

CARE QUALITY COMMISSION – FUNDAMENTAL STANDARDS (from 01 April 2015)

***These regulations have prosecutable clauses relating specifically to harm or the risk of harm**

Regulation	The purpose of the regulation is to:	To meet the requirement of the regulation, the provider must:	Enforcement (if provider is not meeting the regulation)
Regulation 5: Fit and Proper Person - Directors	Require providers to take proper steps to ensure that their directors (both executive and non-executive) are fit and proper for the role. It makes it clear that individuals who have authority in organisations that deliver care are responsible for the overall quality and safety of that care.	Carry out all necessary checks to confirm that persons who are appointed to the role of director (or similar senior level role, whatever it might be called) in an NHS trust or NHS foundation trust are of good character, have: <ul style="list-style-type: none"> • The appropriate qualifications and are competent and skilled • A caring and compassionate nature and appropriate aptitude • The relevant experience and ability (including an appropriate level of physical and mental health, taking account of any reasonable adjustments) • Appropriate personal behaviour and business practices • Not been responsible for, or known, contributed to or facilitated any serious misconduct or mismanagement in carrying on a regulated activity 	Breaches of this regulation or its component parts do not constitute a prosecutable offence in themselves. However, CQC can take other regulatory action against breaches of the regulation or any of its components. Additionally, breaches of other regulations, including the fundamental standards detailed in Regulations 10 to 21, may give CQC cause to question whether they have resulted from a breach of this regulation.
Regulation 9: Person Centred Care	Ensure that each service user receives care that is personalised specifically for them, that meets their needs and reflects their preferences.	<ul style="list-style-type: none"> • Assess each service user's needs and preferences in collaboration with the service user or relevant person • Design and deliver care and treatment that is appropriate for each individual, that meets their needs and that they make all reasonable efforts to accommodate preferences • Make available information and support that helps people understand the care and treatment options, so they are able to make informed choices and decisions about their care and treatment • Ensure that relevant persons have opportunities and information to be involved with and manage (as appropriate) the service user's care and treatment if they wish, and the provider should make any reasonable adjustments to facilitate this 	Breaches of this regulation or its components do not constitute a prosecutable offence in themselves. However, CQC can take regulatory action against breaches of this regulation or any of its component parts. In addition, where CQC deems that a breach of this regulation constitutes a breach of a regulation(s) that carries offence clauses, for example, if care and treatment is provided without the consent of the relevant person(s) and results in any form of abuse or puts the service user at risk of abuse, is unsafe or does not meet their nutritional needs, then CQC can move directly to prosecution without serving a warning notice.
Regulation 10: Dignity and Respect	Ensure that service users are treated with respect and dignity at all times while receiving care and treatment.	<ul style="list-style-type: none"> • Demonstrate respect for service users by treating them with care and compassion, addressing them in the manner they have indicated they prefer and treating all services users equally regardless of their level of understanding or ability to express their views • Maintain service users' privacy at all times, including, for 	Breaches of this regulation or its components do not constitute a prosecutable offence in themselves. However, CQC can take other regulatory action against breaches of this regulation or any of its component parts. In addition, where CQC deems that a breach of

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		<p>example, if they are asleep or unconscious</p> <ul style="list-style-type: none"> • Understand the level of autonomy and independence that each service user requires and should enable and promote their involvement in the community that is important to them (where this is relevant to their care and treatment) • Have due regard to the age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation of each service user, as defined in the Equality Act 2010. 	<p>this regulation constitutes a breach of a regulation(s) that carries offence clauses, then we can move directly to prosecution without serving a warning notice. For example, if care and treatment is provided without the consent of the relevant person(s), or, where relevant, as a result of a best interest decision-making process in accordance with the Mental Capacity Act 2005, and results in any form of abuse or puts the service user at risk of abuse, is unsafe or if it does not meet the person's nutritional needs.</p>
Regulation 11: Need for Consent*	<p>Ensure that all service users (relevant persons) have given consent in accordance with this regulation before any care or treatment is delivered.</p>	<ul style="list-style-type: none"> • Ensure that they obtain consent or lawful authority • The person who obtains the consent must have the necessary knowledge and understanding of the care and treatment that they are asking consent for, so that they can discuss the risks and benefits and answer any questions from the service user • Provide information about the care or treatment in a format that the service user or relevant person understands. The format in which consent is given may depend on the circumstances. For example, where appropriate, consent may be implied from actions such as a person rolling up their sleeve to have their blood pressure taken, or offering their hand when asked if they would like help to move. Expressed consent may be given verbally, although this should be captured in the service user's notes. Consent may also be formally documented (normally using a form in this case). 	<p>This regulation relates to all of the fundamental standards, and breaches of it or its components constitute a prosecutable offence. This means that where care and treatment is given without valid consent, and/or it is against the specified wishes of the service user or without lawful authority, CQC can move directly to prosecution without first serving a warning notice.</p>
Regulation 12: Safe Care and Treatment*	<p>Prevent service users from receiving unsafe care and treatment, in order to prevent any avoidable harm or risk of harm. CQC understands that there may be inherent risks in carrying out care and treatment, and will not consider it to be unsafe if providers can demonstrate that they have taken all reasonable steps to ensure the health and safety of</p>	<ul style="list-style-type: none"> • Take appropriate steps to assure itself that the care and treatment it delivers is safe for all service users. • Ensure that care and treatment is designed and delivered with due regard to individual needs and circumstances, and that it is designed and delivered in partnership with other providers where care and treatment is shared or transferred, to ensure the health, safety and welfare of service users • Ensure that it acts in accordance with relevant legislation in 	<p>This regulation relates to all of the fundamental standards and breaches of it, or its components, constitute a prosecutable offence. This means that where care and treatment is considered unsafe or there is a risk that it will become so, CQC can move directly to prosecution without first serving a warning notice.</p>

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	service users, and to manage any risks that may arise during care and treatment.	<p>relation to infection prevention and control and the management of medicines.</p> <p>A provider would not be able to meet any of the requirements of this regulation if it did not deploy sufficient numbers of suitably qualified, competent, skilled and experience staff to provide the care and treatment being planned or being delivered, or if it did not have access to the necessary equipment or medicines, or did not use equipment safely</p>	
Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment*	Safeguard service users from suffering any form of abuse or improper treatment, such as discrimination or unlawful restraint, while receiving care and treatment. This would include inappropriate deprivation of liberty under the terms of the Mental Capacity Act 2005.	<ul style="list-style-type: none"> • Take appropriate steps to ensure a zero tolerance approach to abuse, including neglect and subjecting service users to degrading treatment, and to prevent service users from being abused by its staff or others with whom they come into contact when using the services and those visiting • Take appropriate steps to ensure a zero tolerance approach to unlawful discrimination or restraint and to unnecessary or disproportionate restraint or deprivation of liberty • Take timely and appropriate action, including investigation and/or referral to an appropriate body where any form of abuse is suspected, occurs, is discovered, or reported by a third party (which may be external to the provider) 	Where service users suffer abuse or are placed at risk of any form of abuse, CQC can move directly to prosecution without first serving a warning notice. CQC may deem any breaches of other regulations to have led to abuse, or be a major contributory factor in not preventing abuse, and in these cases CQC may move directly to prosecution without serving a warning notice.
Regulation 14: Meeting Nutritional and Hydration Needs*	Ensure that service users receive adequate nutrition and hydration to sustain life and good health, and to mitigate the risks of malnutrition and dehydration, while they receive care and treatment.	<ul style="list-style-type: none"> • Assess each service user's nutrition and hydration needs on an ongoing basis and provide food and drink (including parenteral nutrition and dietary supplements) to meet them, including accommodating any religious/cultural needs and reflecting their preferences • Ensure that food is nutritious, presented in an appetising manner, can easily be consumed (the service user can eat it regardless of any limitations they may have) and is easily accessible to the service user • Provide help if the service user needs support to eat and drink. Adequate water should always be available and accessible to the service user and the provider should help them if they need support to drink. • Engage (where appropriate) relevant expertise to ensure that the nutrition and hydration it provides adequately 	Breaches of this regulation or its components constitute a prosecutable offence. This means that where service users are not given adequate nutrition and hydration and there is subsequently a risk to their life or good health, CQC can move directly to prosecution without first serving a warning notice. CQC may also consider breaches of this regulation to constitute unsafe or inappropriate care and treatment, and/or to constitute abuse.

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Regulation 15: Cleanliness, Premises and Equipment*	Ensure that the premises and/or equipment used to deliver care and treatment is clean, stored securely and suitable for the intended purpose.	<p>meets the needs of each service user</p> <ul style="list-style-type: none"> • Act in accordance with current legislation and guidance relating to premises and equipment • Ensure that premises are located and designed/configured to meet the service user’s needs as far as possible, and that they have due regard to make premises accessible to service users • Ensure premises are appropriately secure so service users feel safe • Ensure that equipment is used for its intended purposes and in accordance with the manufacturer’s instructions • Make every effort to ensure the equipment is suitable for use, where the equipment required to deliver care and treatment is owned by the service user, or is supplied by a third party • Address any issues relating to the suitability and cleanliness of equipment in a timely manner and that it made appropriate support or alternative arrangements for the service user to receive their care and treatment. 	Where premises and equipment are unsafe and put service users at risk of harm, or where harm has occurred, CQC can move directly to prosecution, without first serving a warning notice.
Regulation 16: Receiving and acting on Complaints	Ensure that anyone can make a complaint* about any aspect of care and treatment planned and/or provided, and to ensure that providers investigate complaints and take appropriate and timely action to rectify any failures identified by the complainant or investigation.	<ul style="list-style-type: none"> • Must promote an open culture in which anyone feels able to raise concerns and, where they feel that they need to raise it further as a complaint. This will include making information about raising concerns and making complaints accessible, and providing support to enable people to raise concerns and make complaints. • Have systems for assessing, investigating and responding to complaints in a timely manner. • Demonstrate that changes have been made as a result of any failure identified by a complaint or related investigation. <p>It should be noted that receiving complaints is not necessarily an indication that a regulation is being breached.</p>	Breaches of this regulation do not constitute a prosecutable offence in themselves (other than that outlined above), but where CQC deems a breach of this regulation constitutes a breach of a regulation that carries prosecutable offence clauses, then CQC could move directly to prosecution without serving a warning notice. For example, where care and treatment is provided without the consent of the relevant person(s), results in any form of abuse or puts service users at serious risk of abuse, is unsafe or does not meet the nutritional or hydration needs of services users.
Regulation 17: Good Governance	Ensure that providers operate systems and processes that enable all other regulatory requirements to be met.	<ul style="list-style-type: none"> • Have oversight of planning, delivery and monitoring of all care and treatment, what action is taken to mitigate risks to the quality and safety of care and treatment, and what action is taken in response to issues raised by monitoring activities. This includes ensuring that it has access to all 	Other breaches of this regulation or its components do not constitute a prosecutable offence in themselves. However, CQC may take other regulatory action in response to a breach of this regulation. Additionally, CQC may

Regulation	The purpose of the regulation is to:	To meet the requirement of the regulation, the provider must:	Enforcement (if provider is not meeting the regulation)
		<p>relevant information about its service(s), including information about the experience of service users and others, which is necessary to manage the risks to service users if it is not meeting the requirements of the regulations.</p> <ul style="list-style-type: none"> • Take timely and appropriate corrective action where there is a risk of a regulatory breach occurring, or where a regulatory breach has occurred • Securely maintain appropriate and accurate records as follows: <ul style="list-style-type: none"> ○ Records about all aspects of the care and treatment of each service user. ○ Relevant records about persons it employs for designing and delivering care and treatment. ○ Any other records which may be appropriate for managing the carrying on of regulated activities. • Continually evaluate and make improvements to the systems and processes that are used to achieve the above. 	<p>consider that a breach of this regulation, or one of its components, constitutes a breach of a regulation which carries an offence. For example, a breach of this regulation may be considered to constitute unsafe or inappropriate care and treatment and/or may constitute abuse.</p>
Regulation 18: Staffing	<p>Ensure that providers deploy enough suitably qualified, competent and experienced staff to enable them to meet all other regulatory requirements.</p>	<ul style="list-style-type: none"> • Continually assess whether it is able to deploy enough suitable staff to meet all the needs of service users at all times, including in response to their changing needs • Support its staff to access training, professional development, supervision and appraisal throughout the duration of employment to enable them to appropriately perform the duties required of their role; this includes supporting them to obtain further qualifications where required for their role • Enable registered health and social care professionals to demonstrate to the relevant professional regulator that they meet professional standards (a requirement of their ability to practise) so that they can continue to function effectively in the role for which they are employed 	<p>Breaches of this regulation, or its components, do not constitute a prosecutable offence in themselves. However, CQC can take a range of other regulatory action in response to breaches of the regulation. In addition, CQC may consider that a breach of this regulation, or one of its components, constitutes a breach of a regulation that carries a prosecutable offence.</p>
Regulation 19: Fit and Proper Persons – Employed	<p>Ensure that providers only employ staff who are able to deliver care and treatment (appropriate to their role). This regulation applies to all staff carrying on a regulated activity, including permanent</p>	<ul style="list-style-type: none"> • Operate robust recruitment procedures, including undertaking any relevant checks • Have a procedure for ongoing monitoring of staff to ensure they remain able to meet requirements, and appropriate arrangements to deal with staff that are no longer fit to 	<p>Breaches of this regulation, or its components, do not constitute a prosecutable offence in themselves. However, CQC may take other regulatory action in response to breaches of this regulation. Additionally, CQC may consider that</p>

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	staff, locums, temporary/agency/bank staff, trainees / students / contractors.	<p>carry out the duties required of them.</p> <p>Employing unfit persons, or continuing to allow unfit persons to stay in a role, may lead CQC to question the fitness of a provider.</p>	a breach of this regulation, or one of its components, constitutes a breach of a regulation which carries a prosecutable offence.
Regulation 20: Duty of Candour*	Ensure that providers are open and honest with service users and other relevant persons (people acting lawfully on the behalf of service users) when things go wrong with care and treatment, and that they provide them with reasonable support, truthful information and a written apology.	<ul style="list-style-type: none"> • Ensure an open and honest culture exists across and at all levels within its organisation • Ensure it has systems in place for knowing about notifiable safety incidents* and must tell the relevant person(s), in a timely manner, when such an incident has occurred. This includes providing a truthful account of the incident, providing an explanation in writing about the enquiries and investigations that will be undertaken and offering an apology in writing • Maintain appropriate written records and offer reasonable support in relation to the incident. <p>* The regulation, detailed above provides an explanation of what is meant by 'notifiable safety incident', 'harm', and 'an apology'.</p>	Where a provider fails to inform relevant person(s), within a reasonable amount of time of a notifiable incident, fails to provide a truthful account to relevant persons, fails to advise relevant persons of the enquiries and investigation process it will undertake, fails to offer reasonable support, and/or fails to offer an apology, then CQC can move directly to prosecution, without first serving a warning notice.