EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) (AMENDMENT) REGULATIONS 2015

2015 No. 64

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations amend the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 to extend the duty of candour and fit and proper persons requirement for directors to all registered providers of regulated activities from April 2015. They also introduce a new requirement on all registered providers to display any ratings they are awarded by the Care Quality Commission (CQC), from April 2015.

2.2 The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (S.I. 2014/2936) set out the requirements (including fundamental standards) that all providers must meet in order to be registered with CQC. These requirements apply to all providers of a regulated activity including NHS bodies (e.g. NHS Trusts, NHS Foundation Trusts, and Special Health Authorities), independent providers and voluntary sector organisations. The 2014 Regulations were made on 6th November 2014, and commence fully for all registered providers on 1st April 2015.

2.3 The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 introduced two new requirements from 27th November 2014 which currently only apply to health service bodies. The first of these, the duty of candour, requires NHS bodies registered with CQC to be open and transparent with service users or their relevant representative, and provide specific information where certain safety events occur. The second new requirement requires NHS bodies registered with CQC to take proper steps to ensure that their directors are fit and proper for their role.

2.4 These Regulations also make several consequential amendments to the 2014 Regulations. These amendments ensure the 2014 Regulations accurately reflect the extension in the scope of the fit and proper persons requirement, so that they apply consistently to the 'controlling mind' of all registered providers, including sole traders and partnerships. They also clarify the definition of 'adult placement scheme' for the purposes of section 20A of the Health and Social Care Act 2008 ("the 2008 Act").

2.5 These Regulations introduce a clause that means the 2014 Regulations will cease to have effect seven years after they have been introduced. This is in line with Government policy, and prevents the regulations from applying indefinitely.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 The 2008 Act established the CQC and gave it the function of maintaining a registration system for providers of health and adult social care who carry out regulated activities (section 8 of the 2008 Act). Providers of regulated activities are then required to meet the requirements imposed by regulations under section 20 of the 2008 Act.

4.2 The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 were made on 6th November 2014 and will come into force fully on 1st April 2015. Those Regulations replace the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. They prescribe the kinds of activities that are regulated activities for the purposes of Part 1 of the 2008 Act, and the requirements that apply in relation to the way in which those activities are carried on.

4.3 In addition to these Regulations, the Care Quality Commission (Registration) Regulations 2009 (S.I. 2009/3112) set out further requirements on registered providers under section 20 of the Act. The Care Quality Commission (Registration) Regulations also make provisions in respect of systems and processes around registration.

4.4 Finally section 91(2) of the Care Act 2014 amended section 46 of the 2008 Act to impose a duty on the CQC to conduct performance assessment reviews of the carrying on of such registered service providers and such regulated activities as may be prescribed and to publish reports of such assessments. These Regulations introduce a new requirement on relevant registered providers to display CQC's performance assessment of their services (known as a 'rating') prominently at their premises and on their website.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

6.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The introduction of the fit and proper person requirement and the duty of candour as CQC registration requirements are part of a wide-ranging set of changes designed to improve the regulation of health and adult social care providers, and provide assurance that service users receive safe, quality care and treatment.

7.2 The Government set out its plan to introduce these new measures in *Patients First and Foremost - The Initial Government Response to the Report of The Mid Staffordshire*

NHS Foundation Trust Public Inquiry[1] published in March 2013, and in *Hard Truths: The Journey to Putting Patients First*[2], published in November 2013.

7.3 The policy intention behind the duty of candour and the fit and proper persons requirement are set out below. Each of these measures is already in place for NHS bodies, and the government has been clear that these measures would apply to all registered providers from April 2015.

7.4 The introduction of these measures has been separated for NHS bodies and non NHS bodies for several reasons. Firstly, it was possible to introduce the measures more quickly for non-NHS providers because their introduction does not need to be tied to a common commencement date, as is the case with measures that affect private organisations. Secondly, unlike NHS bodies, non-NHS providers registered with CQC are not under a contractual obligation to check the fitness of directors or operate a duty of candour, so they would benefit from having more time to prepare for the introduction of the measures. Thirdly, with regards to the fit and proper persons requirement, there is much greater variation in organisational structure amongst non-NHS providers, particularly within the adult social care sector, so it benefits the regulator to have more time to develop its approach to regulating non-NHS providers in this respect.

Requirements in relation to the fitness of directors

7.5 The overall policy objective of the fit and proper persons requirement is to ensure that the 'controlling mind' of a care provider is fit for that role. The existing regulations require that persons employed by a provider are fit for their role, and that those people registered as managers or sole-traders are fit for their role, but there is a gap when it comes to ensuring the fitness of directors. These regulations fill this gap in relation to non-NHS registered providers.

7.6 Regulation 6 amends the 2014 Regulations to extend the new fit and proper person test for directors to all registered providers. The criteria which a director must meet in order to be fit include that they must be "of good character"; have the qualifications, competence, skills and experience necessary for the relevant position; and be capable of undertaking the relevant position, after any reasonable adjustments have been made. They must also not have been responsible for any serious misconduct or mismanagement in the course of carrying on a regulated activity.

7.7 A director will be deemed to be unfit if they meet the criteria set out in Part 1 of Schedule 4 of the 2014 Regulations. This includes, for example, if they are an undischarged bankrupt; are the subject of a bankruptcy order or an interim bankruptcy order; or have an undischarged arrangement with creditors. Directors will also be unfit if they are included on any barring list preventing them from working with children or vulnerable adults, or are prohibited from holding the position under any other law. This means that a person subject to a disqualification order under the

[1] https://www.gov.uk/government/publications/government-initial-response-to-the-mid-staffs-report
[2] https://www.gov.uk/government/publications/mid-staffordshire-nhs-ft-public-inquiry-government-response

Company Directors Disqualification Act 1986[3] or under the Charities Act[4], for example, would not meet the fit and proper person requirement in relation to a registered provider that was a company or charity respectively.

7.8 Failure to comply with the fit and proper person test could, ultimately, lead to a condition (under section 12(5) of the Act) being placed on a provider's registration requiring removal of the person concerned.

7.9 Regulations 5, 7 and 8 amend regulations 4, 6 and 7 respectively of the 2014 Regulations, which relate to the fitness of individual service providers, partners in a partnership which is a service provider, nominated individuals and registered managers, in order to bring them in to line with the fit and proper persons requirement for directors. The changes mean that those persons must have the required 'competence' for their role, and that the matters listed in Part 2 of Schedule 4 of the 2014 Regulations are considered when assessing the character of those persons.

Requirements in relation to the duty of candour

7.10 Regulation 10 extends the duty of candour to all registered providers, requiring them to be open with service users. When a specified safety incident has occurred in respect of care provided, the regulation sets out a clear set of legal duties about how and when to notify service users (or relevant representatives) and what threshold of harm constitutes a safety incident for which notification is required.

7.11 The duty of candour was developed in response to issues and concerns identified in a number of reviews and inquiries including the Mid Staffordshire NHS Foundation Trust Public Inquiry and the Berwick Review into Patient Safety. It also reflects the findings of the Dalton-Williams Review[5] into the threshold for the duty of candour. All of these reviews endorse the need for a culture of candour and for a statutory duty of candour to support this culture change. The duty of candour regulation sets a clear requirement that candour is not optional and the withholding of information relating to harm is not acceptable.

7.12 The threshold at which the duty of candour applies is linked to the current arrangements for reporting safety incidents. NHS and non-NHS bodies use slightly different reporting arrangements, each with different terminology. These regulations reflect those differences in the way they describe the threshold for NHS and non-NHS bodies.

Requirements relating to display of ratings

7.13 Regulation 11 inserts a new regulation (20A) into the 2014 Regulations, which places a requirement on providers to display the rating given to them by CQC in a

[3] http://www.legislation.gov.uk/ukpga/1986/46/contents
[4] http://www.legislation.gov.uk/ukpga/2011/25/contents/enacted
[5] Building a Culture of Candour: a review of the threshold for the Duty of Candour and of the incentives for care organisations to be candid, March 2014 – http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf

conspicuous way, at the premises from which they deliver services. The regulation also requires those providers who operate a website, to display the rating CQC has given their services in a conspicuous place on their website. The regulation is non-prescriptive and CQC will publish guidance on how providers' compliance with this requirement will be assessed.

7.14 Section 46 of the 2008 Act[6] (as amended by section 91 of the Care Act 2014)[7] places a duty on CQC to carry out performance assessments of providers of health and adult social care services. These assessments of quality will be summarised in the form of a rating. The Government stated in the Committee stage of the Care Act that it would also consider whether to introduce a requirement through regulations that providers registered with CQC must display their rating.

7.15 A requirement to publish ratings is consistent with one of the key purposes of ratings, which is to provide the public with a straightforward means of assessing a provider's performance. Requiring all providers to prominently display their rating is a simple and effective measure to ensure that people who use services are informed of the quality of the health and social care services in an easy to understand format.

7.16 Without this legal compulsion to display a rating, it is likely that only providers with a "good" or "outstanding" rating will display their rating whereas poorer performing providers might not. Guidance from CQC or the Department of Health would not provide sufficient compulsion to providers to display their rating.

8. Consultation outcome

8.1 The Department of Health's proposed approach for developing the new regulations was included as part of CQC's consultation document *A New Start*[8] published in June 2013, which set out CQC's new approach to inspecting and regulating providers. Further detail on the proposed regulations was published in *"Hard Truths - The Journey to Putting Patients First"* in November 2013.

8.2 The Department ran a consultation on the proposal to introduce the fit and proper person requirement for director level posts in *Strengthening Corporate Accountability in Health and Social Care*[9] in July 2013, with a further consultation on the draft regulations[10] between March and April 2014, which received 41 responses.

8.3 In response to the Francis Inquiry recommendation that a statutory obligation should be imposed to observe a duty of candour policed by the CQC, the Department of Health undertook a series of reviews and consultations to develop the duty of candour. The first review, *"A promise to learn – a commitment to act: improving the safety of patients in England"* published 6 August 2013 recommended that, for serious

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[6] http://www.legislation.gov.uk/ukpga/2008/14/section/46

[7] http://www.legislation.gov.uk/ukpga/2014/23/section/91/enacted

[8] http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

[9] https://www.gov.uk/government/consultations/improving-corporate-accountability-in-health-and-social-care

[10] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/298328/Corporate_accountability_consultation_response..pdf

incidents, CQC regulations should require that the patient or carer affected by a safety incident is notified and supported.

8.4 The threshold at which the duty of candour applies for non NHS bodies was informed by a review, conducted by Sir David Dalton, Chief Executive of Salford Royal NHS Foundation Trust and Professor Sir Norman Williams, President of the Royal College of Surgeons, into the threshold for NHS Bodies. It was also tested via consultation. The agreed threshold for non-NHS providers and adult social care providers is the same as the existing CQC notification requirement for serious injuries. The advantage of this is that providers are already familiar with the threshold, and it is similar in scope to the threshold already in place for NHS bodies.

8.5 The Department accepted the recommendation of the review and undertook a final consultation on the proposed duty of candour regulation for inclusion in the fundamental standards between March and April 2014, which received 116 responses.[11]

8.6 The Department undertook a separate consultation on the display of ratings regulations between September and October 2014[12].

8.7 The changes we have made to the regulations in response to the consultations are outlined in full in our consultation response document, available here: https://www.gov.uk/government/consultations/fundamental-standards-for-health-and-social-care-providers

And here:
https://www.gov.uk/government/consultations/transparency-in-care-visible-ratings-for-health-and-care-providers

In summary, the changes include:

For the duty of candour:

- Developed the definition of an incident that needs to be notified to the service user.
- Redrafted the regulations to make it clearer that the written notification must contain an apology.
- Strengthened the definition of a relevant person to be clearer about what happens where a service user dies or lacks mental capacity.

For the fit and proper persons requirement:

- Improved the wording to ensure the fitness requirement is more proportionate, especially around serious misconduct and mismanagement;

[11] https://www.gov.uk/government/consultations/statutory-duty-of-candour-for-health-and-adult-social-care-providers
[12] https://www.gov.uk/government/consultations/transparency-in-care-visible-ratings-for-health-and-care-providers

- Made it clearer how a person's criminal history should be considered when reaching a judgement about their fitness

For the display of ratings requirement:

- The provider must also display the date on which the rating was awarded.
- Made it clearer that the overall rating for the provider and separate ratings for different premises are all required to be displayed at the provider's headquarters. If the headquarters is also a location at which services are provided and that location has a separate location specific rating, then this must be displayed instead.

9. Guidance

9.1 In accordance with section 23 of the 2008 Act, the CQC is required to produce guidance about compliance with these Regulations, and has a duty to consult on that guidance. CQC carried out a full consultation on the guidance on the Regulated Activities regulations over summer 2014. The guidance will come in to force in tandem with the commencements of the Regulations.

9.2 CQC will consult on guidance on the display of ratings requirement and the extension of the duty of candour and fit and proper person requirement ahead of the publication of complete guidance on the registration requirements, which will coincide with the coming into force of the requirements in April 2015.

10 Impact

10.1 The impact assessments, published alongside these Regulations, set out the impact of the duty of candour, the fit and proper persons requirement, and the display of ratings on all providers.

10.2 The cost of introducing the fit and proper person's requirement for all providers registered with CQC (including NHS and non-NHS providers) has been calculated at £20.9m over ten years. Providers who do not currently carry out the necessary checks on their directors will face the costs of the additional actions they must take to do so. CQC will absorb the costs of undertaking the necessary monitoring and enforcement activity associated with the new requirement. It has not been possible to quantify the benefits of the proposal, however the main benefits are expected to be the reduction in the risks of poor quality care for health service users associated with poor management or governance from an unfit director and the increase in accountability of directors for their actions. Analysis suggests that these benefits are likely to outweigh the quantified costs above.

10.3 The cost of introducing the duty of candour for all providers registered with CQC (including NHS and non-NHS providers) has been calculated at £49.0m over 10 years. The main costs associated with this are the initial set up costs for providers in developing a policy on candour and ensuring that relevant staff are made aware of, and have the ability to meet, their new responsibilities. We anticipate some moderate

costs associated with any additional staff time or administration costs associated with further training and support to drive organisational and cultural change, but these are not considered to be strict direct costs of the proposal. The benefits of the proposal are likely to include improvements in patient satisfaction, in patient safety, a reduction in patient complaints, and reputational benefits for providers. In addition, there are ethical benefits associated with being open and honest, and these have been reflected by the wide support this policy has received during the consultation.

10.4 The cost of introducing the display of ratings requirement for health and social care providers within scope of the requirement is £2.6m over ten years. The main cost to providers are the familiarisation costs of understanding the requirement and the cost of physically displaying their rating on their premises and on their website. These figures only relate to the cost of requiring those providers who have been given a rating to display that rating. Costs associated with producing the rating (providing information to CQC and undergoing an inspection) are not a consequence of this regulation and therefore not included in this figure.

11. Regulating small business

11.1 The Regulations will apply to small businesses. This is because there are many small businesses who carry out regulated activities, and therefore are required to register with CQC and meet these registration requirements. Small providers carry a similar risk of providing poor care as larger providers so it is not appropriate to exempt them from these Regulations.

12. Monitoring and review

12.1 The 2014 Regulations contain a requirement that the Secretary of State review them after five years, and, and again each successive period of five years from then on, in order to keep them up-to-date and relevant, and to take account of changes in delivery of care. The report must in particular set out the objectives intended to be achieved by the regulatory system established by the 2014 Regulations, assess the extent to which those objectives are achieved, and assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

12.2 These Regulations amend the review arrangements. Regulation 3 amends regulation 1 of the 2014 Regulations to introduce a new sunset provision, meaning the 2014 Regulations (as amended) will cease to have effect seven years after their introduction in April 2015. Regulation 16 amends Regulation 27 of the 2014 Regulations to remove the need to review the 2014 Regulations every five years following 1st April 2020, to account for the fact that the Regulations will have been subject to the sunset provision before that requirement for a subsequent review could take effect.

13. Contact

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