

TRUST BOARD – 22 DECEMBER 2014

FIT AND PROPER PERSONS, DIRECTORS; AND DUTY OF CANDOUR

DIRECTOR:	Director of Corporate and Legal Affairs
AUTHOR:	Director of Corporate and Legal Affairs
DATE:	22 December 2014
PURPOSE:	(concise description of the purpose, including any recommendations) To brief the Trust Board on the implementation of new health and social care standards and specifically the fit and proper persons requirements and duty of candour, effective from 27 November 2014.
PREVIOUSLY CONSIDERED BY:	(name of Committee) N/A
Objective(s) to which issue relates *	<input checked="" type="checkbox"/> 1. Safe, high quality, patient-centred healthcare <input checked="" type="checkbox"/> 2. An effective, joined up emergency care system <input checked="" type="checkbox"/> 3. Responsive services which people choose to use (secondary, specialised and tertiary care) <input checked="" type="checkbox"/> 4. Integrated care in partnership with others (secondary, specialised and tertiary care) <input checked="" type="checkbox"/> 5. Enhanced reputation in research, innovation and clinical education <input checked="" type="checkbox"/> 6. Delivering services through a caring, professional, passionate and valued workforce <input checked="" type="checkbox"/> 7. A clinically and financially sustainable NHS Foundation Trust <input checked="" type="checkbox"/> 8. Enabled by excellent IM&T
Please explain any Patient and Public Involvement actions taken or to be taken in relation to this matter:	The implementation of the new requirements is at the heart of the Government's approach to increasing transparency and accountability in the health and social care systems.
Please explain the results of any Equality Impact assessment undertaken in relation to this matter:	Will be considered as part of the Trust's programme to implement the new fundamental standards.
Organisational Risk Register/ Board Assurance Framework *	<input type="checkbox"/> Organisational Risk Register <input type="checkbox"/> Board Assurance Framework <input checked="" type="checkbox"/> Not Featured
ACTION REQUIRED *	
For decision <input type="checkbox"/>	For assurance <input checked="" type="checkbox"/>
	For information <input checked="" type="checkbox"/>

- ♦ We treat people how we would like to be treated
- ♦ We do what we say we are going to do
- ♦ We focus on what matters most
- ♦ We are one team and we are best when we work together
- ♦ We are passionate and creative in our work

* tick applicable box

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: TRUST BOARD

DATE: 22 DECEMBER 2014

REPORT BY: DIRECTOR OF CORPORATE AND LEGAL AFFAIRS

SUBJECT: FIT AND PROPER PERSONS : DIRECTORS; AND DUTY OF CANDOUR

1. INTRODUCTION

- 1.1 Against the backdrop of the Francis Inquiry report into Mid-Staffordshire NHS Foundation Trust and failings at the Winterbourne View Hospital the Government has legislated (via the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) and made important changes to health and social care standards which are regulated by the Care Quality Commission (CQC).
- 1.2 Key changes are that breaches of some fundamental standards are strict liability offences and (where breaches of fundamental standards are criminal offences) the CQC can now prosecute without giving prior notice. The risk of prosecution and conviction is therefore significantly increased. Whilst fines can be imposed for breaches, the level is relatively modest and the real damage in the event of prosecution and conviction is likely to be reputational.
- 1.3 This report summarises the key changes and identifies immediate actions to be taken in response.
- 1.4 Further reports on the new standards will be submitted to the Trust Board in due course.

2. FUNDAMENTAL STANDARDS OF CARE

- 2.1 The 2014 Regulations introduce 12 fundamental standards which replace the previous CQC essential standards.
- 2.2 The fundamental standards provide that:
- (a) care and treatment must be appropriate and reflect service users' needs and preferences (Regulation 9);
 - (b) service users must be treated with dignity and respect (Regulation 10);

- (c) care and treatment must only be provided with consent (Regulation 11);
- (d) care and treatment must be provided in a safe way (Regulation 12);
- (e) service users must be protected from abuse and improper treatment (Regulation 13);
- (f) service users' nutritional and hydration needs must be met (Regulation 14);
- (g) all premises and equipment used must be clean, secure, suitable and used properly (Regulation 15);
- (h) complaints must be appropriately investigated and appropriate action taken in response (Regulation 16);
- (i) systems and processes must be established to ensure compliance with the fundamental standards (Regulation 17);
- (j) sufficient numbers of suitably qualified, competent, skilled and experienced staff must be deployed (Regulation 18);
- (k) persons employed must be of good character, have the necessary qualifications, skills and experience, and be able to perform the work for which they are employed (Regulation 19);
- (l) health service bodies must be open and transparent with service users about their care and treatment (Regulation 20).

2.3 The new standards will come into force in April 2015 except that two Regulations for NHS bodies came into force on 27th November 2014: Regulation 5 fit and proper persons: Directors; and Regulation 20 duty of candour.

3. REGULATION 5 : FIT AND PROPER PERSONS: DIRECTORS

- 3.1 Creating a fit and proper person test for healthcare leaders was one of the key recommendations of the Francis Report.
- 3.2 The test applies to all health service bodies, ie NHS Trusts, NHS Foundation Trusts and Special Health Authorities.
- 3.3 Health service providers currently have a general obligation to ensure that they only employ individuals who are fit for their role.
- 3.4 The introduction of the fit and proper persons requirement for Directors imposes an additional requirement. The purpose is to require providers to take proper steps to ensure that their Directors (or equivalent) are fit and proper for the role.

- 3.5 The fit and proper persons test will apply to Directors (both Executive Directors and Non-Executive Directors) and individuals “performing the functions of, or functions equivalent or similar to the functions of, such a Director”. The test will therefore apply to senior managers who exercise functions similar to the Directors of the organisation.
- 3.6 The Regulations provide that health service bodies must not appoint or have in place an individual as a Director or equivalent unless:-
- the individual is of good character;
 - the individual has the qualifications, competence, skills and experience which are necessary for the relevant office or position or the work for which they are employed;
 - the individual is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the office or position for which they are appointed or to the work for which they are employed;
 - the individual has not been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England, would be a regulated activity;
 - none of the grounds of unfitness specified in the Regulations apply to the individual: bankruptcy; on a barred list; legal impediment.
- 3.7 To meet the requirements, a provider has to:-
- provide evidence that appropriate systems and processes are in place to ensure that all new Directors and existing Directors or equivalent are, and continue to be, fit, and that no appointments meet any of the unfitness criteria set out in the Regulations;
 - make every reasonable effort to assure itself about an individual by all means available;
 - make specified information about Board Directors available to the CQC;
 - be aware of the various best practice guidelines available and to have implemented procedures in line with this best practice;
 - where a Board member no longer meets the fit and proper persons requirement, inform the regulator in question where the individual is

registered with a healthcare or social care regulator, and take action to ensure the position is held by a person meeting the requirements.

- 3.8 It is important to note that it is for the Trust to ensure that the requirements of the fit and proper persons test are met. The CQC will not undertake a fit and proper persons test of a Director or determine what is serious mismanagement or misconduct but will examine how the Trust has discharged its responsibility under the new Regulation.
- 3.9 It is a breach of the Regulation to have in place someone who does not satisfy the test. Evidence of this could be if:
- a provider does not have a proper process in place to enable it to make the assessments required by the fit and proper person test;
 - a Director is unfit on a 'mandatory' ground, such as a relevant conviction or bankruptcy (to be determined by the provider);
 - on receipt of information about a Director's fitness, a decision is reached on the fitness of the Director that is not in a range of decisions that a reasonable person would make.

4. CQC APPROACH TO THE FIT AND PROPER PERSONS REQUIREMENTS FOR DIRECTORS

- 4.1 On 20 November 2014, the CQC published guidance for NHS bodies on the fit and proper persons requirement for Directors.
- 4.2 The guidance describes how the CQC will approach the fit and proper persons requirement during the registration process; during the inspection process; during a 'focused' inspection (ie, where there is a serious systemic failure of a provider); and when information is received from a member of the public or the provider's staff about an existing Board member (here, the CQC will also have regard to its Whistleblowing and Safeguarding protocols, respectively, where relevant).
- 4.3 During the registration process, the CQC will require the Chair of the NHS provider to declare that appropriate checks have been undertaken in reaching a judgement that all Directors are deemed to be fit and none meet any of the unfit criteria. This will be a self-declaration.
- 4.4 During the inspection process, the CQC will use the following key line of enquiry (KLOE) and prompts under the 'well-led' key question, as follows:
- **W3 How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?**

- Prompt : Do leaders have the skills, knowledge, experience and integrity that they need – both when they are appointed and on an ongoing basis?
 - Prompt : Do leaders have the capacity, capability and experience to lead effectively?
- 4.5 The CQC will seek to confirm that the provider has undertaken appropriate checks and is satisfied that, on appointment and subsequently, all new and existing Directors are of good character and are not unfit. This may involve checking personnel files and Directors' appraisal records.
 - 4.6 The CQC will report on the fit and proper persons test under 'well-led' in its inspection reports. If the CQC find that providers do not reflect the characteristics of 'good', it will assess whether they 'require improvement' or are 'inadequate'. The CQC will also consider whether a regulation has been breached, including Regulation 5.
 - 4.7 Where a concern arises about the fitness of a Director following the CQC's receipt of information from a member of the public or the provider's staff, the CQC will convene a panel, led by the Chief Inspector of Hospitals (or a person designated by them), to determine whether the information is significant and should be considered by the provider.
 - 4.8 Where the provider is asked by the CQC to respond, the response received will either satisfy the Chief Inspector that due process has been followed or lead to a request for further dialogue with the provider, a follow-up inspection, or regulatory action using the CQC's current enforcement policy.
 - 4.9 Interestingly, in its guidance the CQC states that "there are some core public information sources about providers that we believe are relevant for providers to use as part of their fit and proper persons requirement due diligence. For example, this includes, but is not limited to, information from public inquiry reports, serious case reviews and Ombudsman reports....".
 - 4.10 In circumstances where a provider is unable to demonstrate that it has undertaken the appropriate checks in respect of its Directors, and the CQC decides to take regulatory action, providers may appeal to the first-tier Tribunal. The Tribunal hears appeals against decisions of the Secretary of State to restrict or bar an individual from working with children or vulnerable adults and decisions to cancel, vary or refuse registration of certain health care, child care and social care provision.

- 4.11 Providers may also challenge by way of judicial review if they consider that a decision breaches public law principles such as being unreasonable, irrational and unfair.
- 4.12 The CQC states in its guidance that, as the fit and proper persons requirement is a new Regulation, it expects to learn from what they find. This learning will inform the development of the CQC's guidance on meeting all of the new fundamental standards which is to be issued before 1 April 2015.

5. FIT AND PROPER PERSONS : IMMEDIATE ACTIONS TO BE TAKEN

- 5.1 Having regard to the 2014 Regulations, the CQC guidance and advice from the NHS Trust Development Authority about the impact on NHS Trust Chairman and Non-Executive Director appointments, the Director of Human Resources will prepare and submit a report to the Trust Board on 5th February 2015.
- (a) clarifying (for confirmation by the Board) the Trust 'Director equivalent' postholders to whom it is judged that the fit and proper person test applies;
- (b) identifying how the Trust meets/will meet the specific requirements of the fit and proper person test and assure itself of the suitability of individuals, both in post and to be appointed in future;
- (c) setting out recommendations relating to any necessary changes to the Trust's recruitment, performance management and disciplinary arrangements for Chief Executives, Directors and Director equivalents and also, specifically, in relation to:-
- (I) contracts of employment for the Chief Executive, Executive Directors and Director equivalents;
 - (II) reference requests for Directors and Director equivalents;
 - (iii) pre-employment checks for Directors and Director equivalents;
 - (iv) annual fit and proper person declarations for Directors and Director equivalents;
 - (v) checklists for recruitment to Director and Director equivalent posts.

6. REGULATION 20 DUTY OF CANDOUR

6.1 The introduction of Regulation 20 is a direct response to the Francis Inquiry's recommendation that a statutory duty of candour be imposed on healthcare providers.

6.2 Like most NHS bodies, UHL is already subject to a contractual duty of candour under the NHS Standard Contract.

6.3 To meet the requirements of the new Regulation, an NHS body has to:-

- (a) make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity;
- (b) tell the relevant person in person as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification;
- (c) provide an account of the incident which, to the best of the health service body's knowledge, is true of all the facts the body knows about the incident as at the date of the notification;
- (d) advise the relevant person what further enquiries the health service body believes are appropriate;
- (e) offer an apology;
- (f) follow this up by giving the same information in writing, and providing an update on the enquiries;
- (g) keep a written record of all communication with the relevant person.

6.4 The Regulations provide definitions as follows:-

- (i) **Notifiable safety incident** means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or severe harm, moderate harm or prolonged psychological harm to the service user;
- (ii) **Severe harm** means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition;

- (iii) **Moderate harm** means harm that requires a moderate increase in treatment, and significant, but not permanent harm;
- (iv) **Moderate increase in treatment** means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);
- (v) **Prolonged psychological harm** means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;
- (vi) **Apology** means an expression of sorrow or regret in respect of a notifiable safety incident.

7. CQC APPROACH TO THE DUTY OF CANDOUR

7.1 On 20th November 2014, the CQC published guidance for NHS bodies on the duty of candour.

7.2 The guidance describes how the CQC will approach the duty of candour requirement during the registration process; during the inspection process; and when information is received from a member of the public or the provider's staff relating to the statutory duty of candour (here, the CQC will also have regard to its Whistleblowing and Safeguarding protocols, respectively, where relevant).

7.3 During the registration process, the CQC will test with the provider that it understands the requirement of the Regulation and ask what systems are in place to ensure that they will be able to meet the requirements.

7.4 During the inspection process, the CQC will use the following two specific key lines of enquiry (KLOEs) to assess whether the provider is delivering good quality care:-

- **S2: Are lessons learned and improvements made when things go wrong?**

Prompt: Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?

- **W3: How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?**

Prompt: Does the culture encourage candour, openness and honesty?

- 7.5 The CQC will report on the duty of candour under the safety key question in its inspection report at provider level. If the CQC finds care that does not reflect the characteristics of 'good' as they are described in the CQC provider handbook, the CQC will assess whether the service 'requires improvement' or is 'inadequate'. The CQC will also consider whether a Regulation has been breached.
- 7.6 As the statutory duty of candour is a new Regulation, the CQC states that it expects to learn from what they find. This learning will inform the development of the CQC's guidance on meeting all of the new fundamental standards which is to be issued before 1st April 2015.
- 7.7 It is worth noting that, in parallel, the General Medical Council and Nursing and Midwifery Council are consulting on a new Professional Duty of Candour which would mean that there would be an obligation on doctors, nurses and other health professionals to inform patients when something goes wrong.

8. DUTY OF CANDOUR : IMMEDIATE ACTIONS TO BE TAKEN

- 8.1 Having regard to the 2014 Regulations and the CQC guidance, the Chief Nurse will prepare and submit a report to the Quality Assurance Committee meeting to be held on 29th January 2015 identifying how the Trust meets/will meet the specific requirements of the statutory duty of candour.
- 8.2 The report to be submitted to the January 2015 Quality Assurance Committee will : (a) use as a checklist the 32 specific points of CQC guidance which providers must have regard to in meeting the requirements of the statutory duty of candour; and
- (b) set out initial thoughts on how staff will be trained so that they are aware of their duties and understand how the duty of candour fits alongside their existing professional responsibilities; and to discharge the duty.
- 8.3 The Quality Assurance Committee will report to the Trust Board on 5th February 2015 the outcome of its consideration of the report identified above.

9. RECOMMENDATIONS

- 9.1 The Trust Board is recommended to:
- (a) receive and note this report,
- (b) agree that the Director of Human Resources will prepare and submit a report to the Trust Board on 5th February 2015 on how the Trust meets/will meet the specific requirements of the fit and proper persons test (section 5 of this reports refers);and

- (c) agree that the Chief Nurse will prepare and submit a report to the Quality Assurance Committee on 29th January 2015 on how the Trust meets/will meet the specific requirements of the statutory duty of candour (section 8 of this report refers).

Stephen Ward
Director of Corporate and Legal Affairs

12th December 2014