EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) REGULATIONS 2014

2014 No. XXXX

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 prescribe the kinds of activities that are regulated activities for the purposes of Part 1 of the Health and Social Care Act 2008 ("the Act") and the requirements that apply in relation to the way in which those activities are carried on. Providers of these regulated activities are required to register with the Care Quality Commission (CQC). They replace the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These Regulations set out the requirements 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 regulations contain new fundamental standards relating to safety and quality that all providers of regulated activities must meet. The fundamental standards will commence for all providers on 1st April 2015.

2.2 The Regulations also introduce two new requirements which only apply to health service bodies. The first of these is the Duty of Candour, requiring providers to be open with service users or their relevant representative. The second new requirement requires providers to take proper steps to ensure that their directors are fit and proper for their role. These two requirements will commence 21 days after these regulations are made.

2.3 The fundamental standards set in law a clear baseline below which care must not fall and CQC will be able to take enforcement action against providers that do not meet these standards. Some of these standards have offences attached, and CQC will be able to bring prosecutions if these are breached and the breach causes avoidable harm or risk of such harm. Those registration requirements that relate to harm of service users have a maximum penalty of an unlimited fine, or a fine up to £50,000 if section 85(2) of the Legal Aid Sentencing and Punishment of Offenders Act 2010 is not in force on the day these Regulations are made. Requirements that require providers to provide information to the regulator, or in the case of the Duty of Candour, to service users, have a lower maximum fine set at a level four on the standard scale.

2.4 CQC has the option of issuing a penalty notice in lieu of prosecution for these offences and other offences under Part 1 of the Act. The instrument prescribes these offences and specifies the monetary amount of the penalty in each case.

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

3.1 None

4. Legislative Context

4.1 The Act established 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 Act). Providers of regulated activities are then required to meet the requirements imposed by regulations under section 20 of the Act.

4.2 The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 came in to force on 1st April 2010. Those regulations prescribed the kinds of activities that were regulated activities for the purposes of Part 1 of the Act and the requirements that apply in relation to the way in which those activities are carried on.

4.3 These new regulations supersede (and revoke) the 2010 Regulations. The scope of regulated activities (in Schedule 1 of these Regulations) covered by the system is largely unchanged. The number of requirements on providers has been reduced, clarified, and made more specific.

4.4 In addition to these Regulations, the Care Quality Commission (Registration) Regulations 2009 (SI 2009/3112) set out further requirements made under section 20 of the Act, where the offence for failure to comply is punishable with a fine of up to level 4 on the standard scale. The Care Quality Commission (Registration) Regulations also make provisions in respect of systems and processes around registration.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

The Minister of State for Care Services has made the following statement regarding Human Rights:

"In my view, the provisions of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 are compatible with the Convention rights."

Norman Lamb MP

7. Policy background

7.1 The introduction of fundamental standards, the fit and proper person requirement for directors 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 fundamental standards are intended to be common-sense statements that describe the basic requirements that providers should always meet, and set out the outcomes that patients or care service users should always expect from health and social care services. All providers registered with CQC will have to meet them.

7.3 These changes implemented by the Regulations stem from a number of recommendations arising from several inquiries, reviews, consultations and policy initiatives. These include:

- The Mid Staffordshire NHS Foundation Trust Public Inquiry[1] (the Francis Inquiry);
- Transforming care: A national response to Winterbourne View Hospital[2];
- A promise to learn – a commitment to act: Improving the safety of patients in England[3]; and
- Healthy Living and Social Care theme of the Red Tape Challenge[4].

7.4 One of the key themes emerging from the Mid Staffordshire NHS Foundation Trust Public Inquiry, which was also echoed by the Winterbourne Serious Case Review, was a lack of clarity in the registration requirements that inhibited CQC taking effective action against providers where harm to patients had occurred. The Francis Inquiry report recommended the introduction of new fundamental standards of safety and quality below which care should never fall.

7.5 The Government set out its plan to introduce the fundamental standards in *Patients First and Foremost - The Initial Government Response to the Report of The Mid Staffordshire NHS Foundation Trust Public Inquiry*[5] published in March 2013, and in *Hard Truths: The Journey to Putting Patients First*[6], published in November 2013.

7.6 The Department committed to incorporate the fundamental standards into the requirements for registering with CQC. The policy intention behind the fundamental standards is therefore to clarify the requirements that providers must meet, and improve the regulations so that providers understand more clearly the standards that they have to meet, and to make it more straightforward for CQC to bring prosecutions for the most serious breaches of the requirements. This is intended to improve the quality of care, act as both a deterrent and a spur to prevent poor care from occurring, and also improve the ability of the regulator to take action and hold providers to account where care is poor.

7.7 References to these commitments have been made in both Houses as part of the response to the Francis Inquiry report, and also during the passage of the Care Act 2014[7]. In particular, section 81 of the Care Act 2014 provides that the Duty of Candour must be introduced as a requirement for registration with CQC[8].

7.8 Part 3 of the regulations (4 to 7) sets out the requirements in relation to persons registered in respect of the carrying on, or management of, a regulated activity, and requires certain information to be available in relation to those persons. Regulation 8(2) also puts in place provisions to clarify who is to be regarded as

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[1] http://www.midstaffspublicinquiry.com/report

[2] https://www.gov.uk/government/publications/winterbourne-view-hospital-department-of-health-review-and-response

[3] https://www.gov.uk/government/publications/berwick-review-into-patient-safety

[4] http://www.redtapechallenge.cabinetoffice.gov.uk/themehome/healthy-living-and-social-care-2/

[5] https://www.gov.uk/government/publications/government-initial-response-to-the-mid-staffs-report

[6] https://www.gov.uk/government/publications/mid-staffordshire-nhs-ft-public-inquiry-government-response

[7] http://www.publications.parliament.uk/pa/cm201314/cmhansrd/cm140311/debtext/140311-0004.htm
http://www.publications.parliament.uk/pa/cm201314/cmpublic/care/140121/am/140121s01.htm
http://www.publications.parliament.uk/pa/cm201314/cmpublic/care/140128/am/140128s01.htm
http://www.publications.parliament.uk/pa/cm201314/cmpublic/care/140204/am/140204s01.htm

[8] http://www.legislation.gov.uk/ukpga/2014/23/section/81/enacted

carrying on the regulated activity, where two or more persons are carrying on the regulated activity in different capacities.

Requirements in relation to the fitness of directors

7.9 Regulation 5 introduces a new fit and proper person test for directors of a health service body that require registration with CQC (ie NHS Trusts, NHS Foundation Trusts and some Special Health Authorities). The aim of this regulation is to ensure that directors of health services bodies are fit to hold that position. The criteria that a director must meet 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.

7.10 A director will be deemed to be unfit if they meet the criteria set out in Part 1 of Schedule 4. 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 Company Directors Disqualification Act 1986[9] or under the Charities Act[10] would not meet the fit and proper person requirement in relation to a registered provider that was a company or charity respectively.

7.11 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.

Requirements relating to the fundamental standards

7.12 Part 4 of the Regulations (8 to 20) sets out the fundamental standards of safety and quality. These are standards below which the quality of care must not fall or providers will be in breach of their registration with the CQC. The fundamental standards include requirements to ensure that service users are treated with dignity and respect; receive suitable nutrition; are safeguarded from abuse and receive care in an environment which is clean and safe.

7.13 The fundamental standards generally require providers to meet a set of desired outcomes. For example, regulation 12 puts in place a requirement that care and treatment must be provided in a safe way for service users, and regulation 14 requires providers to ensure that service users' nutrition and hydration needs are met. Where there is evidence that these outcomes have not been met, the regulation has been breached and the onus is on the provider to demonstrate that it had taken all reasonable steps to prevent that breach.

7.14 One of the key aims of the new regulations is to allow CQC to bring a prosecution for the most serious breaches of those registration requirements that are

[9] http://www.legislation.gov.uk/ukpga/1986/46/contents
[10] http://www.legislation.gov.uk/ukpga/2011/25/contents/enacted

likely to lead to harm. Those registration requirements that relate directly to the risk of harm to service users therefore have offences attached to them, and maximum penalty attached of a £50,000 fine (or an unlimited fine if section 85(2) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 is in force when the Regulations are made). These are regulation 11 (consent), as well as regulations 12 (safe care and treatment), 13 (safeguarding service users from abuse and improper treatment) and 14 (meeting nutritional and hydration needs) where failing to meet the requirement results in avoidable harm or exposes the service user to a significant risk of such harm occurring.

7.15 The Regulations also establish a number of offences in relation to registration requirements that are not directly related to harm of service users – these are related to providing information to CQC about complaints (regulation 16(3)), providing information to the Commission about the carrying on of the regulated activity (regulation 17(3)) and informing service users about failings in their care under the Duty of Candour (regulation 20(2)(a) and (3)). A lower maximum penalty of a fine up to level four on the standard scale is attached to these offences.

Requirements in relation to the Duty of Candour

7.16 Regulation 20 introduces a new Duty of Candour on "health service bodies" (i.e. NHS Trusts, NHS Foundation Trusts, and Special Health Authorities), 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 on health service bodies about how and when to notify service users (or relevant representatives) about the safety incidents and what threshold of harm constitutes a safety incident for which notification is required.

7.17 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[11] 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. Regulation 20 sets a clear requirement that candour is not optional for health service bodies and the withholding of information relating to harm is not acceptable.

7.18 Part 4 details in regulation 21 the Codes of Practice and guidance that registered persons must have regard to for the purposes of compliance with the Regulations.

7.19 Regulation 22 creates offences for failing to comply with certain registration of the requirements in Part 4 and also includes a due diligence defence relating to any proceedings for such a breach. Regulation 23 lays down the penalties for those who commit such an offence.

Penalty notices

7.20 Part 5 of the Regulations makes provision for the Commission to issue fixed penalty notices (pursuant to sections 86 and 87 of the Act), in lieu of prosecuting for

[11] 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

the a number of offences set out in both the 2008 Act, these Regulations the Care Quality Commission (Registration) Regulations 2009. The monetary amount of the penalty for each fixed penalty offence is set out in Schedule 5. These have been set in order to be proportionate to the seriousness of the offence. The monetary amount reflects the fact that, in most cases, the notice will have a greater financial impact on registered managers, who will be individuals, than on registered providers who are likely to be organisations.

7.21 The most serious offences of not being registered (section 10 of the Act), failing to comply with conditions in relation to registration (section 33 of the Act), carrying on a regulated activity while registration is cancelled or suspended (section 34 of the Act) and failing to comply with those registration requirements (Regulation 22 of the Regulations) that have a maximum penalty of a £50,000 fine will attract penalty notices of £4,000 in cases where the offence is committed by a service provider and £2,000, where the offence is committed, where applicable, by a registered manager. Failure to meet the Duty of Candour requirement will attract a penalty notice of £1,250 in cases where the offence is committed by a service provider and £625 where the offence is committed by a registered manager. Failure to provide information to CQC or obstructing inspectors can result in a penalty notice of £300.

7.22 Schedule 1 lists the activities that are regulated activities for the purposes of section 8(1) of the Act. Schedule 2 of the regulations contains general exceptions to the regulated activities which exclude specific providers from the scope of regulation. Briefly, these exemptions include:

- activities carried on in the course of a personal relationship for no commercial consideration;
- activities undertaken by providers covered by the Care Standards Act;
- some medical or dental services provided under arrangements made on behalf of a service user by their employer, a government department, or an insurance provider;
- forensic medicine or dental services carried out on behalf of policing bodies;
- some primary ophthalmic services;
- some services provided in registered pharmacies;
- provision of emergency first aid;
- medical and dental services provided by or on behalf of the armed services;
- treatment provided in school to school pupils by a school nurse;
- treatment by a medical practitioner who is either a service provider registered for treatment of disease, disorder or injury, or is employed by such a provider, and the practitioner is on the performers list of a designated body or is employed by a designated body for professional appraisal.

8. Consultation outcome

8.1 The Department of Health's proposed approach for developing the Fundamental Standards was included as part of CQC's consultation document *A New Start*[12] published in June 2013, which set out the Commission's new approach to inspecting

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

and regulating providers. In light of the responses received on the proposed Fundamental standards, further detail on the proposed standards was published in *"Hard Truths - The Journey to Putting Patients First" in November 2013*. A further consultation[13] on the draft regulations for the Fundamental Standards happened between January 2014 and April 2014, receiving over 250 responses.

8.2 A separate consultation was run on the proposal to introduce the fit and proper person requirement for director level posts in *Strengthening corporate accountability in health and social care*[14] in July 2013, with a further consultation on the draft regulations[15] 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 policy around the regulation. 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 incidents, CQC regulations should require that the patient or carer affected by a safety incident is notified and supported.

8.4 A review of the threshold for the Duty of Candour was announced in Hard Truths. The Secretary of State invited Sir David Dalton, Chief Executive of Salford Royal NHS Foundation Trust and Professor Norman Williams, President of the Royal College of Surgeons, to conduct the review of the threshold for healthcare organisations. The review concluded that the Duty of Candour should apply to all cases of 'significant harm'. This new classification would cover the National Reporting and Learning System categories of 'moderate', 'severe' and 'death', but would also include 'prolonged psychological harm'.

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.[16]

8.6 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

In summary, the changes include:

For the fundamental standards:

[13] https://www.gov.uk/government/consultations/fundamental-standards-for-health-and-social-care-providers

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

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

[16] https://www.gov.uk/government/consultations/statutory-duty-of-candour-for-health-and-adult-social-care-providers

- Changes to the offences to reflect the fact that not all of the fundamental standards have offences attached.
- Redrafting of the regulations in many areas to improve clarity.
- Inclusion or clarification of certain definitions or terms, setting out more clearly under each regulation those important areas that providers are expected to meet

For the Duty of Candour:

- Developed the definition of an incident that needs to be notified to the service user.
- Clarified that the healthcare harm definitions that are used to identify significant harm will apply to NHS bodies only.
- 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.
- Made clear that the duty applies to NHS bodies only from October 2014 with the intention of extending the duty to other providers from April 2015, subject to Parliamentary approval.

For the fit and proper persons requirement:

- Improved the wording to ensure the fitness requirement is more proportionate, especially around serious misconduct and mismanagement;
- Made it clearer how a person's criminal history should be considered when reaching a judgement about their fitness
- Made clear that this requirement applies to NHS bodies only from October 2014, with the intention of extending the fit and proper person requirement to other providers from April 2015, subject to Parliamentary approval.

8.7 The complete analysis of responses to the consultation on all the regulations will be published at the same time as this instrument.

9. Guidance

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

9.2 CQC's overarching approach for its new guidance will be to ensure it mirrors the regulations as clearly as possible and also spells out the intent of each regulation. The guidance will concisely set out what providers could do to meet the regulations. CQC also intends to include clearer advice intended to help providers demonstrate evidence of how they could meet the regulations at point of registration and evidence of how they are continuing to meet the regulations on an on-going basis.

9.3 CQC has been testing its new approach for the guidance with stakeholders, including both providers and patients. The Commission has been testing to see that

providers understand the purpose of regulations guidance and how the regulations fit within CQC's assessment framework.

9.4 The existing guidance "*Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance*"[17] issued by the Department of Health in 2010, under section 21 of the 2008 Act, is attached. This guidance will be revised in light of the changes proposed to the regulations.

10. Impact

10.1 The impact of the fundamental standards, the Duty of Candour, and the fit and proper person's requirement on the bodies to which they will apply are detailed in the impact assessments available alongside the instrument.

10.2 The impact of the Fundamental Standards has been calculated as a £2.12m net-benefit over ten years. The main cost for providers will be in familiarising themselves with the new regulations. There will be costs to CQC, providers and the justice system from an anticipated increase in the number of prosecutions brought. Clearer regulations should help to reduce the burden of regulation on providers by making it easier to understand what the regulations mean. We have identified a number of mechanisms through which these benefits are likely to flow, which were confirmed by our work with providers during the consultation. CQC will be able to better reflect the severity of breaches of the registration requirements and better hold providers to account for serious failings. Enforcement will be more proportionate, better targeted and therefore more likely to be effective. The quality of care should improve as simpler regulations mean that providers have a better understanding of what is required of them, whilst more effective enforcement might also have a deterrent effect on providers delivering poor care.

10.3 The cost of introducing the fit and proper person's requirement for NHS bodies has been calculated at £0.78m 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.

10.4 The cost of introducing the Duty of Candour for NHS bodies has been calculated at £20.8m 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 the 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

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17 http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093762

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 the have been reflected by the wide support this policy has received during the consultation.

11. Regulating small business

11.1 The regulations will apply to small businesses. This is because there are a 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 meeting these regulations.

12. Monitoring and review

12.1 The Department will keep the regulations under review in order to keep them up-to-date and relevant and to take account of changes in delivery of care. The regulations commit the Department to carry out a review, set out the conclusions of the review in a report, and publish the report before 1st October 2019.

12.2 The report must in particular set out the objectives intended to be achieved by the regulatory system established by these 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.

13. Contact

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John.Culkin@dh.gsi.gov.uk can answer any queries regarding the instrument.