

BRIEFING: COMPLYING WITH THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) REGULATIONS 2014

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 deal with the fit and proper persons test and the duty of candour which came into force in November 2014 and with fundamental standards which come into force on 1 April 2015. This briefing includes an updated version of our earlier advice on the fit and proper persons test and the duty of candour and provides guidance on meeting the fundamental standards.

FIT AND PROPER PERSONS TEST

The regulations

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (the 2014 Regulations) places a duty on NHS providers not to appoint a person or allow a person to continue to be an executive director or equivalent or a non-executive director (NED) under given circumstances.

The requirement for fit and proper persons

Providers must not appoint a person to an executive director level post (including associate directors) or to a non-executive director post unless they are:

- Of good character;
- Have the necessary qualifications, skills and experience;
- Are able to perform the work that they are employed for after reasonable adjustments are made;
- Can supply information as set out in Schedule 3 of the Regulations (see the Role of the CQC below).

Paragraph 5 (4) of regulations states that in assessing whether a person is of good character, the matters considered must include those listed in Part 2 of Schedule 4. Part 2 of Schedule 4 refers to:

- Whether the person has been convicted in the United Kingdom of any offence or been convicted elsewhere of any offence which, if committed in any part of the United Kingdom, would constitute an offence, and
- Whether the person has been erased, removed or struck off a register of professionals maintained by a regulator of health care or social work professionals.

The CQC's definition of good character is not the objective test of having no criminal convictions but instead resets upon a judgement as to whether the person's character is such that they can be relied upon to do the right thing under all circumstances. This implies discretion for boards and councils in reaching a decision and allows for the fact that people can and do change over time.

The regulations list categories of persons who are prevented from holding the office and for whom there is no discretion:

- The person is an undischarged bankrupt or a person whose estate has had a sequestration awarded in respect of it and who has not been discharged;

- The person is the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order or an order to like effect made in Scotland or Northern Ireland;
- The person is a person to whom a moratorium period under a debt relief order applies under Part VIIA (debt relief orders) of the Insolvency Act 1986(40);
- The person has made a composition or arrangement with, or granted a trust deed for, creditors and not been discharged in respect of it;
- The person is included in the children's barred list or the adults' barred list maintained under section 2 of the Safeguarding Vulnerable Groups Act 2006, or in any corresponding list maintained under an equivalent enactment in force in Scotland or Northern Ireland;
- The person is prohibited from holding the relevant office or position, or in the case of an individual from carrying on the regulated activity, by or under any enactment;
- The person has 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 discharging any functions relating to any office or employment with a service provider.

In implementing the provision providers must have regard to the guidance issued by the CQC beginning on page 16 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>. It will be the responsibility of the chair of the provider to discharge the requirement placed on the provider, to ensure that all directors meet the fitness test and do not meet any of the 'unfit' criteria.

The CQC expects senior leaders to set a tone and culture of the organisation that leads to staff adopting a caring and compassionate attitude. It is important therefore that in making appointments boards and councils take account of the values of the organisation and the extent to which candidates provide a good fit with those values.

The role of the CQC

The regulations give the CQC powers to assess whether both executive and non-executive directors (but not foundation trust governors) are fit to carry out their role and whether providers have put in place adequate and appropriate measures to ensure that directors are fit and proper persons.

The CQC has the right to require the provision of information set out in Schedule 3 of the Regulations and such other information as is kept by the organisation that is relevant to the individual as follows:

1. Proof of identity including a recent photograph.
2. Where required for the purposes of an exempted question in accordance with section 113A(2)(b) of the Police Act 1997(38), a copy of a criminal record certificate issued under section 113A of that Act together with, after the appointed day and where applicable, the information mentioned in section 30A(3) of the Safeguarding Vulnerable Groups Act 2006 (provision of barring information on request)(39).
3. Where required for the purposes of an exempted question asked for a prescribed purpose under section 113B(2)(b) of the Police Act 1997, a copy of an enhanced criminal record certificate issued under section 113B of that Act together with, where applicable, suitability information relating to children or vulnerable adults.

4. Satisfactory evidence of conduct in previous employment concerned with the provision of services relating to:
 - (a) health or social care, or,
 - (b) children or vulnerable adults.
5. Where a person (P) has been previously employed in a position whose duties involved work with children or vulnerable adults, satisfactory verification, so far as reasonably practicable, of the reason why P's employment in that position ended.
6. In so far as it is reasonably practicable to obtain, satisfactory documentary evidence of any qualification relevant to the duties for which the person is employed or appointed to perform.
7. A full employment history, together with a satisfactory written explanation of any gaps in employment.
8. Satisfactory information about any physical or mental health conditions which are relevant to the person's capability, after reasonable adjustments are made, to properly perform tasks which are intrinsic to their employment or appointment for the purposes of the regulated activity.
9. For the purposes of this Schedule:
 - (a) 'the appointed day' means the day on which section 30A of the Safeguarding Vulnerable Groups Act 2006 comes into force;
 - (b) 'satisfactory' means satisfactory in the opinion of the Commission;
 - (c) 'suitability information relating to children or vulnerable adults' means the information specified in sections 113BA and 113BB respectively of the Police Act 1997

Where the CQC receives information from a third party regarding an alleged lack of fitness of a director the CQC will convene a panel to determine whether the information is significant and should be considered by the provider. The consent of the director concerned will be sought to pass information to the provider. Where the CQC does not obtain such consent it will consider whether to share the information with the provider. It will then be for the provider to consider whether the director in question remains or is a fit and proper person under the regulations.

The role of the CQC in determining whether information is satisfactory should be confined to forming a view on the quality of the evidence and whether it has been taken account of rather than attempting to second guess the decision of a board. Similarly the CQC should be examining the robustness and effectiveness of procedures rather than on the individual directors that are in post as a result of the procedures.

The CQC will expect providers to take account of some core public information sources about providers in making appointments; for example information from public inquiry reports, serious case reviews and Ombudsmen reports. The CQC will make further information available on its website.

During inspections the CQC will assess compliance with the test as part of the well-led domain. Where a provider cannot demonstrate that it has undertaken the appropriate checks in the appointment of its board members the CQC will decide whether or not to take regulatory action, and what action to take on a case by case basis. Where the CQC decides to take regulatory action providers may appeal to the First-tier Tribunal and or seek leave for judicial review.

The role of Monitor

Standard condition G4 of the provider license requires that a foundation trust must not appoint or allow an unfit person to remain in post without Monitor's permission. At present Monitor's definition is the narrower definition set out in the Schedule 7 of the National Health Service Act 2006 as amended by the Health and Social Care Act 2012.

Monitor is able to use its enforcement powers to deal with a breach of a license condition by requiring the foundation trust to remove the unfit person from office or by taking such action itself.

The role of councils of governors

The role of the nominations committee (with a majority of governor members) or the nominations committee for non-executive director appointments (if there are two nominations committees) is to interview and otherwise assess the candidates and to recommend suitable candidates for appointment to meetings of the full council. The committee also recommends to the council whether or not to approve the appointment of the chief executive. Councils of governors may also remove the chair or non-executive directors from post.

The degree to which nominations committees involve themselves in chair and NED appointments prior to interview varies greatly from trust to trust and it is not intended to cover all eventualities here. As a minimum however nominations committees and through them councils of governors will need to satisfy themselves that the relevant checks set out in the table above have been carried out and they will want to satisfy themselves that the board has adequate assurances on the robustness of procedures.

Where a candidate has made a declaration in respect of their character that does not comply with the regulations or in respect of past mismanagement and has offered an explanation of the circumstances, the nominations committee will need to investigate and form a view as to whether the explanation is sufficient to allow the candidate to continue in the appointments process.

Where the nominations committee decides to recommend such a candidate for appointment, the meeting of the council will need to satisfy itself that the investigation carried out by the nominations committee was robust.

Where a chair or NED declares a change in the status of their character or where such a change becomes known, the council of governors will need to decide on a procedure to investigate and determine the case if such a procedure is not already in place.

Where Monitor or the CQC consider that serious mismanagement has occurred within the trust or where there has been a serious breach of a licence condition councils of governors will need to decide on a procedure to investigate and deal with any cases if such a procedure is not already in place.

We do not believe that there is a general issue within the NHS of unfit individuals being recruited to provider boards and our organisations have all argued for a nuanced approach to implementing the regulations.

The definition of how NHS providers are expected to be 'privity to' particular evidence about whether an individual is 'fit and proper' to undertake a given role, is of particular concern because at face value, the absence of evidence of action could be taken as evidence against the individual. For instance, taken to its extreme, a failure to whistle-blow

could become a career limiting decision unless the individual concerned can demonstrate that they had good reason for not doing so.

Complying with the fit and proper persons test

	Standard	Assurance process	Evidence
	At appointment		
1.	<p>Providers should make every effort to ensure that all available information is sought to confirm that the individual is of good character as defined in Schedule 4, Part 2 of the regulations.</p> <p>(Sch.4, Part 2: Whether the person has been convicted in the United Kingdom of any offence or been convicted elsewhere of any offence which, if committed in any part of the United Kingdom, would constitute an offence.</p> <p>Whether the person has been erased, removed or struck-off a register of professionals maintained by a regulator of health care or social work professionals.)</p>	<p>Employment checks in accordance with NHS Employment Check Standards issued by NHS Employers including:</p> <ul style="list-style-type: none"> ▪ two references, one of which must be most recent employer; ▪ qualification and professional registration checks; ▪ right to work checks; ▪ proof of identity checks; ▪ occupational health clearance; ▪ DBS checks (where appropriate); ▪ search of insolvency and bankruptcy register; ▪ search of disqualified directors register. 	<p>References;</p> <p>Outcome of other pre-employment checks;</p> <p>DBS checks where appropriate;</p> <p>Register search results;</p> <p>List of referees and sources of assurance for FOIA purposes.</p>

	Standard	Assurance process	Evidence
2.	Where a provider deems the individual suitable despite not meeting the characteristics outlined in Schedule 4, Part 2 of these regulations, the reasons should be recorded and information about the decision should be made available to those that need to be aware.	<p>Report and debate at the nominations committee(s).</p> <p>Report and recommendation at the council of governors (for NEDs) or the board of directors (for EDs) for foundation trusts, reports to the board for NHS trusts.</p> <p>Decisions and reasons for decisions recorded in minutes.</p> <p>External advice sought as necessary.</p>	Record that due process was followed for FOIA purposes.
3.	Where specific qualifications are deemed by the provider as necessary for a role, the provider must make this clear and should only employ those individuals that meet the required specification, including any requirements to be registered with a professional regulator.	<p>Requirements included within the job description for all relevant posts.</p> <p>Checked as part of the pre-employment checks and references on qualifications.</p>	<p>Person specification</p> <p>Recruitment policy and procedure</p>
4.	<p>The provider should have appropriate processes for assessing and checking that the individual holds the required qualifications and has the competence, skills and experience required, (which may include appropriate communication and leaderships skills and a caring and compassionate nature), to undertake the role; these should be followed in all cases and relevant records kept.</p> <p><i>N.B. While this provision most obviously applies to executive director appointments in terms of qualifications, skills and experience will be relevant to NED appointments.</i></p>	<p>Employment checks include a candidate's qualifications and employment references.</p> <p>Recruitment processes include qualitative assessment and values-based questions.</p> <p>Decisions and reasons for decisions recorded in minutes.</p>	<p>Recruitment policy and procedure</p> <p>Values-based questions</p> <p>Minutes of council of governors.</p> <p>Minutes of board of directors.</p>

	Standard	Assurance process	Evidence
5.	In addition to 4. above, a provider may consider that an individual can be appointed to a role based on their qualifications, skills and experience with the expectation that they will develop specific competence to undertake the role within a specified timeframe.	<p>Discussions and recommendations by the nominations committee(s).</p> <p>Discussion and decision at board of directors or council of governors meeting.</p> <p>Reports, discussion and recommendations recorded in minutes of meetings.</p> <p>Follow-up as part of continuing review and appraisal.</p>	<p>Minutes of committee, board and or council meetings.</p> <p>NED appraisal framework</p> <p>NED competence framework</p> <p>Notes of ED appraisals</p>
6.	When appointing relevant individuals the provider has processes for considering a person's physical and mental health in line with the requirements of the role, all subject to equalities and employment legislation and to due process.	Self-declaration subject to clearance by occupational health as part of the pre-employment process.	Occupational health clearance
7.	Wherever possible, reasonable adjustments are made in order that an individual can carry out the role.	<p>Self declaration of adjustments required.</p> <p>NHS Employment Check Standards</p> <p>Board/council of governors decision</p>	Minutes of board meeting/council of governors meeting

	Standard	Assurance process	Evidence
8.	<p>The provider has processes in place to assure itself that the individual has not been at any time responsible for, privy to, contributed to, or facilitated, any serious misconduct or mismanagement in the carrying on of a regulated activity; this includes investigating any allegation of such potential behaviour. Where the individual is professionally qualified, it may include fitness to practise proceedings and professional disciplinary cases.</p> <p>(‘Regulated activity’ means activities set out in Schedule 1, Regulated Activities, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Schedule 1 covers the provision of:</p> <ul style="list-style-type: none"> personal care; accommodation for persons who require nursing or personal care; accommodation for persons who require treatment for substance misuse; treatment of disease, disorder or injury; assessment or medical treatment for persons detained under the 1983 Act; surgical procedures; diagnostic and screening procedures; management of supply of blood and blood derived products etc.; transport services, triage and medical advice provided remotely; maternity and midwifery services; termination of pregnancies; services in slimming clinics; nursing care; family planning services. <p>‘Responsible for, contributed to or facilitated’ means that there is evidence that a person has intentionally or through neglect behaved in a manner which would be considered to be or would have led to serious misconduct or mismanagement.</p> <p>‘Privy to’ means that there is evidence that a person was aware of serious misconduct or mismanagement but did not take the appropriate action to ensure it was addressed.</p> <p>‘Serious misconduct or mismanagement’ means behaviour that would constitute a breach of any legislation/enactment CQC deems relevant to meeting these regulations or their component parts.”)</p> <p><i>N.B. This provision applies equally to executives and NEDs.</i></p>	<p>Consequences of false or inaccurate or incomplete information included in recruitment packs.</p> <p>Checks set out in 1. Above i.e.</p> <p>Employment checks in accordance with NHS Employers pre-employment check standards including:</p> <ul style="list-style-type: none"> self-declarations of fitness including explanation of past conduct/character issues where appropriate by candidates; two references, one of which must be most recent employer; qualification and professional registration checks; right to work checks; proof of identity checks; occupational health clearance; DBS checks (where appropriate); search of insolvency and bankruptcy register; search of disqualified directors register. <p>Included in reference requests.</p>	<p>NED Recruitment Information pack</p> <p>Reference Request for ED/NED</p>

	Standard	Assurance process	Evidence
9.	<p>The provider must not appoint any individual who has been responsible for, privy to, contributed to, or facilitated, any serious misconduct or mismanagement (whether lawful or not) in the carrying on of a regulated activity; this includes investigating any allegation of such potential behaviour. Where the individual is professionally qualified, it may include fitness to practise proceedings and professional disciplinary cases.</p> <p>N.B. The CQC accepts that providers will use reasonable endeavours in this instance.</p> <p>The existence of a compromise agreement does not indemnify the new employer and providers will need to ensure that their Core HR policies address their approach to compromise agreements.</p>	<p>Consequences of false, inaccurate or incomplete information included in recruitment packs.</p> <p>Core HR policies for appointments and remuneration</p> <p>Checks set out in Section 1 above.</p> <p>Included in reference requests.</p>	<p>NED and ED Recruitment Information packs</p> <p>Core HR policies</p> <p>Reference Request for ED/NED</p>
10.	<p>Only individuals who will be acting in a role that falls within the definition of a 'regulated activity' as defined by the Safeguarding Vulnerable Groups Act 2006 will be eligible for a check by the Disclosure and Barring Service (DBS).</p> <p><i>N.B. The CQC recognises that it may not always be possible for providers to access a DBS check as an individual may not be eligible.</i></p>	<p>DBS checks are undertaken only for those posts which fall within the definition of a "regulated activity" or which are otherwise eligible for such a check to be undertaken.</p>	<p>DBS policy</p> <p>DBS checks for eligible post-holders</p>

	Standard	Assurance process	Evidence
11.	As part of the recruitment/appointment process, providers should establish whether the individual is on a relevant DBS list.	Eligibility for DBS checks will be assessed for each vacancy arising.	DBS policy
	Continuing provisions		
12.	The fitness of directors is regularly reviewed by the provider to ensure that they remain fit for the role they are in; the provider should determine how often fitness must be reviewed based on the assessed risk to business delivery and/or the service users posed by the individual and/or role.	<p>Assessment of continued fitness to be undertaken each year as part of appraisal process.</p> <p>Checks of insolvency and bankruptcy register and register of disqualified directors to be undertaken each year as part of the appraisal process.</p> <p>Board/Council of Governors reviews checks and agrees the outcome.</p>	<p>Continual to be assessed as part of appraisal process</p> <p>Register checks if necessary</p> <p>Board/council minutes record that process has been followed.</p>

	Standard	Assurance process	Evidence
13.	<p>If a provider discovers information that suggests an individual is not of good character after they have been appointed to a role, the provider must take appropriate and timely action to investigate and rectify the matter.</p> <p>The provider has arrangements in place to respond to concerns about a person's fitness after they are appointed to a role, identified by itself or others, and these are adhered to.</p>	<p>Core HR policies provides for such investigations.</p> <p>Revised contracts allow for termination in the event of non-compliance with regulations and other requirements.</p> <p>Contracts (for EDs and director-equivalents) and agreements (for NEDs) incorporate maintenance of fitness as a contractual requirement.</p>	<p>Core HR polices</p> <p>Contracts of employment (for EDs and director-equivalents)</p> <p>Service agreements or equivalent (for NEDs)</p>
14.	<p>The provider investigates, in a timely manner, any concerns about a person's fitness or ability to carry out their duties, and where concerns are substantiated, proportionate, timely action is taken; the provider must demonstrate due diligence in all actions.</p>	<p>Core HR policies include the necessary provisions.</p> <p>Action taken and recorded as required</p>	<p>Core HR policies</p>
15.	<p>Where a person's fitness to carry out their role is being investigated, appropriate interim measures may be required to minimise any risk to service users.</p>	<p>Core HR policies</p>	<p>Managerial action taken to backfill posts as necessary.</p>
16.	<p>The provider informs others as appropriate about concerns/findings relating to a person's fitness; for example, professional regulators, CQC and other relevant bodies, and supports any related enquiries/investigations carried out by others.</p>	<p>Core HR policies</p>	<p>Referrals made to other agencies if necessary.</p>

In the table above, unless the contrary is stated or the context otherwise requires, "ED" means executive directors and director equivalents.

FUNDAMENTAL STANDARDS

Person-centred care

Regulation 9 specifies that the care and treatment of service users must be appropriate, meet their needs and reflect their preferences. To meet this standard provider organisations must

- Carry out an assessment of the care and treatment needs of then service user in the context of their preferences, involving the service user or their representative as appropriate;
- Aim to meet the service users' preferences while ensuring that their needs are met;
- Ensure that the service user understands their options for care and treatment and has the opportunity to discuss the risks and benefits of those options with a healthcare professional;
- Ensure that the service user or their representative is involved in decisions relating to their care and/or treatment to the maximum extent;
- Provide appropriate opportunities for people or their representatives to manage their care or treatment;
- Involve people using services in decisions relating about the way in which the service is delivered in so far as it relates to their care or treatment;
- Provide relevant persons with the information they would reasonably need to participate in decisions on their care and treatment;
- Make reasonable adjustments to enable the service user to receive their care or treatment;
- Where meeting a service user's nutritional and hydration needs, have regard to the service user's well-being.

The CQC cannot prosecute providers for breach of the regulation or any of its parts, but the CQC may decide to take regulatory action.

The CQC's guidance, <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>, gives more detail on what providers might do to meet the standard. The underlying principles for providers are that they must do what is practicable and reasonable in each instance to comply with the standard. Clearly a culture that promotes involving people in their treatment will be as important as having the right systems and processes in place. However boards will want to assure themselves that what is reasonable and practicable in delivering patient-centred treatment is being achieved.

Dignity and respect

Regulation 10 stipulates that patients and service users must be treated with dignity and respect.

To comply with the regulation provider organisations must:

- Ensuring the privacy of the patient or service user;
- Support the autonomy, independence and involvement in the community of the patient or service user;
- Give due regard to any relevant protected characteristics (as defined in section 149(7) of the Equality Act 2010) of the patient or service user. The protected characteristics are age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation.

A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 34 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>. The CQC cannot prosecute providers for breach of the regulation or any of its parts, but the CQC may decide to take regulatory action.

The dignity and respect regulation applies to both facilities and to the way in which individuals are treated. The requirement for separate sleeping and bathroom facilities for each sex is not subject to a reasonableness test, although other aspects of the privacy dimension of the regulation are subject to the provider organisation making all reasonable efforts: to hold discussions in private spaces and to respect the privacy preferences of the patient/service user, for example.

The CQC's guidance appears to acknowledge that autonomy brings with it different and sometimes additional risks. In recognising the need to support independence as safely as possible the guidance ostensibly recognises that while risks associated with supporting independence can be identified and controlled they cannot be completely eliminated. The logic of the acknowledgment is that in enforcing the regulation the CQC will accept that from time to time controls will not deliver the desired outcome and adverse incidents will occur.

To comply with the provisions on protected characteristics provider organisations will need to ensure that they do not discriminate unlawfully either directly or indirectly. It is likely that NHS provider boards will already have sources of assurance available to them in this respect.

Need for consent

To comply with regulation 11 provider organisations must ensure that they obtain the consent lawfully and that the person who obtains the consent has the necessary knowledge and understanding of the care and/or treatment for which they are seeking consent. A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 37 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>.

The CQC can bring a criminal prosecution for a breach of this regulation or a breach of part of the regulation. To bring prosecution it is not necessary for the CQC to first take other regulatory action or issue a warning notice. It is a defence to this offence that the provider organisation took all reasonable steps to comply and acted with all due diligence.

Provider organisations already have well functioning systems in place to ensure that consent is obtained, but given the consequences of any system failure boards will probably wish to check the health of their systems and assurances on them.

Safe care and treatment

Regulation 12 sets out what provider organisations must do to deliver safe treatment. This includes:

- Assessment and control of the risks to the health and safety of patients or service users;
- Ensuring staff have the qualifications, competence, skills and experience to provide safe care and treatment;
- Ensuring premises are fit for purpose and safe for use;
- Ensuring equipment is safe for such use and is used safely;
- Ensuring equipment or medicines are available in sufficient quantities to ensure safe treatment;
- Ensuring medicines are managed properly and safely;
- Ensuring effective infection control including health care associated infections;

- Ensuring that shared responsibility for care or treatment and transfer to other providers is dealt with safely and effectively.

A component of the regulation is that provider organisations must have regard to nationally recognised guidance and the section of the CQC's guidance beginning on page 41 of the following:

<http://www.cqc.org.uk/content/regulations-service-providers-and-managers>. In effect the requirement is that provider organisations should follow such guidance. The CQC guidance contains further detail on how to comply with the regulation. Effective systems of risk management operated with diligence and rigour go to the heart of complying with the regulation.

The CQC can bring a criminal prosecution for a breach of this regulation or a breach of part of the regulation if the breach results in avoidable harm to the patient or service user or if a person using the service is exposed to significant risk of harm. The regulations themselves make no mention of 'exposed to significant risk of harm' and the guidance does not define it further, however the implication is that the CQC will consider prosecutions for 'near miss' situations if the fact that significant harm did not occur was fortuitous rather than because of the operation of a last line of defence.

Oversight of robust, effective risk management and assurance systems to ensure patient safety goes to the heart of a boards work. Nevertheless boards may wish to review the operation and effectiveness of their risk management systems in the light of the new criminal offence.

Safeguarding service users from abuse and improper treatment

The expectation set out in regulation 13 is that provider organisations have a 'zero tolerance approach' to abuse, unlawful discrimination and unlawful restraint. Abuse is defined in the regulation as: any behaviour towards a service user that is an offence under the Sexual Offences Act 2003; ill-treatment whether of a physical or psychological nature, including degrading treatment; theft, misuse or misappropriation of money or property and neglect.

Restraint is defined in the guidance as when someone: 'uses, or threatens to use, force to secure the doing of an act which the service user resists, or restricts the service user's liberty of movement, whether or not the service user resists, including by use of physical, mechanical or chemical means. An offence is committed where such restraint is unnecessary or disproportionate restraint, or where a person is unlawfully deprived of liberty.

A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 48 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>.

The CQC can go straight to prosecution if a failure to meet the sections of the regulation dealing with abuse, discrimination or unlawful restraint results in avoidable harm or significant risk of harm. Once again it is a defence that the provider organisation took all reasonable steps to comply and acted with all due diligence, so boards will wish to be assured that this is the case.

Meeting nutritional and hydration needs

To comply with regulation 14 provider organisations must make sure that people using their services have enough to eat to meet their nutrition needs and enough to drink to meet their hydration needs. Provider organisations

must ensure that people using their services have their nutritional needs assessed and that food is provided to meet those needs. This will include prescribed nutritional supplements and/or parenteral nutrition. Provider organisations must take account of preferences and religious and cultural backgrounds when providing food and drink and must provide the support necessary to enable people to eat and drink.

A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 54 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>. The CQC can go straight to prosecution if a failure to meet the regulation results in avoidable harm or significant risk of harm. It is a defence that the provider organisation took all reasonable steps to comply and acted with all due diligence, so once again, boards will wish to be assured that this is the case.

Premises and equipment

To comply with regulation 15 provider organisations must ensure that premises are clean, fit purpose, well maintained and accessible. They must also ensure that equipment is clean, suitable, properly maintained, stored securely and used properly. It should be noted that legal responsibility remains with the registered provider organisation even where they delegate responsibility through contracts or legal agreements to a third party, independent suppliers, professionals, supply chains or contractors. Where the service user or patient owns the equipment needed to deliver their care and treatment, or the provider does not provide it, the provider must still make every effort to make sure that it is clean, safe and suitable for use.

A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 59 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>. The CQC cannot prosecute under this regulation but it can take regulatory action. However where a breach of this regulation results in unsafe care or treatment regulation 12 in respect of safe care and treatment, against which criminal charges can be brought, will apply. Boards will therefore wish to confirm assurances in respect of premises and equipment.

Receiving and acting on complaints

To comply with regulation 16 providers must have an effective and accessible system for identifying, receiving, handling and responding to complaints made by anyone. All complaints must be investigated thoroughly and, where failures have been identified, any necessary action must be taken. The regulation does not define what a complaint is, so it is important that provider organisations have their own robust and justifiable definition so that they can demonstrate compliance. However the guidance states that complaints may be made either orally or in writing, suggesting a broad definition of complaints along the lines of: any expression of dissatisfaction.

The CQC cannot prosecute in regard to this element of the regulation, but it can take regulatory action. However regulation 20 on the duty of candour also applies to the complaints procedure and prosecutions can be brought under regulation 20. A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 64 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>.

When requested to do so, providers must provide CQC with a summary of complaints, responses and other related correspondence or information within 28 days of the request being made. Failure to comply with this element of the regulation is an offence and the CQC can move straight to prosecution without a warning notice being issued.

Provider organisations already have complaints procedures in place, however complaints systems in the NHS have been under increasing scrutiny of late and it is important that NHS providers check that their complaints processes are up to date and functioning well.

It is also important that providers can demonstrate that they are learning from complaints at all levels of the organisation, from trends in feedback and complaints, and can cite examples of where complaints have led to service change and improvement.

Good governance

To meet regulation 17 provider organisations must ensure that the systems and processes that underpin good governance are in place and operate well. This will include systems of risk management, assurance and checks on assurance. One of the key outcomes should be an enhanced ability to assess, monitor and drive improvement in the quality, safety and experience of the services provided. The regulation places a duty on provider organisations continually to evaluate and seek to improve their governance and auditing practice.

Provider organisations are required under the regulation to maintain accurate, complete and detailed records for each person to whom they provide a service and records relating to the employment of staff and the overall management of the regulated activity. Provider organisations are required under the regulation to seek and act on feedback from patients/service users, those acting on their behalf, staff and other stakeholders to enable them to evaluate their services and drive improvement. A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 68 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>. Failure to comply with this element of the regulation is not an offence, but the CQC may take regulatory action.

When requested, provider organisations must give to the CQC a written report setting out how they assess, monitor, and where necessary improve the quality and safety of their services within 28 days of the request being made. Failure to comply with this element of the legislation is an offence and the CQC can move straight to prosecution without first issuing a warning notice.

Sound corporate governance underpinned by robust systems and processes is part and parcel of the work of provider organisations' boards and is subject to periodic review in accordance with the provisions of the foundation trust Code of Governance. Those boards that have not yet commissioned an external review of their governance arrangements may wish to consider whether it would be timely to do so in the light of the regulations.

Staffing

To meet regulation 18 provider organisations must ensure that sufficient numbers of suitably qualified, competent, skilled and experienced staff are available to meet the needs of patients/service users at all times as well as to meet the other regulatory requirements. Provider organisations must ensure that their staff receive the support, training,

professional development, supervision and appraisals necessary for them to carry out their duties effectively and so that they continue to meet the professional standards necessary to practise.

A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 75 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>.

The CQC cannot prosecute for a breach of this regulation but it may take regulatory action. Provider organisations will need to be cognisant and take account of any recommended guidelines on staffing levels including NICE guidelines where available and need to take account of the views of their staff in determining staffing. There is currently no legal requirement to follow guidelines such as those produced by NICE, but organisations that choose not to follow the guidelines should have followed a rigorous process in deciding otherwise and should have a body of evidence available to them to assure themselves on the decision.

Fit and proper persons employed

To comply with regulation 19 provider organisations must ensure that persons employed to carry on a regulated activity must:

- (a) be of good character;
- (b) have the qualifications, competence, skills and experience which are necessary for the work to be performed by them; and
- (c) be able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the work for which they are employed.

'Regulated activity' means activities set out in Schedule 1, Regulated Activities, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. It is a matter for the provider organisation to decide whether a person is of good character but they must take account of all available information to confirm that the person is of good character, and have regard to the matters outlined in Schedule 4, Part 2 of the regulations:

- Whether the person has been convicted in the United Kingdom of any offence or been convicted elsewhere of any offence which, if committed in any part of the United Kingdom, would constitute an offence, and
- Whether the person has been erased, removed or struck off a register of professionals maintained by a regulator of health care or social work professionals.

The CQC will expect that processes followed to assess good character take account of honesty, trust, reliability and respect. In common with directors, employees must be able to provide information in accordance with Schedule 3 of the regulations: <http://www.legislation.gov.uk/ukdsi/2014/9780111117613/schedule/3>. If a provider organisation considers that an applicant is suitable, despite them having information about anything set out in Schedule 3, their reasons for reaching that decision should be recorded for future reference.

There is a requirement that provider organisations review the fitness of their staff on a regular basis and take appropriate action where necessary including ensuring that staff found to be unfit no longer carry out the regulated activity. Appraisals are likely to be a suitable vehicle for such reviews. Provider organisations will need to ensure that they have effective and fair procedures in place to deal with concerns about a person's fitness, but where there is the possibility of imminent risk organisations should be able to respond immediately.

Where a qualification is not required by law it is for provider organisations to decide what qualifications are necessary for a role. In either case provider organisations must take steps to ensure that appointed staff hold the necessary qualifications and remain fit and qualified to practise.

A component of the regulation is that boards must take account of the section of the CQC's guidance beginning on page 79 of the following: <http://www.cqc.org.uk/content/regulations-service-providers-and-managers>.

The CQC cannot bring a prosecution for a breach of any element of this regulation unless it also constitutes a breach of one of the other prosecutable regulations. It can however take regulatory action.

Duty of candour

Regulation 20 makes it a statutory requirement that health service bodies to act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

'Regulated activity' means activities set out in Schedule 1, Regulated Activities, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. In this context a 'relevant person' is the patient or service user. In the event of the patient or service user's death, or if they under 16, or over 16, but lack capacity in relation to the matter the relevant person can be someone lawfully acting on their behalf

As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must:

- (a) notify the relevant person that the incident has occurred in accordance with the paragraph below and;
- (b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

The notification must:

- (a) be given in person by one or more representatives of the health service body;
- (b) provide an account, which to the best of the health service body's knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification;
- (c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate;
- (d) include an apology; and
- (e) be recorded in a written record which is kept securely by the health service body.

This must be followed by a written notification to the relevant person containing:

- (a) the information provided orally as described above;
- (b) details of any enquiries to be undertaken;
- (c) the results of any further enquiries into the incident; and
- (d) an apology.

All correspondence between the parties must be kept by the health service body. If the patient or service user or the person acting on their behalf cannot be contacted in person or declines to speak to the representative of the

health service body the above paragraphs do not apply, but the health service body must keep a written record of attempts to contact or to speak to service user, patient or their lawful representative.

Further definitions

The regulations provide definitions as follows:

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.

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.

Moderate harm means harm that requires a moderate increase in treatment, and significant, but not permanent, harm.

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).

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.

Apology means an expression of sorrow or regret in respect of a notifiable safety incident.

Most of the requirements under the duty of candour are clear cut. NHS provider organisations will already have in place arrangements to comply with the contractual duty and these are likely to be adaptable to deal with the statutory duty. Nevertheless boards are likely to wish to be assured that the processes they have put in place are compliant with the statutory duty and are delivering the required outcome.

The CQC's approach

The CQC has included consideration of the duty in its key lines of enquiry (KLOEs) for inspections and intends to use the regulations to promote and encourage good practice and to acknowledge good practice where it is found. The CQC has committed to working with provider organisations to develop processes by which compliance with the duty can be assessed and to reserve use of prosecution for those cases where there is evidence of deliberate withholding or manipulation of information.

The duty on providers to ensure an open and honest culture across and at all levels within its organisation is not in itself controversial, and indeed parallels the existing contractual duty of candour. However NHS provider boards will need to assure themselves that they comply fully with the spirit of openness implied by the duty. While processes and procedures can be put in place quite quickly alongside measures to deliver compliance, culture change

generally takes place over a much longer timescale and it is often the case that behaviours will change before attitudes.

Please find our consultation response here: <http://www.foundationtrustnetwork.org/resource-library/fit-and-proper-persons-and-duty-of-candour/?preview=true>.

Display of CQC ratings on NHS provider organisation premises and websites

Regulation 20A of the Fundamental Standards sets out the requirement to display ratings ('performance assessments') at their physical premises and on their website(s). This will be a legal requirement from 01 April 2015. This Annex summarises CQC's guidance but we strongly recommend you read the full guidance (13 pages) and approach CQC for clarification about how you can meet the display requirements with respect to any logistical or practical challenges for your own trusts' premises and services. CQC's guidance for the display of ratings can be found [here](#).

Specific requirements placed on healthcare providers

To comply with this duty CQC offers the following guidance for NHS Trusts and Foundation Trusts:

- **You must display your ratings at each and every premises where you provide a regulated activity**, even if the premises is not registered with the CQC, and in your main place of business. Vehicles and patient's homes are exempt.
- Your ratings must be displayed at all premises **no later than 21 calendar days after your inspection report has been published on CQC's website**. This applies even if you have submitted a request for a review of ratings.
- **There are up to three different types of posters outlined by CQC:**
 - The provider poster (with information on the trust rating overall),
 - Premises poster (for information relating to services provided at a specific site)
 - Activity poster (for information relating to specific core services).
- **Posters need to include specific information:** CQC has made posters for displaying ratings available to download from [their website](#). You may also design your own poster but it must be as readable as the CQC template.
- **Which posters need to be displayed?** There is a table in the guidance that sets out CQC's expectations for different sectors on how posters should be displayed and at which locations. In brief:
 - the premises poster should be displayed at each site, with the provider poster used if there is no premises level poster (for example, for community or mental health providers) or if a premises level poster is not relevant (for example, an NHS trust head office not in a CQC rated location).
 - You may wish to also display activity posters at the entrances to wards/clinics where core services are delivered.
 - Activity posters should always be displayed alongside either the premises poster or the provider poster.
 - Posters should be printed in colour and at a minimum size of A4 (or larger to ensure visibility).
- **Where posters should be displayed:** CQC expects **hospitals** to display ratings posters at the main entrance(s) to each hospital so as many people as possible can see them. **Community-based services** will need to ensure that the poster(s) are visible to patients when they use services. **Mental Health trusts** will

need to display poster(s) at the main entrance(s) so as many people as possible are able to see them. If some patients do not use the entrance (for example, they are on a locked ward) you must display the poster so those patients can see it. In premises where several registered providers operate, it is up to each provider to ensure the ratings for the services they provide are displayed.

- **Additional information:** Providers are encouraged to display additional information (alongside, not instead of, the CQC poster) for patients if considered that it will aid their fuller understanding of the CQC ratings.
- **Websites:** CQC have developed a 'widget' to help you display your rating online (available [here](#)). Wherever possible, it is advised that ratings be placed on a 'context-specific' page. For example, a hospital rating should be included on the main page for that hospital. If your trust does not have premises specific pages, you are still required to display your premises ratings. You must put your ratings on every website that you operate that describes the services you offer and the ratings should be on a page that can be reached via the main navigation.

NHS Providers' view

From your feedback to date, we recognise that members may find the requirements set out above onerous, or more difficult to implement in some care settings than others. We welcome your on going feedback on the implementation of all of the regulations emanating from the Care Act, and we are in an open dialogue with CQC and others about their implementation. Our consultation responses to date can be found [here](#).

Conclusions

The regulations are intended to comprise a comprehensive suite of requirements that will help the CQC to regulate provider organisation's compliance with fundamental standards. Breach of regulations 11, 12, 13, 14, 16,17 and 20 can lead to directly to the prosecution of organisations with the possibility of substantial fines being imposed in addition to possible damage to the reputation of the organisation involved. It is not known whether prosecution will be the preferred route for breaches given that other regulatory action will be available to the CQC however all provider boards will wish to assure themselves that they have the necessary processes and procedures in place to comply for patient benefit and to support staff appropriately, as well as given the likely national focus on monitoring compliance with the new standards.

NHS Providers
March 2015