A new start

Consultation on changes to the way CQC regulates, inspects and monitors care services

Initial regulatory impact assessment

This Initial Regulatory Impact Assessment has been published to support the proposals contained within the consultation document on CQC's new approach to inspection and regulation. Stakeholders should read this document in full before reading this impact assessment.

This document sets out the initial high level cost and benefit impacts on providers, people and CQC as a basis for starting further engagement with stakeholders throughout this consultation process.

Introduction

The Care Quality Commission (CQC) is committed to making sure it carries out its statutory duty in a way that puts people who use services at the centre of their work. Part of this process includes learning from past actions and changing their current approach to the monitoring, inspection and regulation of providers in order to remain fit for purpose.

The Mid Staffordshire NHS Foundation Trust Public Inquiry identified that people and their families were let down at every level by the individuals and organisations that were meant to protect and care for them. The inquiry uncovered examples of appalling care and a lack of compassion, humanity and leadership. Robert Francis' report on the public inquiry made recommendations for the commissioning, supervisory and regulatory bodies, including CQC.

CQC is committed to rolling out a number of key changes to the way it regulates and inspects providers, including addressing key recommendations made in the Francis Report. CQC's initial thinking around how it could implement some of the changes can be found in the main consultation document, which also includes high level proposals for comment from stakeholders.

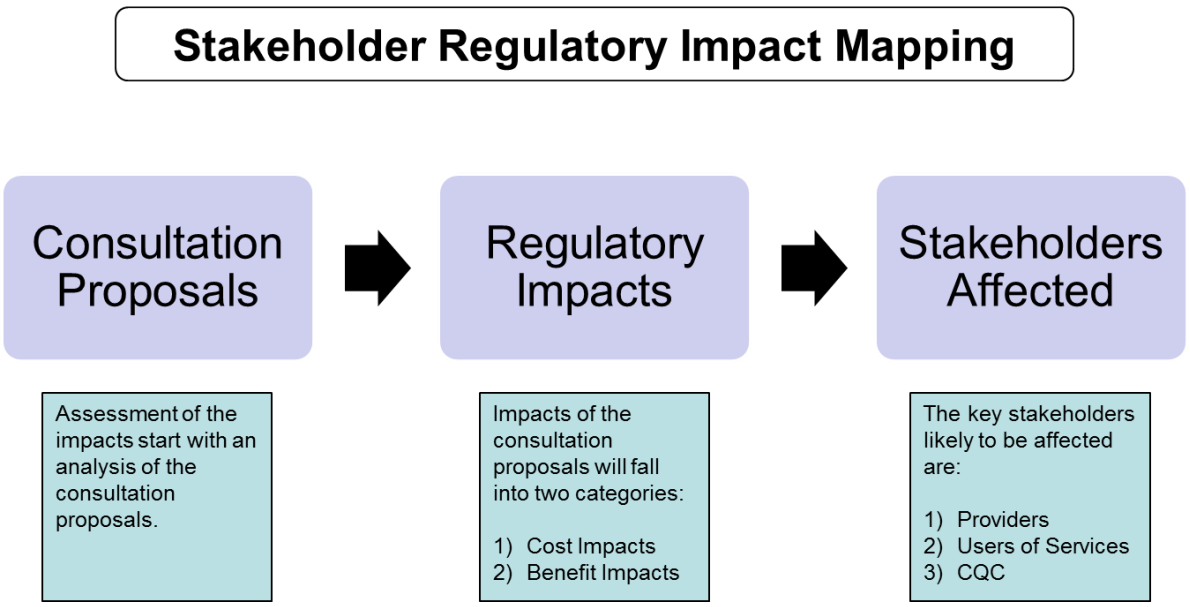
This impact assessment has been designed to accompany the consultation paper and acts as a systematic initial assessment of the impact of the proposals outlined in the consultation paper. Before you read this paper you should read the full

consultation paper, which can be downloaded from:
www.cqc.org.uk/inspectionchanges

Purpose of this Initial Regulatory Impact Assessment

The purpose of this initial impact assessment is to help identify the practical impact of the draft consultation proposals on stakeholders. It aims to engage stakeholders in determining the impact on them, with a plan for this analysis to influence the design of the final proposals. Figure 1 below illustrates the high level process by which we plan to assess these impacts and who these impacts are likely to fall on:

Figure 1: Stakeholder Regulatory Impact Mapping of Consultation Proposals



At every stage of the analysis there are likely to be changes to the impact of the proposals of CQC's new inspection and regulatory regime. A key purpose of this initial impact assessment is to help identify where the potential impacts of CQC's proposals are likely to fall, as well as their anticipated scale and magnitude on stakeholders.

It should be made clear that the illustration of the cost and benefit impacts within this initial impact assessment are 'high level' estimates. CQC plans to roll-out a larger programme of engagement with stakeholders to fully assess these costs and benefits. CQC will provide more details of this in the coming months.

The ultimate aim of this engagement is to influence the design and implementation of the final regulatory model. It also satisfies an aim of the government's Better Regulation Executive (BRE) to trial a new method aimed at improving engagement with the sector so that those affected provide CQC with their own assessments of the likely costs and benefits.

Proposals and Impacts for the new CQC regulatory model

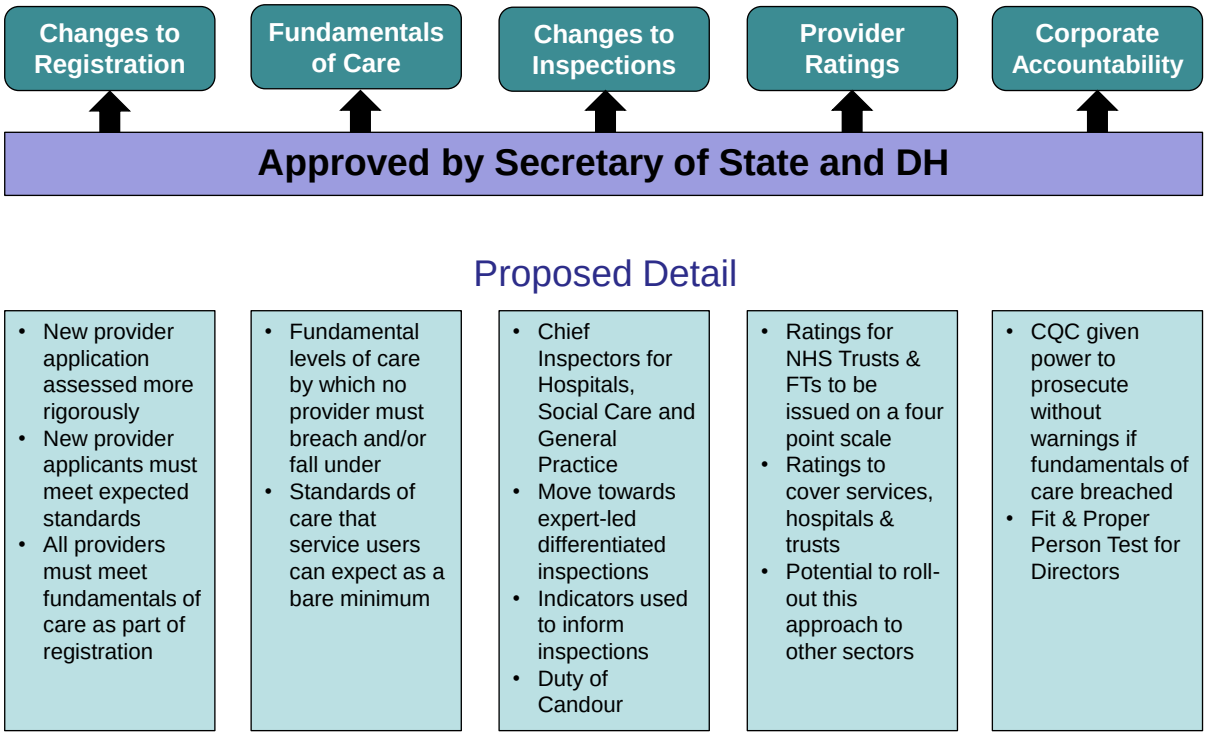
In this section CQC provides a brief summary of the proposals for its new approach to monitoring, inspection and regulation, and a brief description of who these proposals apply to, as well as how stakeholders may be affected by these. Stakeholders should refer to the main consultation document if they require a fuller description and rationale for these proposals.

Stakeholders should note that because CQC has firmly committed to implementing these key changes, this impact assessment focuses on the implementation of these changes so that it maximises the positive outcomes for people, while also minimising any regulatory burden on providers from the way CQC administers these changes. It is the proposed content of these key changes that CQC asks stakeholders to comment on, so that they can shape the formation and roll-out of these key changes in a way that achieves these ends.

Unless otherwise stated, the following proposals will generally affect all providers who fall under CQC's regulatory remit. However there will also be some distinct differences to the way CQC will apply these changes by sector to take into account of differences.

Figure 2 below summarises initial high level proposals around five core policy areas to which CQC is firmly committed:

Figure 2: Summary of agreed changes and proposals for content



Key change: Introducing changes to registration

CQC will introduce a number of registration changes which aim to make sure the registration process is more rigorous.

Rationale
This was agreed by the Department of Health (DH) in *DH Winterbourne Review Condordat: Programme of Action.* It helps to make sure that providers who are unlikely to provide an acceptable level of care are not allowed to hold a CQC registration.

Proposals
CQC proposes that the registration process will be more rigorous for all new providers wishing to be registered, as well as existing providers wishing to register additional services. This will include making better use of information as part of the registration process and drawing in specialist clinical or professional advice where needed to help assess if the service meets accepted good practice.

We propose to assess new providers against a set of expected standards of care as well as ensure that all providers (both current and new) continue to comply with the fundamentals of care and the broader registration requirements.

The Department of Health will develop the new registration requirements and will hold a separate consultation relating to these in the coming months.

Who is affected?
The introduction of these registration changes will affect all new providers wishing to be registered by CQC, as well as existing providers wishing to register additional services.

How are they affected?
Under these proposals we would expect there to be additional costs for new providers applying to be CQC registered. In some cases this more rigorous test may mean a small number of potential entrants will not be allowed into the sector to provide specific services or others might be delayed in making their entrance to the sector. Existing providers wishing to register additional services could face increases in cost depending on the amount of information required at the point of application.

Costs to CQC are likely to increase as it will spend more time scrutinising applications to make sure business models are robust and that the provider is likely to provide an acceptable level of care so as to not breach fundamentals of care once registered. These costs could increase for CQC if it refers applications to specialists when a decision cannot be made.

People are likely to be the key beneficiaries of these registration changes as only new providers who meet the new requirements will be able to provide services – this could correspond to better services and increases in quality of care from such new entrants. People will also be able to gain more clarification on what would be

expected from providers based on core fundamentals of care and expected standards imposed on such providers.

Key change: Introducing fundamentals of care

CQC will introduce fundamentals of care which make explicit the level of care which no provider must breach. These will be universal to all providers registered with CQC who provide health and adult social care services. Fundamentals of care are part of the registration requirements. They are the foundation of good care but not the extent of good care.

Rationale
This was agreed by the Secretary of State and the Department of Health in its response to the Francis Report. Introducing fundamentals of care should facilitate providers understanding of what is and is not expected of them in relation to their provision of care services.

Current proposals
Fundamentals of care set out the basic standards of care that should never be breached; any breach should be seen as unacceptable. CQC will make sure they are driven by the interests of people who use services. Should a provider be found to be breaching any of these fundamentals of care, CQC will have formal powers to take action, including prosecution in the worse cases of poor care delivery. The Department of Health will be consulting on these standards in the coming months.

Who is affected?
The introduction of a set of fundamentals of care will apply to all providers that fall under the remit of CQC.

How are they affected?
All providers will need to comply with these fundamentals of care. It is anticipated that these will not impose additional costs on the majority of providers, as those who already deliver an adequate level of care should currently be meeting these standards. However, there could be additional costs to the worst performing providers in the form of enforcement action, which could range from warning notices instructing providers to improve, to fines and in the worst case revoking the provider's registration with CQC.

There are likely to be minimal costs to CQC as a result of the introduction of fundamentals of care. The likely costs would stem from the development of guidance and approaches to monitoring compliance with these fundamentals of care. However, there could be variable cost elements as a result of taking enforcement action depending on how many providers have breached these fundamentals.

Both people and providers are likely to benefit from the introduction of fundamentals of care. For example, people would have a clearer understanding of what to expect from providers in terms of fundamental safety and quality of care. Similarly providers

should benefit from having greater clarity on what is expected of them, as well as having concrete knowledge as to the level that quality of care must not fall.

Key change: CQC's new model of inspection

CQC's inspection model will change to take into account the differences in the sectors that are regulated by them. CQC will move towards a system of differentiated regulation which will include different ways of inspecting different sectors.

Rationale
CQC has listened to external scrutiny and reviews of its work such as the Kieran Walshe evaluation work and recognised the importance of regulating different sectors in different ways.

Proposals
CQC will appoint three Chief Inspectors to oversee the different sectors that fall under their remit. These will be:

- Chief Inspector of Hospitals
- Chief Inspector of Social Care
- Chief Inspector of General Practice .

The Chief Inspectors will be responsible for forming judgments about the quality of providers, devising and operating a new risk-based, intelligence-driven inspection model, managing the delivery of inspections and acting as the CQC's public face and authoritative voice on the status of care quality within and across providers.

CQC also propose to move away from generalist inspections and towards inspections that are expert-led and by inspectors who specialise in particular service areas. This will be supported by the development of a revised intelligence risk model which will help to identify those organisations at greatest risk of delivering poor quality care. We will make use of data and information and develop key indicators which will help to facilitate the conditions under which CQC will inspect organisations of different risk and their subsequent performance under the proposed inspection regime. These proposals will all contribute to CQC's aim of moving to a system of differentiated regulation, achieved in part by making such changes to the way they inspect different sectors that fall under their regulatory remit.

Who is affected?
CQC's new model of inspection will apply to all providers that fall under its regulatory remit. NHS and independent hospitals services will be impacted by the work of the Chief Inspector of Hospitals. Providers of adult social care will come under the scrutiny of the Chief Inspector of Social Care, as will primary medical services be affected by the Chief Inspector of General Practice.

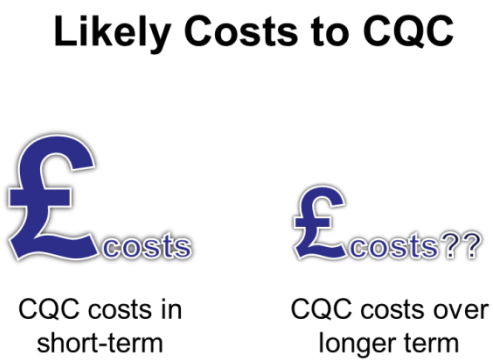
How are they affected?
Costs will heavily depend on how the inspection methodology develops. For example, if the inspection model determines a provider is to have double the number

of inspections in three years than it currently has then costs to providers (and CQC) will also rise. Figure 3 illustrates the costs providers are likely to face depending on judgement by the Chief Inspectors (note that the categories are purely for illustrative purposes are likely to change based on any methodology proposed by the Chief Inspectors):

Figure 3: Differences in costs to providers based on Chief Inspector judgement

CQC will face higher initial costs associated with carrying out these longer more intensive inspections. There could also be costs associated with transitioning towards expert-led inspections in the form of training costs and establishing access to wider expertise. Figure 4 illustrates the costs to CQC which shows that short-term costs are likely to be higher than longer-term costs (this assumes that the level of standards do not change):

Figure 4: Differences in short-term and longer term costs to CQC



People are likely to be the key beneficiaries as these differentiated ways of inspecting different sectors should reduce instances of poor quality care and bad practice as these are more quickly picked up and dealt with.

Key change: Introduction of ratings

CQC will introduce a series of provider ratings which will help inform both patient choice and commissioning decisions.

Rationale
The Care Bill re-introduces legislation from the Health and Social Care Act 2008 which will allow CQC to publish ratings for health and social care providers. This builds on the work carried out by the Nuffield Trust in, *Rating Providers for Quality: a policy worth pursuing? (March 2013)* and sets out advice on a rating system for hospitals, care homes, providers of home care and GP practices.

Proposals
Ratings will be an expression of CQC's regulatory judgments with the purpose of encouraging improvement and supporting people who use services and commissioners to compare services and make choices. To achieve this CQC will publish provider ratings on their website, giving clear and transparent rationale for our judgments.

CQC plans to consult with stakeholders in the coming months on the detailed methodology for creating ratings for all NHS trusts and proposals for CQC's approach to adult social care ratings.

Who is affected?
In time, the introduction of a set of ratings should apply to all providers of health and adult social care. For now, we will begin with rating NHS acute trusts and aim to introduce new style inspections from October 2013. These inspections will allow CQC to begin publishing shadow ratings from December 2013.The programme will extend to all NHS trusts over time and begin rating adult social care later in 2014/15 and primary care in 2015/16. Ratings may also be extended to dental practices and cosmetic businesses in future.

How are they affected?
It is estimated that there would be some additional costs on these providers to comply with an initial inspection in order to establish a preliminary rating on the provider. It is also anticipated that there will be some additional costs on such providers for providing any information to CQC that would aid any decision in producing a rating.

Commissioners and people who use services are likely to be the key beneficiaries of provider ratings as a key objective of this policy would be to support informed choice. For commissioners, ratings would offer the key benefit of better understanding of the quality of service, and the outcomes they are commissioning, when deciding how much of their budget to spend with specific providers. For people who use services, the introduction of a provider rating would better support making informed choices between providers, which should hopefully help to raise the quality bar amongst different providers. There are also some benefits to providers as the introduction of ratings would help facilitate peer-review and benchmarking so they can see how they

are performing in comparison to others and identify areas where they might want to improve.

Key change: Corporate Accountability Proposals

There will be more of a focus to hold providers to account for failing to honour their commitments to provide safe quality care.

Rationale
Subject to the passing of the Care Bill, CQC will be granted a range of new powers from April 2014 which will help facilitate the development of any actions aimed at holding providers to account should they not be providing an acceptable level of care.

Proposals
We plan to specifically hold Board Members to account should the provider not be providing an acceptable level of care. We would also expect all directors to be "fit-and-proper" as well as ensuring that providers are open and honest with people who use the service and their families about things that have gone wrong and why they happened.

The Department of Health will shortly consult on the accountabilities of the Board members in parallel to the consultation published alongside this initial Regulatory Impact Assessment.

Who is affected?
All directors and board members of providers will be affected if they come under CQC's regulatory remit.

How are they affected?
We do not anticipate there to be any additional to costs to providers if they currently provide an acceptable level of care to patients. However, board members and directors who are held responsible for any care quality failings could be impacted financially should they be removed from posts. Such organisations could face greater scrutiny and will likely see their costs increase should CQC decide to take any actions, such as prosecution, associated with the care quality failings.

CQC, users of services as well as their families are likely to be the key beneficiaries of these proposals. For CQC we would likely benefit from a reduction in quality failings stemming from poor direction from board directors. Users of services should benefit as swifter action is taken against senior management for any user subject to poor quality care, and should also act as a deterrent to other providers which could help bring the level of care up to an acceptable standard.

Changes specific to acute hospitals provided by the NHS and independent organisations

In this section we set out the high level cost and benefit impacts of the proposed changes on stakeholders that will only apply to acute hospitals provided by the NHS and independent organisations.

Chief Inspector of Hospitals

The Chief Inspector of Hospitals will undertake a number of duties that are likely to impact on stakeholders. Specifically these are:

- Judging the performance of all hospitals in England, including NHS hospitals and independent sector hospitals.
- Publishing ratings on hospitals.
- Playing a central role in the assurance that the fundamental standards are being met by all trusts. Where trusts are in breach of these standards, the Chief Inspector will determine what action should be taken, including whether a trust is entered into a failure regime.
- Leading a new national NHS inspection team that will undertake in-depth, intensive inspections; the principal focus of these inspections will be on organisations that are of concern to CQC.
- Leading regional teams of dedicated inspectors who will undertake routine inspections on a regular basis of all hospitals/NHS trusts.
- Responsible for overseeing the development of a methodology for inspections, the operational delivery of the inspection programme, and for raising the quality of the inspections that are performed so that they are able to properly identify areas of concern and issues of compliance.
- Working closely with NHS England, Monitor, the NHS Trust Development Authority and the NHS Information Centre for Health and Social Care to determine the sets of data which will be used to contribute to judgements and ratings about hospitals and NHS trusts.

How are acute hospitals likely to be affected by these proposals?

It is not possible to assess what the size and scale of the impacts are likely to be on acute hospitals at this stage, however there are likely to be a number of costs around the following themes including:

- Information provided to the Chief Inspector to facilitate any of the proposals above.

- Any costs should providers be found in breach of any of the fundamentals of care in order to take action to meet these standards and that this effort is maintained in the future.

NHS acute trusts, foundation trusts and independent organisations providing acute services are encouraged to consider their own assessments of the likely impacts of the proposals outlined above. In the coming weeks we will be holding a series of engagements with stakeholders to fully assess the likely impacts of these proposals.

The surveillance model – developing risk indicators for NHS trusts and foundation trusts (FTs)

The surveillance model is being developed with the core purpose of developing a series of risk indicators for NHS trusts and FTs which aims to identify providers most at risk of providing poor quality care or breaching fundamental standards. The proposals likely to have impacts on stakeholders include:

- Developing a model which allows CQC to anticipate and respond more quickly to services where standards are dropping or that are showing signs of failing.
- Developing a series of indicators and intelligence for the model based on three tiers:
    - Tier 1: signalling a decline in quality or immediate concern will prompt a response by CQC.
    - Tier 2: checked if tier 1 indicators signal concern. Used to help understand the issues raised and to focus key lines of enquiry.
    - Tier 3: development set of indicators and analysis which will be used to test and improve sets of indicators that CQC have in tier 1 and 2.
- Trialling the model for NHS acute trusts to identify the indicators for each of the five domains. This will include scoping the key quality and safety issues for the sector and identifying available data to measure these. This approach will subsequently be applied to NHS mental health trusts, community health trusts and ambulance trusts in future.

How are acute hospitals likely to be affected by these proposals?

All acute hospitals will directly be affected by these proposals. The single biggest cost impacts to such providers could be associated with providing and collating information requests which would help inform the development and monitoring of these three tiers of indicators and intelligence contained within the proposed model. There could also be IT and other system and process costs associated with capturing the information which would differ depending on the trust.

There will be benefits to users of services as the surveillance model should be able to detect potential problems associated with the provision of care services, which will allow swifter action to be taken by inspection teams via instruction from the Chief Inspector of Hospitals.

NHS acute trusts, foundation trusts and independent organisations providing acute services are encouraged to consider their own assessments of the likely impacts of the proposals outlined above. In the coming weeks we will be holding a series of engagements with stakeholders to fully assess the likely impacts of these proposals.

The inspection methodology for acute NHS and independent hospitals

The current inspection model will change to take into account the differences within the different sectors that CQC regulates. The proposals likely to have impacts on NHS trusts are:

- A move to target intensive inspections at organisations that are identified as 'higher risk' which would include those with significant or longstanding problems and trusts applying to become foundation trusts.
- A change in the average length of time taken to undertake an inspection – which could be 15 days, with an average of 6-7 days on site – to make a thorough assessment of the quality and safety of care.
- A development of a set of triggers for inspections which would identify which providers would need an intensive inspection, as well as development of any methodology leading to the decision to undertake an announced or unannounced inspection.

How are acute hospitals likely to be affected by these proposals?

We will be carrying out a fuller consultation on proposals for CQC's inspection methodology later in the year. However, it is likely that acute hospitals who fall under CQC's intensive inspection regime will face higher costs relating to increases in staff time spent providing information and supporting the inspection team. Costs could also increase in proportion to the number of inspections taken place, as well as any costs associated with having to take actions based on the recommendations put forward in the inspection report.

NHS acute trusts, foundation trusts and independent organisations providing acute services are encouraged to consider their own assessments of the likely impacts of the proposals outlined above. In the coming weeks we will be holding a series of engagements with stakeholders to fully assess the likely impacts of these proposals.

Acute NHS and FT ratings

We will introduce ratings for all NHS acute trusts and FTs starting with the publication of ratings for these trusts from December 2013 over a two-year period. The proposals likely to have impacts on NHS trusts and FTs are:

- Ratings for NHS trusts are made at domain, service, hospital and trust levels.
- Ratings to be awarded on a four-point scale, ranging from trusts which are classified as “Outstanding” to Inadequate” because they have either breached a fundamental standard and/or many services are not meeting quality standards.
- Frequency of subsequent ratings reviews to be determined by the first initial rating (which sets the benchmark for the provider in question). Higher rated trusts will have less frequent inspections, in the absence of any concerns raised by surveillance.
- All trusts to be under intelligence based surveillance that can trigger inspections at any time which may lead to a change in their rating.

How are NHS trusts and FTs likely to be affected by these proposals?

We will be carrying out a fuller consultation on proposals for the development and roll-out of ratings for NHS trusts and FTs later in the year. However it is highly likely that providers who are given “good” or “outstanding” ratings are likely to face less cost impacts than providers who don’t meet the criteria to be awarded these ratings. Costs could also increase in proportion to any review that lowers a provider’s ratings, as costs will decrease in relation to a trust improving its rating through better performance.

Acute NHS trusts and foundation trusts and independent organisations providing acute services are encouraged to consider their own assessments of the likely impacts of the proposals outlined above. In the coming weeks we will be holding a series of engagements with stakeholders to fully assess the likely impacts of these proposals.

Introduction of a single failure regime

NHS trusts and FTs who continue to perform badly will be subject to a single failure regime, the details of which will be developed in partnership with Monitor and the NHS Trust Development Authority (NHS TDA). Our initial proposals that are likely to impact on NHS trusts are:

- Provision of a new formal notice which is underpinned by legislation (subject to the passing of the Care Bill) which will require the board of the NHS trust or

foundation trust with its commissioners to improve if CQC thinks significant improvement is required in the quality of care provided.

- Referral of the trust to Monitor or the NHS TDA to take the appropriate action if the trust fails to achieve the necessary improvements – this could mean Monitor or the NHS TDA bringing in expert clinical support to make the improvements.
- If care still fails to improve, the Chief Inspector, through the CQC, will be able to direct Monitor or the NHS TDA to appoint a special administrator, suspending the board of the trust as a result.

How are NHS trusts and FTs likely to be affected by these proposals?

Only NHS trusts who enter the integrated failure regime will face cost implications, which is assumed to be a small minority. These costs will depend heavily on the type of enforcement action, or sanctions, placed on the NHS trust but are likely to stem from making the necessary improvements for alleviating poor performance and/or the production of any turnaround plan should one be requested. CQC will be consulting on their use of enforcement powers separately, the results of which will contribute to the development of the integrated failure regime.

Acute NHS trusts and foundation trusts are encouraged to consider their own assessments of the likely impacts of the proposals outlined above. In the coming weeks we will be holding a series of engagements with stakeholders to fully assess the likely impacts of these proposals.

Next steps

The information on likely cost and benefit impacts contained within this initial regulatory impact assessment are preliminary and likely to change in the coming months as proposals are worked up more fully. CQC plans to hold a series of engagements in the coming months to further quantify the effects of these proposals on stakeholders. More information on this will be provided at a later stage.