will not ask for their consent and will not disclose the identity of the person who provided the information to us.

When we share information of concern with a provider, we will ask them to detail the steps they have taken to assure themselves of the fitness of the director. We will also indicate what type of response we will expect from them after we notify them about the concern. This response will need to include assurance from a provider that:

- they have used a fair and proportionate process to establish the primary facts of any matter giving rise to a concern about the director (the investigation stage)
- having ascertained the primary facts, they have assessed whether the facts establish that the director falls within any of the categories in Regulation 5(3) (the assessment stage)

If the response does not satisfy CQC that the provider has followed a robust process and reached a reasonable decision, we will either ask the provider for further information, carry out a follow-up inspection, or potentially take regulatory action.

If a provider has demonstrated that they applied the appropriate checks but CQC has concerns that the decision it has made about the fitness of a director is a decision that no reasonable person would have made, we will apply our enforcement policy to decide if there has been a breach of the regulations.

Current approach to FPPR	New approach to FPPR
• We review information of concern and send a selection to the provider for comment	• We will send all information we receive to the provider and ask them to detail their current processes. We will assess the information and, where necessary, carry out an investigation and assessment

Consultation questions

- 15a Do you agree with the proposal to share all information with providers? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]
- 15b Do you think this change is likely to incur further costs for providers?

Interpretation of 'serious misconduct and serious mismanagement'

Regulation 5(3)(d) states that "the individual has not been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England would be a regulated activity".

Providers have asked CQC to clarify what is meant by "serious mismanagement" and "serious misconduct". Our new guidance (set out in Annex A) is intended to help providers interpret and implement the regulation.

Consultation question

16 Do you agree with the proposed guidance for providers on interpreting what is meant by "serious mismanagement" and "serious misconduct"?

How to respond

You can respond through our online form at: www.cqc.org.uk/nextphase

You can write to us at: Freepost RTTE-JTBT-ZTHH Next Phase Consultation Care Quality Commission 151 Buckingham Palace Road LONDON SW1W 9SZ

If you have any questions about this consultation, please email: **nextphase@cqc.org.uk**. You can also tweet us your thoughts at: **#CQCNextPhase**

Please reply by Tuesday 8 August 2017.

Thank you for taking the time to contribute to the development of our future work. Your feedback and comments are important in helping us get it right.

Summary of consultation questions

PART 1: REGULATING IN A COMPLEX CHANGING LANDSCAPE

1.1 Clarifying how we define providers and improving the structure of registration

1a What are your views on our proposal that the register should include all those with accountability for care as well as those that directly deliver services?

1b What are your views on our proposed criteria for identifying organisations that have accountability for care (see page 12)?

2 We have suggested that our register show more detailed descriptions of services and the information we collect. What specific information about providers should be displayed on our register?

1.2 Monitoring and inspecting new and complex providers

3a Do you agree with our proposals to monitor and inspect complex providers that deliver services across traditional hospital, primary care and adult social care sectors? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

3b Please explain the reasons for your response.

1.3 Provider-level assessment and rating

4a Do you agree that a provider-level assessment in all sectors will encourage improvement and accountability in the quality and safety of care? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

4b What factors should we consider when developing and testing an assessment at this level?

1.4 Encouraging improvements in the quality of care in a place

5a Do you think our proposals will help to encourage improvement in the quality of care across a local area?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

5b How could we regulate the quality of care services in a place more effectively?

PART 2: NEXT PHASE OF REGULATION

2.1 Primary medical services

6a Do you agree with our proposed approach to monitoring quality in GP practices? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

6b Please give reasons for your response.

7a Do you agree with our proposed approach to inspection and reporting in GP practices? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

7b Please give reasons for your response.

8a Do you agree with our proposal to rate population groups using only the effective and responsive key questions? (Safe, caring, and well-led would only be rated at practice level.) [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

8b Please give reasons for your response.

9a Do you agree with our proposal that the majority of our inspections will be focused rather than comprehensive?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

9b Please give reasons for your response.

10a Do you agree with our proposed approach for regulating the following services?

i. Independent sector primary care [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

ii. NHS 111, GP out-of-hours and urgent care services[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

iii. Primary care delivered online

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

iv. Primary care at scale

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

10b Please give reasons for your response (naming the type of service you are commenting on).

2.2 Adult social care services

11a Do you agree with our proposed approach to monitoring quality in adult social care services, including our proposal to develop and share the new provider information collection as a single shared view of quality?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

11b Please give reasons for your response.

12a Do you agree with our proposed approach to inspecting and rating adult social care services?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

12b Please give reasons for your response.

13a Do you agree with our proposed approach for gathering more information about the quality of care delivered to people in their own homes, including in certain circumstances announcing inspections and carrying out additional fieldwork? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

13b Please give reasons for your response.

14a Do you agree with our proposed approach for services which have been repeatedly rated as requires improvement?

[Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

14b Please give reasons for your response.

PART 3: FIT AND PROPER PERSONS REQUIREMENT

15a Do you agree with the proposal to share all information with providers? [Strongly agree/ Agree/ Neither agree or disagree/ Disagree/ Strongly disagree]

15b Do you think this change is likely to incur further costs for providers?

16 Do you agree with the proposed guidance for providers on interpreting what is meant by "serious mismanagement" and "serious misconduct"?

Annex A: Guidance for the implementation of the fit and proper persons requirement

Fit and proper person requirement: Serious misconduct and serious mismanagement and good character

Contents

Part A – Introduction

- Part B Serious mismanagement or misconduct
- Part C Good character
- Part D Procedure for Assessing compliance with the regulation
- Part E Enforcing the regulation

A. Introduction

1.1 All registered providers subject to Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (the 2014 Regulations) are required to satisfy themselves as to the fitness of their directors. This requires diligent enquiries at the appointment stage, and effective performance management for the duration of the appointment. It is for providers to ensure they comply with this Regulation when recruiting directors by complying with all relevant guidance.

1.2 In this document the use of the word 'director' encompasses shadow directors, by which we mean individuals who are not directors but their roles and responsibilities are the same as or equivalent or similar to directors of the service.

The criteria that must be satisfied:

1.3 Registered providers must satisfy themselves that all of their all of their directors meet all the requirements relating to fitness in Regulation 5(3) of the 2014 Regulations.

1.4 The requirements that each registered provider must satisfy in respect of each director are:

(a) the individual is of good character,

- (b) the individual has the qualifications, competence, skills and experience which are necessary for the relevant office or position or the work for which they are employed,
- (c) the individual is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the office or position for which they are appointed or to the work for which they are employed,
- (d) the individual has not been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England, would be a regulated activity, and
- (e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual.

When can concerns arise?

1.5 The fitness of a director or proposed director may be called into question at any time. This may be during a recruitment process or may be in the course of the director's employment or when he or she is acting as a self-employed director.

1.6 If a director comes within any of the categories in Part 1 of Schedule 4 to the 2014 Regulations they must be removed from their position as a director.

1.7 In all other cases, the registered provider is required to make an assessment of the individual's fitness If the registered provider decides that a director does not meet any of the requirements set out in paragraphs 1.4 (a) – (e) above, it must relieve that director of their responsibilities as a director. This does not necessarily mean that the director should be dismissed from his or her employment.

B. Serious mismanagement or misconduct

What is misconduct?

2.1 "Misconduct" means conduct which breaches a legal or contractual obligation imposed on the director. It could mean acting in breach of an employment contract, breaching relevant regulatory requirements (such as mandatory health and safety rules), breaching the criminal law or engaging in activities which are morally reprehensible or likely to undermine public trust and confidence.

What is mismanagement?

2.2 "Mismanagement" means being involved in the management of an organisation or part of an organisation in such a way that the quality of decision making and actions of the managers falls below any reasonable standard of competent management.

2.3 The following gives examples of behaviour that may amount to mismanagement:

- Transmitting to a public authority or any other person inaccurate information without taking reasonably competent steps to ensure it was correct.
- Failing to interpret data in an appropriate fashion.
- The suppression of reports where the findings may be compromising for the organisation.
- Failure to have an effective system in place to protect staff who have raised concerns.
- Failure to learn from incidents, complaints and when things go wrong.
- Failure to model and promote standards of behaviour expected of those in public life, including protecting personal reputation, or the interests of another individual, over the interests of service users, staff or the public.
- Failure to implement quality, safety and or process improvements in a timely manner, where there are recommendations or the need is otherwise manifest.

When should proven misconduct or mismanagement be assessed to be "serious misconduct or mismanagement"?

2.4 Providers will have to reach their own decision as to whether any facts which are alleged reach the threshold of being "serious misconduct or mismanagement". The Shorter Oxford English Dictionary defines serious as:

"Important, grave, having (potentially) important especially undesired consequences, giving cause for concern of significant, degree, amount, worthy of consideration"

2.5 Misconduct differs from mismanagement, in that a single incident of misconduct may be so serious as to amount to serious misconduct, whether the provider also concludes that this was incompatible with continued employment or not. However, any serious misconduct renders a director unfit within the terms of the fit and proper person requirement.

2.6 However, an isolated incident is unlikely to constitute serious mismanagement unless it is so serious as to call into question the confidence the organisation and the public can have in the individual concerned.

2.7 Serious mismanagement is likely to consist of a course of conduct over time. Any assessment of its seriousness needs to consider the impact of the mismanagement on the quality and safety of care for service users, the safety and well-being of staff, and the effect on the viability of the provider.

2.8 Not all misconduct or mismanagement in which a director has had some involvement will reach the threshold of "serious". Where there is evidence of misconduct or mismanagement that is not judged to be "serious", the provisions of Regulation 5(3)(d) do not apply. However, it will be for the provider (as the employer) to determine the most appropriate response, so as to ensure that performance is managed and the quality and safety of services is assured.

2.9 Isolated incidences of the following types of behaviour could be considered by a provider to amount to misconduct or mismanagement which does not reach the required threshold of seriousness:

- Intermittent poor attendance;
- Minor breaches of security;
- Minor misuse of an employer's assets;
- Failure to follow agreed policies or processes when undertaking management functions where the failures had limited repercussions or limited effects, or were for a benevolent or justifiable purpose.

2.10 The following are examples of misconduct and mismanagement which providers would be expected to conclude amounted to serious misconduct or mismanagement, unless there are exceptional circumstances which makes it unreasonable to determine that there is serious misconduct or mismanagement:

- Fraud or theft;
- Any criminal offence other than minor motoring offences;
- Assault;
- Sexual harassment of staff;
- Bullying;
- Victimisation of staff who raise legitimate concerns;
- Any conduct which can be characterised as dishonesty, including:
 - Deliberately transmitting information to a public authority or to any other person which is known to be false;
 - Submitting or providing false references or inaccurate or misleading information on a CV;
- Disregard for appropriate standards of governance, including resistance to accountability and the undermining of due process;
- Failure to make full and timely reports to the Board of significant issues or incidents, including clinical or financial issues;
- Repeated or ongoing tolerance of poor practice, or failure to promote good practice, leading to departure from recognised standards, policies, or accepted practices;
- Continued failure to develop and manage business, financial, or clinical plans.

2.11 As part of reaching an assessment as to whether any actions of omissions of the director amount to "serious misconduct or mismanagement", providers should consider whether an individual director played a central or peripheral role in any wider misconduct or mismanagement. The more central the role of the director, the more likely it is that the conduct of the director should be assessed to be serious misconduct or mismanagement. The provider should also consider whether there are any mitigating factors which could be relied upon to downgrade conduct that should otherwise be assessed to be serious misconduct or mismanagement so that the conduct did not meet that threshold of seriousness.

What key factors should be considered when concerns arise regarding serious misconduct or mismanagement?

2.12 Providers are invited to note the following points:

- The relevant matters can arise in the director's current role, in a former role within the provider's organisation, when the director carried out any role where he or she was concerned with a service which is regulated by CQC or which, if provided outside the UK, would be a regulated activity if the activity was carried out within the UK;
- Allegations about a director's conduct whilst engaged in any other type of business or non-business activity is not relevant for Regulation 5(3)(d), but it is likely to be relevant to the director's good character (Regulation 5(3)(a)) and/or his or her competence, skills and experience (Regulation 5(3)(b));
- A director's conduct comes within Regulation 5(3)(d) if he or she has been "responsible for" serious misconduct or mismanagement, namely that he or she was one of the decision makers that led to the serious misconduct or mismanagement;
- A director's conduct comes within Regulation 5(3)(d) if he or she has "contributed to" serious misconduct or mismanagement, namely where the director was not one of the lead decision makers that led to the serious misconduct or mismanagement but where, by action or omission, the director took some significant step or steps to assist the lead decision makers who were responsible for that misconduct or mismanagement;
- A director's conduct comes within Regulation 5(3)(d) if he or she has "facilitated" any serious misconduct or mismanagement, namely that he or she took steps or failed to take steps which he or she ought to have taken which enabled those primarily responsible for the misconduct or mismanagement to carry out the acts or omissions which constituted the serious misconduct or mismanagement;
- A director's conduct also comes within Regulation 5(3)(d) if he or she has been "privy to" serious misconduct or mismanagement, in that the director was aware that misconduct or mismanagement was happening in an organisation and failed to respond to that knowledge by acting in an appropriate manner. An appropriate response to serious misconduct or mismanagement will depend on the circumstances and the internal governance arrangements of the organisation in which the director worked, but it could include:

- drawing the serious misconduct or mismanagement to the attention of an appropriate senior member of staff;
- o making a formal complaint;
- drawing the serious misconduct or mismanagement to the attention of a suitable person outside the provider's organisation;
- Providers would be entitled to conclude a director had been "privy to" serious misconduct or mismanagement if the director knew sufficient details of that misconduct or mismanagement (or the circumstances was such that it is reasonable to conclude that the director ought to have known of that mismanagement or misconduct) to require appropriate action by the individual and failed to take any appropriate action in a timely manner.

2.13 Providers will be expected to follow the procedure set out in below paragraphs [4.1 to 4.8] in section D when assessing whether the behaviour of the director in question amounts to serious mismanagement or misconduct.

C. Good character

What is good character?

3.1 There is no statutory guidance as to how 'good character' in regulation 5(3)(a) of the 2014 Regulations should be interpreted.

3.2 However, the following are some of the features that are normally associated with 'good character':

- Honesty;
- Trustworthiness;
- Integrity;
- Openness (also referred to as transparency);
- Ability to comply with the law.

3.3 To consider that a director is of 'good character' the registered provider should be able to regard the director as a person in whom the provider, CQC, people using services and the wider public can have confidence, and who will comply with the law.

What must a provider take into account when assessing 'good character'?

3.4 Providers <u>must</u> have regard to the following matters specified in part 2 of schedule 4 to the 2014 Regulations when assessing whether a director is of good character:

• Convictions of any offence in the UK;

- Convictions of any offence abroad that constitutes an offence in the UK; and
- Whether any regulator or professional body has made the decision to erase, remove or strike-off the director from their register.

What other things should a provider look for in assessing good character?

3.5 When making decisions about character, providers would also be expected to consider:

- The prior employment history of the director, including the reasons for leaving;
- Whether the director has ever been the subject to any investigations or proceedings by a professional or regulatory body;
- Whether the director has ever breached any of the Nolan Principles of Public Life;
- Whether the director has ever breached any of the duties imposed on directors under the Companies Act;
- The extent to which the director has been open and honest with the provider;
- Any other information which may be relevant, such as disciplinary action taken by an employer.

3.6 Providers will be expected to follow the procedure set out in below paragraphs [4.1 to 4.8] in section D when they receive information or an allegation that a director is not of good character.

D. Procedure for assessing compliance with the regulation

How does the registered provider carry out an assessment?

4.1 Where a provider receives information or an allegation that a director is or may be unfit, the regulated provider will need to carry out a 2 stage process, namely:

- 1. Establish the primary facts of any matter giving rise to a concern about the director by a fair and proportionate process ("the Investigation Stage").
- 2. Having established the primary facts, make an assessment as to whether the facts establish that the director comes within any of the categories in Regulation 5(3) ("the Assessment Stage").

The Investigation Stage

4.2 There may be occasions where there is a dispute about the relevant facts, with different accounts given by different individuals. The provider needs to conduct a sufficiently thorough investigation before reaching a decision as to whether any relevant facts can be established or not. The provider should consider facts proved if, after a reasonable investigation, the

provider considers that it can decide that it is more likely than not that the fact is proved. When undertaking this investigatory process, providers should ensure that they follow their own HR policies (including those governing disciplinary proceedings).

4.3 In some cases, the role performed by a director within the organisation may mean that an external decision maker is appropriate either to undertake an impartial investigation to establish the primary facts or to carry out an impartial assessment as to whether the director comes within one of the categories in Regulation 5(3). The identity of the external decision maker should be carefully considered and their independence should be specifically assured.

4.4 If the concerns are about the director's conduct with another employer, the provider will need to make sufficient attempts to obtain the relevant information from the previous employer(s) and others to establish the primary facts as clearly as is reasonably possible. Furthermore, unless there are very special circumstances, all information gained regarding the director should be shared with the director concerned so they have an opportunity to comment on it before a decision is made about the primary facts of the incident(s).

4.5 However, documentary evidence is not necessary before a "fact" can be established. If the provider receives evidence from someone who saw or heard relevant matters, that can be evidence to support a factual conclusion even if no contemporaneous record was made of the incident. Hearsay evidence can be relevant but providers should exercise caution before making decisions solely based on hearsay evidence and should consider carefully what weight to give to such evidence where there is a conflict of evidence.

The Assessment Stage

4.6 Once a provider has established the primary facts, it will need to decide whether those facts bring the director within any of the categories set out in Regulation 5(3) of the 2014 Regulations.

4.7 If the provider concludes that the primary facts do bring the director within Regulation 5(3), the director <u>must</u> be relieved of his or her directorial responsibilities. If the primary facts do not bring the director within Regulation 5(3), the provider is not required to relieve the director of their directorial responsibilities (although the facts as found by the investigation may still lead the provider to take any other form of disciplinary action or recommend further training or support for the director).

E. Enforcing the regulation

How will CQC enforce the regulation?

5.1 When there is information of concern regarding the fitness of a director CQC will share this information with the provider. The response from the provider will need to satisfy CQC that a robust process has been followed to ensure the fitness of the director or will lead to a request for further dialogue with the provider, a follow-up inspection, or regulatory action.

5.1 When a provider is unable to demonstrate that it has undertaken the appropriate checks when appointing directors, be that externally or through internal promotion, this may potentially be a breach of regulation. We will use our Enforcement Policy to decide whether there is a breach of the regulation and, if so, what regulatory action to take.

5.2 In the case of a new aspirant registrant we will refuse the registration if the provider is unable to satisfy us that appropriate checks have been undertaken in line with best practice.

Further details on how CQC will enforce the regulation are available on the website at:

http://www.cqc.org.uk/content/regulation-5-fit-and-proper-persons-directors

How to respond to this consultation

Online

Use our online form at: www.cqc.org.uk/nextphase

By post

Send your response to: Freepost RTTE-JTBT-ZTHH Next Phase Consultation Care Quality Commission 151 Buckingham Palace Road LONDON SW1W 9SZ

For enquiries about this consultation, please email: **nextphase@cqc.org.uk**

If you would like a summary of this document in another language or format, or you have general queries about CQC, you can:

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