



Department
of Health

New regulations to expand the scope of performance assessments of providers regulated by the Care Quality Commission (December 2017)

Response to the Consultation

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Ministerial Foreword



A core theme in the Government's response to The Francis Report (Report of the Mid-Staffordshire NHS Foundation Trust public inquiry) was the need for greater transparency about the quality and safety of health and social care services. This is why, through the Care Act 2014, the Government placed a duty on the Care Quality Commission (CQC) to carry out and publish ratings of providers of health and adult social care. We intended these ratings to be easy for people who use services, their families and carers, to see and understand, while also providing a reliable assessment of a provider's performance. This is the second of two sets of changes this year to expand the scope of ratings to other sectors, grounded in CQC's experience in applying ratings since 2014.

When ratings were first introduced by the Care Quality Commission (Reviews and Performance Assessments) Regulations 2014, the focus was on ensuring that the CQC provided ratings for those sectors where a rating would have the most benefit. This was initially limited to NHS Trusts and NHS Foundation Trusts, GP practices, adult social care providers and independent hospitals.

I announced the first changes in September, to apply ratings to six additional types of service. This second set of changes places a duty on the CQC to rate all providers of regulated activities, apart from a short list of excluded services. This will give the public more transparency about the quality and safety of services than ever before. The excluded services are those that are already rated by another regulatory body, are very small in number meaning the public has limited choice, or are relatively low-risk with limited frequency of inspections that would not be adequate for ratings.

The way care is provided is changing and will continue to do so, with emerging technologies, new care models with services more focused on patient experience and service boundaries no longer a barrier. This simplified duty to produce ratings is designed to be flexible enough to cope with changes to services. It will mean that in future there will be less need to make changes to regulations to respond to new types of services and care models.

We consulted on this proposal between September and November this year. This document summarises what we heard and the regulations we will be bringing forward as a result.

Philip Dunne MP

Minister of State for Health

Policy Background

1. Section 46 of the Health and Social Care Act 2008 (as amended by the Care Act 2014) places a duty on the Care Quality Commission (CQC) to carry out reviews, and assess and publish a report of its assessment, of the performance of providers of health and adult social care services. The assessment must be by reference to indicators of quality devised by the CQC and is provided by the CQC in the form of a rating - 'Outstanding', 'Good', 'Requires Improvement' or 'Inadequate'.
2. The purpose of a CQC rating is to provide the public with a clear, authoritative summary of the quality and safety of a health or social care provider's services. Where choice exists between providers, a rating can help the public in exercising that choice in an informed way. A rating also provides the public with a clear summary about how their local services are performing, and when combined with the detailed inspection report provides a means through which the public, service commissioners and other stakeholders can challenge providers to improve.
3. The CQC began publishing ratings in October 2014; however this has been limited to NHS Trusts, NHS Foundation Trusts, GP practices, adult social care providers and independent hospitals.

Consultation on rating additional providers

4. In August 2016, we consulted on proposals to expand the scope of the CQC's duty to extend performance assessments and ratings to a variety of additional providers who carry out regulated activities, namely:
 - Independent Community Health Service Providers
 - Cosmetic Surgery Providers
 - Independent Ambulance Services
 - Independent Dialysis Units
 - Refractive Eye Surgery Providers
 - Substance Misuse Centres
 - Termination of Pregnancy Providers
5. Following that consultation, we wanted to progress the changes we had consulted on but we had concerns that we had failed to engage certain types of providers, for example some of those falling under the umbrella of 'independent community health service providers'. We therefore introduced regulations changing ratings for all the services we had consulted on but left 'independent community health service providers' out of the first set of regulatory changes.
6. Whilst considering the changes to the ratings regulations, the Department of Health and the CQC have come to the view that it would be beneficial to broaden the scope of the CQC's rating regulations so that with some exceptions, all providers of regulated activities are rated.

This would bring (amongst others) independent community health service providers and independent doctors within the scope of the ratings regulations.

7. There will be some exceptions as set out in the section headed 'Our Approach'. However, the small number of registered service providers that are excluded from ratings will still be regulated by the CQC against the fundamental standards of care and subject to inspection.

Broadening the scope of ratings regulations

8. In our consultation 'New proposal to expand the scope of performance assessments of providers regulated by the Care Quality Commission (September 2017)', we proposed further regulations to bring into the ratings regime the following service types, which were the subject of the previous consultation and are currently only within scope if they are carried out by the providers referred to in paragraph 4.
9. This document sets out our proposal following this second consultation to expand the scope of the CQC's duty to undertake performance assessments and rating of all providers of regulated activities with the exception of a small number of exclusions.
10. Section 46 of the Health and Social Care Act 2008 (as amended by the Care Act 2014), allows the Secretary of State for Health to make regulations to require the CQC to carry out periodic performance assessments of the carrying on of regulated activities by all health and adult social care providers or such as are prescribed.
11. When ratings were originally introduced, delivering assessments for all providers in health and social care was a significant undertaking for the CQC, as they had to develop different methodologies for many different sectors in a short space of time, re-train their staff and create a number of quality assurance systems to ensure ratings were fair and proportionate.
12. The Government wanted to avoid overloading the CQC at that time. Therefore the Care Quality Commission (Reviews and Performance Assessments) Regulations 2014 limited the providers and activities to be rated to those listed in paragraph 3. This was to enable the CQC to focus its reviews and assessment on those providers where choice was more relevant to people and where risk was perceived to be higher. This approach enabled CQC to develop and test its methodologies for those sectors, to ensure its approach was robust before scaling up.

What are the ratings intended to achieve?

13. As we explained in our consultation document, the purpose of a CQC rating is to provide the public with a clear, authoritative, 'at a glance' summary of the quality and safety of a health, or social care, providers' services. A rating is intended to provide the public and commissioners with a clear starting point when it comes to making an informed decision about the services they choose or commission. For service commissioners and other stakeholders, ratings, combined with the detailed CQC inspection report provides the means to challenge providers to improve. Overall, it is intended that ratings will drive greater

competition between providers and ultimately result in the delivery of better quality of care and more responsive service for the public.

Our Approach

14. The intention of this approach is to extend the scope of the CQC's duty to assess and rate most regulated providers except for a small number of exclusions we describe below. We have proposed these exclusions because either:
- The number of providers is so small that ratings would not contribute to consumer choice;
 - The service providers are already regulated by other agencies so a CQC rating could confuse the public;
 - The sector is relatively low risk and is inspected by the CQC too infrequently to make a rating meaningful.
15. However it should be noted that the CQC still have a duty to regulate and inspect any service providing a regulated activity, even if it is excluded from rating.
16. Adopting this exclusion approach also removes the need to continually update the regulations to take account of new types of service provider and new models of care as they arise.

Primary Dental Care

17. Primary care or high street dental practices will be excluded from CQC rating for all services including cosmetic dentistry. All primary dental services will be exempt from rating unless they are provided by an independent hospital, NHS trust or NHS foundation trust.
18. This sector is already regulated by the General Dental Council and the CQC. There is little variation in the regulatory compliance of dental services and the CQC's approach to inspecting this sector is one of focusing on those providers that are highest risk. The CQC currently only inspects approximately 10% of dentists per annum, on a risk and random basis. Such a frequency of inspection would not be adequate for rating and CQC has no plans to increase the rate of inspection for these providers.

Minor Cosmetic Surgery Services

19. Our intention is for cosmetic surgery providers who do not undertake procedures requiring intravenous sedation, general anaesthesia or the insertion of an implant to be exempt from rating. This exclusion will apply to a narrow range of procedures considered to be relatively low risk to the extent that they are a regulated activity, for example the surgical removal of

skin tags or blemishes¹. (However, if such a provider carries out any other regulated activity which is not exempted, they would be rated for that activity and the services which are rated made clear on the report.) Such services are subject to a lower frequency of inspection than other providers in this sector. Such a frequency of inspection would not be adequate for rating and CQC has no plans to increase the rate of inspection for these providers due to the low level of risk.

National Screening Programmes

20. All diagnostic and screening procedures provided as part of a national screening programme by a body established solely for the purpose of such a programme, to the extent that they are regulated activities, will be excluded from rating. Public Health England already has quality assurance processes regarding these services, so we would not wish for the CQC to routinely inspect and rate them. However, Public Health England do not have powers to take enforcement action against these providers and we would need CQC to take action if concerns were raised with them.

Health and Justice Services

21. This is the provision of regulated activities in Prisons, Custody Suites, Secure Training Centres, Immigration Removal Centres, Young Offender Institutions and Sexual Assault Referral Centres².
22. We do not propose to rate services provided by registered providers in these settings because patient choice is extremely limited and as such a rating would be of limited benefit. Also, most of these services are jointly inspected with other bodies so rating by the CQC would be potentially confusing.
23. However, we will continue to rate sexual assault referral services provided in an independent hospital or by an NHS trust or NHS foundation trust or primary medical service.

¹ Curettage, cautery or cryocautery of warts, verrucae or other skin lesions carried out by a medical practitioner are not a regulated activity if carried out without anaesthesia or using a local anaesthetic, nor is the removal of small skin blemishes by the application of heat using an electric current a regulated activity. See paragraph 6(2)(b) Schedule 1 to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

² Sexual assault referral centres are open access one-stop services to help victims of rape or sexual assault, irrespective of age, on the journey to recovery by providing an immediate health and care response with access to criminal justice services, safeguarding services and integrated follow-up. (NHS England; Service specification No. 30 Sexual Assault Referral Centres; Feb 2016)

Hyperbaric Chambers

24. This is the provision of the regulated activity of treatment of disease, disorder or injury by providing hyperbaric therapy i.e. the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber which is gradually pressurised with compressed air.
25. There are very few hyperbaric chambers in England and those in need will access the nearest geographical facility for reasons of urgency. Therefore a rating of this activity will not help the public with decisions they make regarding their care.

Blood and Transplant Services

26. Registered providers of blood and transplant services for which the management of supply of blood and blood derived products, as referred to in paragraph 8 of Schedule 1 to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, if the carrying on of that activity is their sole, main or primary activity, are excluded from rating. Such providers may be registered for other regulated activities. These providers are also very small in number. We understand that only two registered providers (NHS Blood and Transplant and the Anthony Nolen Trust) would fall into this category. There is therefore little value in their being rated, since the public is unable to exercise choice.

Services licenced by the Human Fertilisation and Embryology Authority (HFEA)

27. Some HFEA licensed providers are currently registered with the CQC for the regulated activity of surgical procedures, as they perform surgical egg or sperm collections. However, the carrying out of surgical procedures in connection with any of the activities listed in Schedule 2 (activities for which licences may be granted) to the Human Fertilisation and Embryology Act 1990 and for which a licence has been granted to that person under section 16 (grant of licence) of that Act will continue to be exempt from rating. HFEA licensed providers may carry out other regulated activities which would not be exempt.

Independent pathology laboratories

28. Regulated activity of diagnostic and screening procedures when provided by an independent pathology laboratory solely under a contract for services with another registered service provider is excluded from rating.
29. This activity normally involves testing and analysing blood and tissue samples from patients for the purposes of discovering the presence, cause or extent of disease, disorder or injury

or the use of equipment in order to examine cells, tissues and other bodily fluids for the purposes of obtaining information on the causes and extent of a disease, disorder or injury.

30. Providers of this activity do not normally have any direct contact with patients and do not directly deliver services to patients. Instead, they provide services under contract with and for another registered service provider, such as an NHS hospital or a GP practice.
31. The public are not able to exercise choice regarding such providers. Clinical Pathology Accreditation³ is already in place for these types of services so rating by the CQC would be of little value to the public. However, we do not intend to apply this exemption to an NHS Trust, NHS Foundation Trust, Independent Hospital or a provider whose sole or main purpose is the provision of primary medical services under section 83, 84 or 92 of the NHS Act 2006.

Independent Podiatry Services

32. Orthopaedic foot surgery carried out by a podiatrist or chiropodist, unless provided by an NHS Trusts, NHS Foundation Trusts, provider of primary medical services⁴ or an independent hospital, is excluded from rating.
33. These services which are regulated are relatively low-risk and are subject to a lower frequency of inspection than other providers. Such a frequency of inspection would not be adequate for rating and CQC has no plans to increase the rate of inspections for these providers due to the low level of risk.

Children's homes undertaking regulated activities

34. The majority of children's homes provide some form of health service, ranging from basic first aid to high level health care. However, some of these children's homes offer regulated activities as set out in the Health and Social Care 2008 (Regulated Activities) Regulations 2014. Where this is the case, the provider will need to register with the CQC to ensure that

³ Further information on Clinical Pathology Accreditation, including a search facility for CPA accredited medical laboratories, is available at <https://www.ukas.com/services/accreditation-services/clinical-pathology-accreditation/>

⁴ A provider whose sole or main purpose is the provision of primary medical services under—

- (a) section 83(2) of the 2006 Act (primary medical services);
- (b) section 84 of that Act (general medical services contracts); or
- (c) section 92 of that Act (arrangements by the Board for the provision of primary medical services).

the activities are regulated in the same way as any other healthcare provision, and that they meet essential standards of quality and safety.

35. A small number of providers will therefore need to register both with the Office for Standards in Education, Children's Services and Skills (Ofsted) as a children's home, and with the CQC for the regulated activity they provide under the Health and Social Care Act 2008.
36. For those children's homes that are rated by Ofsted and are registered with the CQC for the provision of regulated activities, additional rating by the CQC would be potentially confusing.

What will happen next?

37. Following this consultation amendments to the Care Quality Commission (Reviews and Performance Assessments) Regulations will be laid in January 2018 and come into force in April 2018.
38. CQC will develop proposals on its approach to the additional sectors that come into scope of its ratings powers, and will consult on those proposals in early 2018. The consultation will include proposals on how CQC will rate the additional sectors that have come into its rating powers and will set out when ratings will be introduced following the consultation. The consultation will also include proposals to develop CQC's approach to regulate and inspect independent healthcare services to bring it into line with the approach to regulating other types of healthcare services in line with the CQC strategy. This includes introducing a more responsive, intelligence-driven approach to regulation, with improved monitoring and inspection activity focused where risk is greatest or quality is improving.

Equality Impact

39. This policy proposal impacts on providers of health and adult social care subject to performance assessment by the CQC, as set out under section 46 and associated regulations under the Health and Social Care Act 2008. The costs will not impact on people who use services, or any group of individuals who use services. The costs to providers of displaying a rating will be small.
40. The general equality duty that is set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:
- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act;
 - Advance equality of opportunity between people who share a protected characteristic and those who do not;
 - Foster good relations between people who share a protected characteristic and those who do not.
41. The general equality duty does not specify how public authorities should analyse the effect of their existing and new policies and practices on equality, but doing so is an important part of complying with the general equality duty.
42. We do not envisage that extending the duty under section 46 to these activities or providers will have an impact on individuals sharing the other protected characteristics under the Equality Act 2010. However, if you do have any concerns that doing so may have an impact in people sharing protected characteristics, we would welcome your comments.

Responses to the Consultation

43. For this consultation, we received a total of 38 complete responses. The consultation ran from 12 September 2017 to 7 November 2017. The consultation attracted responses from a wide range of organisations, including: Royal Colleges, regulators, charitable organisations, professional associations, independent clinicians and members of the public.
44. Where appropriate, we also contacted individuals who had responded to the previous consultation 'Scope of performance assessments of providers regulated by the Care Quality Commission', to alert them of the consultation and to encourage them to reply.

Overall comments on the consultation

45. The majority of responses welcomed the consultation and supported proposals to expand the scope of performance assessments of providers regulated by the CQC. The overall themes from the completed responses were that, these exclusion regulations would:
- Allow the CQC to rate all health and social care providers in respect of the regulated activities offered by providers to ensure care is delivered to the highest standard;
 - Allow the regulation of independent sector providers and independent doctor in a manner that is consistent with fellow NHS providers;
 - Allow the future approach to regulation to be flexible and robust in responding to an evolving health and social care sector.
46. For example, the Royal College of General Practitioners supported the introduction of the regulation by saying:
- “The College is generally supportive of regulation to ensure acceptable standards and promote accountability, whilst addressing long-standing unacceptable performance. Effective regulation should add value to patient care and not distract from the quality of their care.”
47. The consultation also attracted a few concerns. The British Medical Association highlighted that although they believed that the independent sector and independent doctors should be regulated like other NHS providers, the overall performance rating methodology for all providers is too simplistic and cannot adequately capture the complexities of delivering healthcare. The BMA also said:
- “We have significant concerns that a proposal to extend the scope of the CQC’s duty to undertake performance assessments is being considered without any robust evidence being provided by the Department to demonstrate that the ratings already attached to regulated services are being used by patients, their families or representatives to select healthcare providers”

Our response

48. In April 2017, the CQC published a report that was concerned with identifying the impact of their services on the quality of care and overall improvement in health and social care⁵. The report provides evidence which suggests that the CQC ratings do have some influence on the service provider chosen by patients, their families or representatives. The report also contains evidence which would suggest that the CQC ratings can serve as a catalyst for positive change.

Sectors we consulted on

49. In moving to an exclusion approach, there are a small number of registered service providers or regulated activities for which we consider performance assessment and CQC rating to be inappropriate.

50. The Department believes that performance assessment and rating by the CQC should not extend to the following registered service providers and regulated activities. However, they will still be regulated by the CQC against the fundamental standards of care and subject to inspection. The list of exclusions as specified by the regulations, is as follows:

- Primary Dental Care
- Minor Cosmetic Surgery Services
- National Screening Programmes
- Health and Justice Services
- Hyperbaric Chambers
- Blood and Transplant Services
- Services licensed by the Human Fertilisation and Embryology Authority
- Independent Pathology Laboratories
- Independent Podiatry Services
- Children's homes undertaking regulated activities

⁵ CQC, Review of CQC's impact on quality and improvement in health and social care (2017):
<http://www.cqc.org.uk/publications/evaluation/review-cqc%E2%80%99s-impact-quality-and-improvement-health-and-social-care>

Consultation Questions & Results

51. The question list for the consultation was as follows:

- Question 1: What is your name?
- Question 2: What is your email address?
- Question 3: Are you responding as an individual or as part of an organisation?
- Question 4: To what extent do you agree with the statements below?

52. Question 4 had two parts. Individuals and organisations were invited to assess the suitability of two statements with a Likert scale ranging from strongly agree to strongly disagree / not answered.

53. As can be seen from the table below, an overwhelming majority of respondents agreed that it would be appropriate to extend performance assessment and rating by CQC to all but a small number of registered providers as set out by the consultation. 78.95% of the 38 responses agreed that this would be appropriate, with 21% either disagreeing with proposals, not answering or neither agreeing or disagreeing. On the whole, the results would suggest that it would be appropriate for CQC to move to an exclusion approach from its current inclusion one.

Option	Total	Percentage
Strongly agree	16	42.11%
Agree	14	36.84%
Neither	3	7.895%
Disagree	0	0%
Strongly disagree	2	5.263%
Not answered	3	7.895%

54. The second part of question 4 invited individuals and organisations to assess the suitability of the following statement; the criteria we have applied to identify registered providers that would remain exempt from rating are justified and appropriate. 57.9% of the 38 responses agreed that the criterion applied was appropriate, with 42% neither agreeing or disagreeing or disagreeing. The results would suggest that the criteria applied to identify registered providers to remain exempt from rating would be appropriate and justified.

Option	Total	Percentage
Strongly agree	5	13.16%
Agree	17	44.74%
Neither	5	13.16%
Disagree	5	13.16%
Strongly disagree	3	7.895%
Not answered	3	7.895%

55. The main theme from the small number of respondents who disagreed with the proposals was an opposition in principle to excluding services, such as private individual carers, dentists and non-invasive cosmetic surgery

Other Comments

56. Question 5 of the consultation provided respondents with an opportunity to comment further on the proposals. In line with the results to question 4, the comments received were mostly positive, in favour of the proposals.

57. A small number of respondents did not agree that services listed, such as minor cosmetic surgery and independent podiatrists, should remain excluded from CQC performance assessment and rating.

58. Some examples of these comments are listed below:

“We are concerned by the proposals to exclude Independent Podiatry Services from the new performance assessment and ratings regime. Significant complications can arise from podiatric surgery and many podiatry procedures require local anaesthetics, therefore patients may come to harm from a lack of proper regulation in this area of practice.”

“While we are in support of proposals to ensure the highest standards of quality care amongst providers of cosmetic surgery, there is a need for the CQC to consider extending its inspection regime to organisations exclusively providing non-invasive cosmetic procedures.”

59. However, the majority of comments were supportive of the proposals and agreed with the approach as a way of dealing effectively with a constantly changing healthcare sector, as this comment highlights:

“These new regulations will enable CQC to inspect and rate new models of care, including where registered providers who currently fall within scope of ratings are joining new organisational forms.”