

How CQC regulates:

Independent doctor services

Appendix
to the provider handbook

August 2015

Appendix A: Key lines of enquiry

Providers must primarily refer to our [guidance for providers on meeting the regulations](#).

The key lines of enquiry (KLOEs) for inspectors relate to CQC's five key questions that we ask of services. By asking these questions it helps us to make a consistent judgment. We have focused particularly on the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, although inspectors may also consider evidence against the Care Quality Commission (Registration) Regulations 2009. We have mapped these KLOEs to the regulations. Although providers will have a variety of ways to demonstrate how they are meeting the regulations, we have included some examples. They are not meant to be an exhaustive list or a 'checklist'.

Safe

By safe, we mean that people are protected from abuse* and avoidable harm.

*Abuse can be physical, sexual, mental or psychological, financial, neglect, institutional or discriminatory abuse.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:

- Financial position **Regulation 5 (The Care Quality Commission (Registration) Regulations 2009)**
- Person-centred care **Regulation 9**
- Need for consent **Regulation 11**
- Safe care and treatment **Regulation 12**
- Safeguarding service users from abuse and improper treatment **Regulation 13**

- Premises and equipment **Regulation 15**
- Good Governance **Regulation 17**
- Staffing **Regulation 18**
- Fit and proper persons employed **Regulation 19**
- Duty of candour **Regulation 20**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is safe – based on safety related regulations
S1	Are there reliable systems, processes and practices in place to ensure all care and treatment is carried out safely?	<ol style="list-style-type: none"> 1. Staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and report them internally and externally where appropriate. 2. Arrangements are in place to receive and comply with patient safety alerts, recalls and rapid response reports issued through the Medicines and Healthcare products Regulatory Authority (MHRA) and through the Central Alerting System (CAS) and these are reviewed / acted upon promptly by clinical staff. 3. Arrangements are in place to ensure the provider can take appropriate action in the event of a clinical / medical emergency and resuscitation equipment is readily available. 4. Emergency medicines (including oxygen) held on the premises are appropriate, accessible and processes are in place to ensure they are fit for use. 5. There is a clear understanding of RIDDOR and COSHH demonstrated, including how to report RIDDOR incidents. Health and safety risk assessments are regularly carried out.

<p>S2</p>	<p>Are lessons learned and improvements made when things go wrong?</p>	<ol style="list-style-type: none"> 1. The provider identifies and analyses clinical errors, incidents and near misses involving all relevant staff and patients where applicable, including relating to the prescribing and supply of medicines. 2. When things go wrong, thorough and robust investigations and significant event / incident analyses are carried out. Relevant staff and people who use services are involved in the investigation. 3. Lessons are learned, shared and communicated to make sure action is taken to improve safety. There is evidence of action being taken. 4. Any incidents relating to controlled drugs are reported to the Controlled Drugs Accountable Officer via the NHS Local Intelligence Network (LIN). The provider (where appropriate) engages with the Controlled Drugs LIN. 5. Patients are told when they are affected by something that goes wrong, given a meaningful apology in person or to an appropriate person and informed of any actions taken as a result.
<p>S3</p>	<p>Are there reliable systems, processes and practices in place to keep people safe and safeguard them from abuse?</p>	<ol style="list-style-type: none"> 1. There are arrangements in place to safeguard adults and children from abuse that reflect relevant legislation and local requirements. 2. Staff can describe a documented reporting system for raising concerns (such as safeguarding, whistleblowing and complaints) and feel confident to use it. 3. Staff can demonstrate they work within the legal framework for the care and treatment of children and young people. 4. Staff know how to identify, report and respond to suspected or actual abuse. 5. There is a zero tolerance approach to abuse. The provider and staff work within the ethos of the Mental Capacity Act 2005 when working with people who lack capacity.

		<ol style="list-style-type: none"> 6. Individual records are written and managed in a way to keep people safe. This includes ensuring people's records are accurate, complete, eligible, up to date, stored and shared appropriately. 7. Patient records held on a portable or mobile device are appropriately backed up in real time. 8. Portable or mobile devices, on which patient information is held, are encrypted. 9. Records indicate where children and young people are subject to a child protection plan or, in the case of a looked after child, their looked after child status.
S4	How are risks to people who use services assessed and their safety monitored and maintained?	<ol style="list-style-type: none"> 1. There are sufficient numbers of suitably qualified and competent staff, and the provider considers how the service uses the skills of other members of the provider team. 2. Staff are able to identify and respond appropriately to signs of deteriorating health and medical emergencies. 3. Staff participating in the obtaining, storing, handling, prescribing, supplying and disposing of medicines are suitably trained and their competency assessed. 4. If Nurse Independent Prescribers are employed they receive regular supervision and support in their role including updates in the specific clinical areas of expertise for which they prescribe. 5. There is evidence of a comprehensive assessment with clear clinical care pathways and protocols, to help standardise and ensure evidence based care is provided. Staff follow care pathways and protocols. 6. Arrangements are in place which signpost the availability of a chaperone. Staff have received training to undertake the role.
S5	How well are potential risks to the service anticipated and planned for in advance?	<ol style="list-style-type: none"> 1. Risks to safety from service developments and disruption are assessed, planned for, and managed in advance.

		<ol style="list-style-type: none"> 2. Arrangements to respond to emergencies are practised and reviewed. 3. Appropriate indemnity arrangements are in place to cover potential liabilities that may arise.
<p>S6</p>	<p>Are there reliable systems, processes and practices in place to protect people from unsafe use of premises and equipment?</p>	<ol style="list-style-type: none"> 1. Premises are appropriate for the range of services provided. 2. Appropriate equipment is available for children where treated. 3. Premises are visibly clean and the level of cleanliness is monitored. 4. The design, maintenance and use of facilities, premises and equipment keeps people safe. 5. Staff demonstrate competency in the use of equipment. 6. Equipment is used in line with manufacturers' instructions. 7. Personal Protective Equipment (PPE) is available and used where appropriate. 8. Medical devices are purchased in line with the guidance produced by the MHRA. 9. There are sufficient quantities of instruments / equipment, to cater for each clinical session which takes into account the requisite decontamination process. 10. Re-useable equipment is cleaned and / or decontaminated according to manufacturer's instructions, and is cleaned / decontaminated after each use. 11. Single use instruments are not re-used. 12. Providers meet the requirements of relevant legislation including HTM 07-01 Safe Management of Healthcare Waste, The Health and Safety (Sharps Instruments in Healthcare) Regulations 2013 and related guidance and the Health and Social Care Act 2008 Code of Practice on the prevention and control of infections 13. Infection control is audited, including safe management of specimens.

S7	Are reliable systems, processes and practices are in place to ensure proper and safe management of medicines?	<p>There are arrangements in place for the proper and safe management of medicines which includes:</p> <p><u>Medicines management</u></p> <ol style="list-style-type: none">1. There are appropriate documented arrangements for managing medicines that include obtaining, recording, storing, prescribing, dispensing, safe administration and disposal, and they accurately reflect current practice.2. Medicines on the premises are stored securely, in line with legal requirements and manufacturers' instructions, and there is a clear audit trail for ordering, receipt and disposal.3. If medicines requiring cold storage are stored, there is an appropriate, secure and monitored medicines refrigerator available and the provider can evidence the cold chain is maintained. (See guidance here on our website).4. If CD stock is held (for supply / treatment), there is an up to date Home Office licence (if required)5. Private prescriptions and / or FP10s (for private prescription of controlled drugs) are stored safely. <p><u>Prescribing and supplying</u></p> <ol style="list-style-type: none">6. Prescribing of medicines is evidence based.7. If remote or online prescribing is carried out there are strict protocols in place for identifying and verifying the patient and GMC guidance is followed.8. If unlicensed and / or 'Off-label' medicines are used, patients are fully informed and the use of these medicines is supported by evidence.9. If medicines are administered on the premises, a contemporaneous record is kept that is clear, accurate and auditable.
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		<p>10. If medicines are dispensed by the provider, they are packaged and labelled in accordance with legal requirements.</p> <p>11. Patients are given clear information on medicines they take away that includes:</p> <ul style="list-style-type: none">- How and when to take the medicine.- The purpose of the medicine.- What side effects may occur and the action to take if they do. <p><u>Patient Group Directions</u></p> <p>12. Where Patient Group Directions (PGDs) are in use, they are in-date, properly authorised, legally operated, and appropriate governance arrangements are in place. This includes where the provider produces PGDs for others (for example, a community pharmacy) to use. (See guidance here on our website).</p>
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Effective

By effective, we mean that people's care, treatment and support achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:

- Person-centred care **Regulation 9**
- Consent **Regulation 11**
- Safe care and treatment **Regulation 12**
- Staffing **Regulation 18**
- Fit and proper persons employed **Regulation 19**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is effective – based on effective related regulations
E1	Are people's needs assessed and care and treatment delivered in line with current legislation, standards and evidence-based guidance ?	<ol style="list-style-type: none">1. People's care and treatment is planned and delivered in line with evidence based guidelines, standards, best practice and current legislation.2. There is evidence of a comprehensive assessment to establish individual needs and preferences. This includes:<ul style="list-style-type: none">• An up-to-date medical history.• Explanation of the presenting complaint or purpose of the appointment.• A clinical assessment (including diagnosis, referral and ongoing management).

		<p>3. Discrimination on the grounds of age, disability, gender reassignment, pregnancy and maternity status, race, religion or belief are avoided when making care and treatment decisions.</p> <p>4. Patient outcomes are monitored.</p>
E2	Do staff have the skills, knowledge and experience to deliver effective care and treatment?	<p>1. Staff have the right qualifications, skills, knowledge and experience to do their job when they start their employment, take on new responsibilities and on a continual basis.</p> <p>2. Staff are supported to deliver effective care through opportunities to undertake training, learning and development and through meaningful and timely supervision and appraisal.</p> <p>3. Learning needs of staff are identified.</p> <p>4. Registered professionals are up-to-date with their Continuing Professional Development (CPD) and supported to meet the requirements of their professional registration.</p>
E3	Are there effective arrangements in place for working with other health professionals to ensure quality of care for the patient?	<p>1. There are clear protocols for referring patients to specialists / colleagues based on current guidelines.</p> <p>2. When people are referred to another professional / service, all information that is needed to deliver their ongoing care is appropriately shared in a timely way.</p> <p>3. Patients are given a copy of that information.</p> <p>4. There are clear and effective arrangements for following up on people who have been referred to other services.</p>
E4	Is people's consent to care and treatment always sought in line with legislation and guidance?	<p>1. The provider has made information and support available to help people understand the care and treatment options.</p> <p>2. Staff understand and apply the legislation and guidance, including the Mental Capacity Act 2005 and the Children's Acts 1989 and 2004.</p>

		<ol style="list-style-type: none">3. Staff can demonstrate when people may require support in obtaining consent and work within the ethos of the Mental Capacity Act 2005. When providing care and treatment for children and young people assessments of capacity to consent are carried out in line with relevant guidance.4. People report that they are supported to make decisions.5. The process for seeking consent is monitored to ensure it complies with legislation and relevant national guidance.6. Full, clear, detailed information is provided about the costs of initial / further consultations, all treatment, including any options or choices and responding to any queries or concerns during or after treatment. The information should also include costs of medicines supplied, tests (including reporting timescales), further treatment / follow up.
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Caring

By caring, we mean that staff involve and treat people with compassion, kindness, dignity and respect.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:

- Person-centred care **Regulation 9**
- Dignity and respect **Regulation 10**
- Consent **Regulation 11**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is caring – based on caring related regulations
C1	Are people treated with kindness, dignity, respect and compassion while they receive care and treatment?	<ol style="list-style-type: none">1. People report that they are treated with dignity and respect at all times.2. The environment is conducive to supporting people's privacy.3. Staff take time to interact with patients and those close to them in a respectful, appropriate and considerate manner.4. Staff recognise and respect people's diversity, values and human rights.
C2	How are patients and those close to them involved as partners in their care?	<ol style="list-style-type: none">1. People report that they felt the doctor and other members of the provider team listened to them and involved them in making decisions about their care and treatment.2. Treatment is fully explained, including the cost of treatment, and people report they are given enough time to think and ask questions about their consent to care and treatment.

C3	Do people who use services, and those close to them, receive the support they need to cope emotionally with their care and treatment?	1. People report that staff respond to pain, distress and discomfort in a timely and appropriate way.
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Responsive

By responsive, we mean that services are organised so that they meet people's needs.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:

- Person-centred care **Regulation 9**
- Dignity and respect **Regulation 10**
- Complaints **Regulation 16**
- Good governance **Regulation 17**
- Duty of candour **Regulation 20**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is responsive – based on responsive related regulations
R1	Are services planned and delivered to meet the needs of people?	<ol style="list-style-type: none"> 1. The facilities and premises are appropriate for the services that are planned and delivered. 2. Appointment times are scheduled to ensure people's needs and preferences (where appropriate) are met. 3. Providers make reasonable adjustments to the environment, for choice of doctor (or other professional / service) or treatment options to enable people to receive care and treatment. 4. The provider takes into account the needs of different people on the grounds of age, disability, sex, gender reassignment, race, religion or belief, sexual orientation, pregnancy and maternity. 5. There is evidence that the provider gathers the views of patients when planning and delivering services.

R2	Do services take account of the needs of different people , including those in vulnerable circumstances?	<ol style="list-style-type: none"> 1. All reasonable efforts / adjustments are made to enable patients to receive their care or treatment. 2. People report they have access to, and receive, information in the manner that best suits them and that they can understand. 3. There is evidence of reasonable effort and action to remove barriers when people find it hard to access or use services.
R3	Can people access care and treatment in a timely way?	<ol style="list-style-type: none"> 1. Waiting times, cancellations and delays are minimal. 2. People have timely access to urgent treatment. 3. People report that they are aware of how they can access emergency treatment, including out of normal hours.
R4	How are people's concerns and complaints listened and responded to, and used to improve the quality of care?	<ol style="list-style-type: none"> 1. There is a complaints system in place, which is publicised, accessible and understood by staff and people who use the service. 2. There is openness and transparency in how complaints are dealt with. 3. Information is provided about the steps people can take if they are not satisfied with the findings or outcome once the complaint has been responded to. 4. People report that they know how to complain, that the system is easy to use and staff treat them compassionately and give help and support they need to make a complaint.

Well-led

By well-led, we mean that the leadership, management and governance of the organisation assures the delivery of high-quality, person-centred care, supports learning and innovation, and promotes an open and fair culture.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:

- Requirements where the service provider is an individual or partnership **Regulation 4**
- Fit and proper persons: directors **Regulation 5**
- Requirement where the service provider is a body other than a partnership **Regulation 6**
- Safe care and treatment **Regulation 12**
- Safeguarding service users from abuse and improper treatment **Regulation 13**
- Complaints **Regulation 16**
- Good governance **Regulation 17**
- Staffing **Regulation 18**
- Fit and proper persons employed **Regulation 19**
- Duty of candour **Regulation 20**

	Key line of enquiry	Examples of what we should see to demonstrate that the service is well-led – based on well-led related regulations
W1	Do the governance arrangements ensure that responsibilities are clear, quality and performance are regularly considered, and risks are identified, understood and managed?	<ol style="list-style-type: none"> 1. Staff are supported and managed at all times and are clear about their lines of accountability. 2. There is a senior clinical lead responsible for the governance of the safe and effective use of medicines. 3. Where required, there is a registered manager in post who understands their responsibilities and is supported.

		<ol style="list-style-type: none"> 4. Staff are supported to meet their professional standards and follow their professional code of conduct. 5. Care and treatment records are complete, legible and accurate, and are kept secure. 6. Records relating to employed staff include information relevant to their recruitment. 7. There is an effective approach for identifying where quality and / or safety is being compromised and steps are taken in response to issues. These include audits of clinical care, prescribing, notes, infection prevention and risks, incidents and near misses.
W2	How does the leadership and culture reflect the vision and values, encourage openness and transparency, and promote delivery of high-quality care?	<ol style="list-style-type: none"> 1. The provider has systems in place to support communication about the quality and safety of services and what actions have been taken as a result of concerns, complaints and compliments. 2. Candour, openness, honesty and transparency and challenges to poor practice are evident.
W3	How is quality assurance used to encourage continuous improvement?	<ol style="list-style-type: none"> 1. Audit processes have a positive impact in relation to quality governance, with clear evidence of action to resolve concerns. 2. Information about the quality of care and treatment is actively gathered from a range of sources. 3. Staff report that information is shared for continuous learning and improvement.
W4	How are people who use the service, the public and staff, engaged and involved ?	<ol style="list-style-type: none"> 1. The provider has processes in place to actively seek the views of people who use the service and those close to them, and should be able to provide evidence of how they take these views into account in any related decisions.

		<ol style="list-style-type: none">2. Staff report that the provider values their involvement and that they feel engaged and say their views are reflected in the planning and delivery of the service3. Staff and the provider understand the value in staff raising concerns.
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