The registration healthcare key lines of enquiry, prompts and sources of evidence
Assessment framework for registration inspectors

In a *Fresh start for registration* (2015) we committed to using the same five key questions that we use for inspections as a framework for looking at quality at registration. This will ensure a consistent approach across the operating model and will allow us to build a rounded picture of applications.

The supporting questions we ask applicants as part of this process will be appropriate to the health and care activities they are seeking to provide, just as we ask appropriate service-related questions during inspections.

Providers are expected to be compliant with the relevant regulations, and we also expect that all aspirant providers know what 'good' looks like and understand that in granting registration, we expect that they will be at least good at the point of first inspection. You should therefore familiarise yourself with the characteristics of good for each key question so that you are able to explore the providers understanding and evidence of our requirements. The healthcare characteristics of ratings are available here.

Key lines of enquiry and prompts
Our framework of key lines of enquiry (KLOEs) and prompts for registration is set out below together with potential sources of evidence (where applicable) you can gather and explore for each KLOE. They are aligned to the healthcare inspection assessment framework to support our single operating model and shared view of quality. They are a guide; they are not exhaustive and not all suggested sources need to be explored at every registration assessment; you must use your judgement in each assessment.

Sources of evidence
The sources of evidence are listed to inform your assessment. They are not suggested for use as a checklist. Select sources in the light of your planning decisions and the information they provide. Some evidence will only be relevant when you are assessing existing providers known to CQC. Some of the sources of evidence may not be available when registering a new service such as Healthwatch, information from commissioners and other health care professionals.

Organisations you approach will depend on the provider and your planned evidence gathering needs. They may include organisations that commission the provider, such as NHS England and clinical commissioning groups; and local Healthwatch groups.

The key lines of enquiry have been mapped to the requirements regulated by CQC and are available on the intranet. Some prompts may not be applicable to all sectors. Registration inspectors must therefore also refer to service specific inspection KLOES.

Index
KLOEs, prompts and sources of evidence for:

- Safe
- Effective
- Caring
- Responsive
- Well-led

Planning documents
- Registration handbook
- Registration insight report
- Inspection reports/corporate provider reports
- Share your experience forms
- Notifications
- Information of concern enquiries
- RIDDOR/HSE reports
- Coroners' reports
- Demographics and contextual information
- Statement of purpose
- Safeguarding and Freedom to Speak Up
- CQC locations guidance

Other relevant guidance
- Good practice guidance and standards relevant to the service
- Guidance for providers on meeting the regulations - appendices A and B
- Inspector's Handbook – Safeguarding (CQC, 2018)
- Equally Outstanding: Equality & Human Rights (CQC, 2017)
- Mental Health Act (1983) and MHA 1983 Code of Practice
- Mental Capacity Act (2005)
- Relevant NICE guidance
- DHSC Female Genital Mutilation and Safeguarding: Guidance for Professionals (2016)
- DHSC code of practice on the prevention and control of infections (2015)
- NICE Quality Standard on Infection Prevention and Control (2014)
- National Early Warning Score (NEWS) and associated guidance
- NHS Safety Thermometer
- NHS Improvement guidance on patient safety
- NHS Improvement national patient safety alerts
- Fit and Proper Persons Requirement (FPPR)
- Deprivation of Liberty Safeguards (DoLS)
- National Quality Board guidance on safe staffing (2016)
- Medicines and Healthcare products Regulatory Agency (MHRA) guidance and alerts
- NICE guidance on the safe use and management of controlled drugs (2016)
- National Guidance on Learning from Deaths (National Quality Board, 2017) – NHS only
- Serious Incident Framework (NHSI, 2015)

- Equality Act (2010)
- Children's Act (1989)
- End of life care guidance - various sources
- Parliamentary and Health Service Ombudsman
- Registering the Right Support guidance (CQC, 2017)
- Relevant guidance from the Royal Colleges and other professional bodies
- Local Government and Social Care Ombudsman

Safe

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

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

Potential sources of evidence

Records and policies – where applicable and for existing providers

People
- ☐Patient notes, records, care plans, reviews and outcome records.
- ☐Safeguarding (both vulnerable adults and children) policies and processes
- ☐Safeguarding records, including alerts, investigations, outcomes and notifications
- ☐Arrangements for Mental Capacity Act (MCA) assessment
- ☐Same sex accommodation and facilities
- ☐Feedback from local authority safeguarding teams
- ☐Processes to ensure the service appropriately manages risk and any restrictions on freedom, choice and control
- ☐Evidence that people who user services are provided with information on their medication
- ☐Feedback on the service's response to serious incidents or near misses including investigations, reporting, recording, learning and improvement

Staff
- ☐Policies and records re. staff recruitment, induction and training (including for bank, agency and temporary staff)
- ☐HR records (including references and DBS checks where applicable)
- ☐HR policies (including information on the Fit and Proper Persons Requirement, disciplinary and supervision)
- ☐Up to date staff certificates and/or registration with the applicable professional body
- ☐Staff rotas (where applicable) and/or evidence of appropriate numbers and skill mix/distribution of staff grades for shifts
- ☐Processes and policy around shift handover (records where applicable)

Service
- ☐Governance, delegated responsibilities, accountability and decision making policies
- ☐Culture and approach to safety
- ☐Health and safety policies
- ☐Duty of candour policy, including details of how to deal with possible breaches
- ☐Where appropriate, policies and procedures re. observation, supervision, restraint and if needed, rapid tranquilisation
- ☐Infection prevention and control policies, procedures and training arrangements
- ☐Cleaning rotas
- ☐Waste management policies and procedures
- ☐Service-wide, standardised approach to the detection and assessment of the deteriorating patient (e.g. NEWS, PEWS, EWS) and a clearly documented escalation response
- ☐Policies, processes and records covering the maintenance and decontamination of equipment and premises
- ☐Contingency plans for adverse conditions, emergencies and/or major incidents
- ☐Policy covering the safe use of restraint
- ☐Policy around safe manual handling
- ☐Evidence that the service complies with the requirements of the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R
- ☐DoLS policy (and where relevant, applications to the court of protection)
- ☐Arrangements in place to receive and effectively respond to NHSI National Patient Safety and MHRA alerts
- ☐IT policy including guidance on password use/change
- ☐Policies on the storage, transportation, management and disposal of medicines (including controlled drugs and fridge temperatures are being regularly monitored)

☐Agendas and minutes of supervision and team meetings
☐Evidence of effective communication with staff
☐Feedback from staff
☐Freedom to Speak Up policy for staff and process chart for escalation of concerns with correctly named individuals, teams and organisations
☐Safety training plans/records
☐Feedback from registered manager
☐Evidence of effective joint working with other teams
☐Staff awareness of relevant, recent national patient safety and/or MHRA alerts.

Observation – where applicable and for existing providers
☐Access to safety related records and policies
☐Layout and safety of premises
☐Cleanliness of premises and equipment.
☐Appropriate infection prevention and control signage and facilities
☐Do facilities conform to professional standards?
☐Seclusion facilities and/or dedicated safe spaces
☐Online portal for safely storing records and information on safety incidents - or is there evidence of the service's ability to record/store such information safely in another way?
☐Defibrillator on site, emergency medication provision, including oxygen
☐Use of smart cards for patient records and IT awareness, e.g. locking unattended computers
☐Are there unimpeded sight lines and/or have measures been taken to mitigate blind spots where necessary?
☐Access to appropriate alarms and staff call systems and staff alarms

☐Medicines optimisation strategy
☐Policy on the supply of personal protective equipment and supplies
☐For variations, audits of: patient notes/records, infection prevention and control measures, rates of infection, safeguarding alerts and learning, risk management, local physiological track and trigger systems, staff numbers and skill mix, rates of antimicrobial usage, health and safety, controlled drug use, serious incidents and near-misses, mortality and morbidity
☐Certificates (as appropriate) with regards to: gas safety, electrical wiring, portable appliance (PAT) testing, passenger lifts, fire systems, liability insurance and building controls
☐Risk assessments around: Legionella, environmental risks, fire, health and safety, Control of Substances Hazardous to Health (COSHH) assessments and checks
☐Infection related risks management and reporting (HSE/EHO/PHE) processes
☐Policies on safety incidents and near-misses including alerts, investigations, outcomes and improvement plans (including involvement of families and carers)
☐Where applicable, action plans developed as a result of coroner's inquest, and prevention of future death reports
☐Where applicable, completed investigation or root cause analysis reports, the outcomes of investigations and how lessons have been implemented

S1	How will systems, processes and practices keep people safe and safeguard people from abuse?

All health

Relevant regulation: 12, 13, 19

Also consider: 10, 14, 15, 17

Prompt		Notes
S1.1	How will safety and safeguarding systems, processes and practices be developed, implemented and communicated to staff?	
S1.2	What arrangements will be in place to safeguard adults and children from abuse and neglect that reflect relevant legislation and local requirements? How will the provider ensure that staff understand their responsibilities and adhere to safeguarding policies and procedures, including working in partnership with other agencies? How will systems, processes and practices protect people from abuse, neglect, harassment and breaches of their dignity and respect be monitored and improved?	
S1.3	How will people be protected from discrimination, which might amount to abuse or cause psychological harm, inluding harassment and discrimination in relation to protected characteristics under the Equality Act?	
S1.4	How will the rights of people subject to the Mental Health Act 1983 (MHA) be protected and how will staff have regard to the MHA Code of Practice?	

S1.5	How will safety be promoted in recruitment practice, arrangements to support staff, disciplinary procedures, and ongoing checks? (For example, Disclosure and Barring Service checks.)	
S1.6	How will staff identify adults and children at risk of, or suffering, significant harm? How will they work in partnership with other agencies to ensure they are helped, supported and protected?	
S1.7	How will standards of cleanliness and hygiene be maintained? What reliable systems will be in place to prevent and protect people from a healthcare-associated infection?	
S1.8	How will the design, maintenance and use of facilities and premises keep people safe?	
S1.9	How will the maintenance and use of equipment keep people safe?	
S1.10	How will the arrangements for managing waste and clinical specimens keep people safe? (This includes classification, segregation, storage, labelling, handling and, where appropriate, treatment and disposal of waste.)	

S.2	How will risks to people be assessed and their safety monitored and managed so they are supported to stay safe?

All health - *except see service specific inspection KLOES*

S2.4 NOT: ambulance services, GP practices, GP out-of-hours, NHS 111

Relevant regulation: 12, 13

Also consider: 15, 17, 20

Prompt		Notes
S2.1	How will staffing levels and skill mix be planned and reviewed so that people receive safe care and treatment at all times and staff do not work excessive hours?	
S2.2	How will actual staffing levels and skill mix compare with the planned levels? Will cover be provided for staff absence?	
S2.3	How will arrangements for using bank, agency and locum staff keep people safe at all times?	
S2.4	Where applicable, how will arrangements for handovers and shift changes ensure that people are safe?	
S2.5	How will comprehensive risk assessments be carried out for people who use services and risk management plans be developed in line with national guidance? Will risks be managed positively?	
S2.6	How will staff identify and respond appropriately to changing risks to people, including deteriorating health and wellbeing, medical emergencies or behaviour that challenges? Will staff be able to seek support from senior staff in these situations?	

| S2.7 | How will safety be monitored using information from a range of sources (including performance against safety goals where appropriate)?

How will the impact on safety be assessed and monitored when carrying out changes to the service or the staff? | |

S3	How will staff have all the information they need to deliver safe care and treatment to people?
All health	

Relevant regulation: 12, 18, 19

Also consider: 17

Prompt		Notes
S3.1	How will people's individual care records, including clinical data, be written and managed in a way that keeps people safe?	
S3.2	How will all the information needed to deliver safe care and treatment be available to relevant staff in a timely and accessible way? (This may include test and imaging results, care and risk assessments, care plans and case notes	
S3.3	When people move between teams, services and organisations (which may include at referral, discharge, transfer and transition), how will all the information needed for their ongoing care be shared appropriately, in a timely way and in line with relevant protocols?	
S3.4	How will the systems that manage information about people who use services support staff, carers and partner agencies to deliver safe care and treatment? (This includes coordination between different electronic and paper-based systems and appropriate access for staff to records.)	

S4	How will the provider ensure the proper and safe use of medicines, where the service is responsible?

All health

Relevant regulation: 12 , 15

Also consider: 9, 17

Prompt		Notes
S4.1	How will medicines and medicines-related stationery be managed (that is, ordered, transported, stored and disposed of safely and securely)? (This includes medical gases and emergency medicines and equipment.)	
S4.2	How will medicines be appropriately prescribed, administered and/or supplied to people in line with the relevant legislation, current national guidance or best available evidence?	
S4.3	How will people receive specific advice about their medicines in line with current national guidance or evidence?	
S4.4	How will the service make sure that people receive their medicines as intended, and is this recorded appropriately?	
S4.5	How will people's medicines be reconciled in line with current national guidance when transferring between locations or changing levels of care?	
S4.6	How will people receive appropriate therapeutic drug and physical health monitoring with appropriate follow-up in accordance with current national guidance or evidence?	
S4.7	How will people's medicines be regularly reviewed including the use of 'when required' medicines?	

| S4.8 | How will the service make sure that people's behaviour is not controlled by excessive or inappropriate use of medicines? | |

S6	**How will lessons be learned and improvements made when things go wrong?**

All health

Relevant regulation: 17, 20

Prompt		**Notes**
S6.1	How will staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally, where appropriate?	
S6.2	What will the arrangements be for reviewing and investigating safety and safeguarding incidents and events when things go wrong?	
S6.4	How will the learning from lessons be shared to make sure that action is taken to improve safety? How will relevant staff, services, partner organisations and people who use services be involved in reviews and investigations? How will staff participate in and learn from reviews and investigations by other services and organisations?	
S6.5	What arrangements will be in place to effectively respond to relevant external safety alerts, recalls, inquiries, investigations or reviews?	

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

Potential sources of evidence

Records and policies– where applicable and for existing providers

People
☐Experiences of assessments, care planning and outcomes - person's journey
☐Experiences of how technology is used in order to provide effective care

Staff
☐Staff training and induction including use of volunteers
☐Clinical supervision
☐Appraisals & development opportunities
☐How staff contribute to preventing & responding to discrimination
☐Arrangements for revalidation
☐On line checks and/or certificates of registration to applicable professional bodies e.g. GMC, NMC

Observation – where applicable and for existing providers
☐Feedback about whether / how:
- o Assessments, care planning and practice aligns with good practice guidance
- o the provider prevents and responds to discrimination and promotes equality
- o the provider uses technology, and does so in a way that benefits people
☐Good practice guidance and standards in day to day use
☐Availability of specialist equipment

Service
☐Statement of purpose
☐Assessments, care planning and use of technology policies
☐Provider processes to assess frequency and methods of contact prior to accessing service, and local monitoring data of patient outcomes
☐Monitoring and reporting of effective care
☐Participation in local audits including audits for clinical activity, national benchmarking, accreditation, peer review and research
☐Consent records
☐Criteria and protocols for admission, referral, transfer, transition and discharge (including out of hours)
☐Arrangements for multi-disciplinary working with other agencies and/or information sharing agreements
☐Policies and protocols on, consent, mental and physical health care, supporting patients to live healthier lives, medication, pain management, management of pressure ulcers, nutrition and hydration, good food standards, management of serious infections, use of chaperones, management of challenging behaviours for people with learning disabilities, and restrictive practices
☐Ability to identify out-of-hours provider(s)
☐Procedures for dealing with investigation and test results

E1	How will people's needs be assessed and care and treatment delivered in line with current legislation, standards and evidence-based guidance to achieve effective outcomes?

All health - * *except see service specific inspection KLOES*

E1.4 NOT: GP practices, GP out-of-hours, NHS 111

E1.5 NOT: specialist mental health services, specialist substance misuse services

Relevant regulation: 9, 12, 14

Also consider: 10, 13, 17

Prompt		Notes
E1.1	How will people's physical, mental health and social needs be holistically assessed, and their care, treatment and support delivered in line with legislation, standards and evidence-based guidance, including NICE and other expert professional bodies, to achieve effective outcomes?	
E1.2	What processes will be in place to ensure there is no discrimination, including on the grounds of faith, beliefs and protected characteristics under the Equality Act, when making care and treatment decisions?	
E1.3	How will technology and equipment be used to enhance the delivery of effective care and treatment, and to support people's independence?	
E1.4	How will people's nutrition and hydration needs (including those related to culture and religion) be identified, monitored and met? Where relevant, what access will there be to dietary and nutritional specialists to assist in this?	
E1.5	How will a person's pain be assessed and managed, particularly for people who have difficulty communicating?	

E1.6	How will people be told when they need to seek further help and advised what to do if their condition deteriorates?	

E2	How will people's care and treatment outcomes be monitored and how will they be compared with other similar services?

All health

Relevant regulation: 12, 18, 19
Also consider: 9, 17

Prompt		Notes
E2.1	How will information about the outcomes of people's care and treatment (both physical and mental where appropriate) be routinely collected and monitored?	
E2.2	How will this information show that the intended outcomes for people are being achieved?	
E2.3	How will outcomes for people in this service be compared with other similar services and how have they changed over time?	
E2.4	How will there be participation in relevant quality improvement initiatives, such as local and national clinical audits, benchmarking, (approved) accreditation schemes, peer review, research, trials and other quality improvement initiatives? How will all relevant staff be involved in activities to monitor and use information to improve outcomes?	

E3	How will the service make sure that staff have the skills, knowledge and experience to deliver effective care, support and treatment?

All health

Relevant regulation: 12, 14

Also consider: 9, 11, 17, 18

Prompt		Notes
E3.1	How will people have their assessed needs, preferences and choices met by staff with the right skills and knowledge?	
E3.2	How will the learning needs of all staff be identified? How will staff have appropriate training to meet their learning needs that covers the scope of their work, and will there be protected time for this training?	
E3.3	How will staff be encouraged and given opportunities to develop?	
E3.4	What will the arrangements be for supporting and managing staff to deliver effective care and treatment? (This includes one-to-one meetings, appraisals, coaching and mentoring, clinical supervision and revalidation.)	
E3.5	How will poor or variable staff performance be identified and managed? How will staff be supported to improve?	
E3.6	How will volunteers be recruited where required, and how will they be trained and supported for the role they undertake?	

E4	How will staff, teams and services work together within and across organisations to deliver effective care and treatment?

All health - *except see service specific inspection KLOES*

E4.4 NOT: GP practices, GP out-of-hours, NHS 111

E4.5 NHS acute & independent hospitals only

Relevant regulation: 9

Also consider: 12, 17

Prompt		Notes
E4.1	How will all necessary staff, including those in different teams, services and organisations, be involved in assessing, planning and delivering care and treatment?	
E4.2	How will care be delivered and reviewed in a coordinated way when different teams, services or organisations are involved?	
E4.3	How will people be assured that they will receive consistent, coordinated, person-centred care and support when they use, or move between different services?	
E4.4	How will all relevant teams, services and organisations be informed when people are discharged from a service? Where relevant, how will discharge be undertaken at an appropriate time of day and only done when any necessary ongoing care is in place?	
E4.5	How will high-quality services be made available that support care to be delivered seven days a week and how will their effect on improving patient outcomes be monitored?	

E5	How will people be supported to live healthier lives and, where the service is responsible, how will it improve the health of its population?	
All health E5.5 NOT: ambulances		
Relevant regulation: 9, 12 **Also consider: 13, 17**		
Prompt		**Notes**
E5.1	How will people be identified who may need extra support? This includes: • people in the last 12 months of their lives • people at risk of developing a long-term condition • carers	
E5.2	How will people be involved in regularly monitoring their health, including health assessments and checks, where appropriate and necessary?	
E5.3	How will people who use services be empowered and supported to manage their own health, care and wellbeing and to maximise their independence?	
E5.4	Where abnormalities or risk factors are identified that may require additional support or intervention, how will changes to people's care or treatment be discussed and followed up between staff, people and their carers where necessary?	

| E5.5 | How will national priorities to improve the population's health be supported? (For example, smoking cessation, obesity, drug and alcohol dependency, dementia and cancer.) | |

E6	**How will consent to care and treatment be always sought in line with legislation and guidance??**

All health - *except see service specific inspection KLOES*

E6.6 and 6.7 NOT: NHS 111

Relevant regulation: 11

Also consider: 9, 10, 17

Prompt		Notes
E6.1	How will staff understand the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005 and the Children's Acts 1989 and 2004 and other relevant national guidance?	
E6.2	How will people be supported to make their own decisions in line with relevant legislation and guidance?	
E6.3	How and when will a possible lack of mental capacity to make a particular decision be assessed and recorded?	
E6.4	How will the process for seeking consent be monitored and reviewed to ensure it meets legal requirements and follows relevant national guidance?	

E6.5	When people lack the mental capacity to make a decision, how will staff ensure that best interests decisions are made in accordance with legislation?	
E6.6	How will the service promote supportive practice that avoids the need for physical restraint? Where physical restraint may be necessary, how will the provider ensure that it is used in a safe, proportionate, and monitored way as part of a wider person-centred support plan?	
E6.7	How will staff recognise when people aged 16 and over, who lack mental capacity, are being deprived of their liberty, and how will they seek authorisation to do so when they consider it necessary and proportionate?	

Caring

By caring, we mean that the service involves and treats people with compassion, kindness, dignity and respect.

Potential sources of evidence

Records and policies– where applicable and for existing providers

People
☐Does the environment promote people's well-being e.g. through IT?
☐Care files and care plan template - person centred focus/practice or task
☐Orientation (for people admitted to the service), involvement in treatment and care decisions
☐Arrangements for Mental Capacity Act (MCA) assessment
☐Communication needs and how they are met
☐Patient and carer surveys relevant for patients and other feedback methods

Staff
☐Staff training and induction – Equality & Diversity, Human Rights Act, Mental Capacity Act, End of Life Care and communication skills
☐Meeting minutes/agendas
☐Staff meetings

Observation – where applicable and for existing providers
☐How people and staff interact with each other - meaningful interaction or task-led?

Service
☐Policy to orient people admitted to the service
☐For existing providers - Feedback about how caring the provider is from liaison/cooperation with other services, including for example, as needed:
- o   GPs, consultant and specialist doctors
- o   hospital ward staff
- o   Specialist nurses – for example, tissue viability, diabetes, oncology, urology, continence nurses
- o   Physiotherapy and occupational therapy services
- o   Community professionals
- o   Healthwatch
- o   Service commissioners & care managers
- o   Equality and diversity leads

☐Recruitment values
☐Accessibility policy
☐Advocacy policy
☐Chaperone policy that will be clearly visible for people using services
☐Policies and procedures on independence, privacy, dignity, confidentiality and data management
☐Communication of appropriate contact for further information
☐Provider understanding of people who use services and family/carer competency to manage their care at home

C1	How will the service ensure that people are treated with kindness, respect and compassion, and that they are given emotional support when needed?

All health

Relevant regulation: 10
Also consider: 9, 17, 19

Prompt		**Notes**
C1.1	How will staff understand and respect the personal, cultural, social and religious needs of people and how these may relate to care needs, and how will they take these into account in the way they deliver services? How will this information be recorded and shared with other services or providers?	
C1.2	How will staff take the time to interact with people who use the service and those close to them in a respectful and considerate way?	
C1.3	How will staff show an encouraging, sensitive and supportive attitude to people who use services and those close to them?	
C1.4	How will staff raise concerns about disrespectful, discriminatory or abusive behaviour or attitudes?	
C1.5	How will staff understand the impact that a person's care, treatment or condition will have on their wellbeing and on those close to them, both emotionally and socially?	
C1.6	How will people be given appropriate and timely support and information to cope emotionally with their care, treatment or condition? How will they be advised on how to find other support services?	

C2	How will the service support people to express their views and be actively involved in making decisions about their care, treatment and support as far as possible?

All health

Relevant regulation: 9

Also consider: 10, 17, 20

Prompt		Notes
C2.1	How will staff communicate with people so that they understand their care, treatment and condition and any advice given?	
C2.2	How will staff seek accessible ways to communicate with people when their protected equality or other characteristics make this necessary?	
C2.3	How will staff make sure that people who use services and those close to them are able to find further information, including community and advocacy services, or ask questions about their care and treatment? How will they be supported to access these?	
C2.4	How will people be empowered and supported, where necessary, to use and link with support networks and advocacy, so that it will have a positive impact on their health, care and wellbeing?	
C2.5	How will staff routinely involve people who use services and those close to them (including carers and dependants) in planning and making shared decisions about their care and treatment? How will people feel listened to, respected and have their views considered?	

C2.6	How will people's carers, advocates and representatives, including family members and friends be identified, welcomed and treated as important partners in the delivery of their care?	
C2.7	What emotional support and information will be provided to those close to people who use services, including carers, family and dependants?	

C3	How will people's privacy and dignity be respected and promoted?	
All health		
Relevant regulation: 10 **Also consider: 9, 15, 17**		
Prompt		**Notes**
C3.1	How will the service make sure that people's privacy and dignity needs are understood and always respected, including during physical or intimate care and examinations?	
C3.2	How will staff respond in a compassionate, timely and appropriate way when people experience physical pain, discomfort or emotional distress?	
C3.3	How will people be assured that information about them is treated confidentially in a way that complies with the Data Protection Act and that staff support people to make and review choices about sharing their information?	

Responsive

By responsive, we mean that services meet people's needs.

Potential sources of evidence

Records and policies– where applicable and for existing providers

People
☐Assessments, care planning and practice are person centred and responsive
☐Patient records, reviews, assessments and care plans
☐Where applicable, results of feedback and surveys from people who use services. Or evidence that the service intends to collect people's views
☐Availability of translation/interpretation services
☐Relevant policies covering: learning disabilities, equality and diversity, long term conditions, behaviour that challenges, family and carer involvement, home visits and care provided in the community
☐ Information pack for people who use services
☐Evidence that people are supported to raise concerns and informed of the outcome
☐Feedback from people who use services

Staff
☐Staff training and induction
☐Feedback from professionals

Observation – where applicable and for existing providers
☐Technology is used to help people access the service
☐Access to relevant faith-specific materials and facilities
☐Evidence that premises and facilities are accessible and appropriate for the regulated activities that will be/are being delivered there
☐Where applicable, family rooms or facilities for families to stay overnight

Service
☐Evidence that commissioners, local stakeholders and people who use services will be involved in planning and delivering services
☐Accessibility of the service
☐Out of hours provision
☐Local quality indictors agreed with commissioners
☐Process for accessing mental health support and making urgent referrals
☐Criteria and protocols for admission, referral, transfer, transition and discharge (including out-of-hours)
☐Service improvement plans that will/do take account of feedback
☐Provider opening hours/planned opening hours
☐Provider website
☐Performance data e.g. data submissions, response times, test results, waiting times for diagnostics and/or appointments where applicable, average length of stay and delayed discharges, where applicable
☐Audits planned or undertaken to review response times, waiting times, accessibility and complaints system, i.e. number of complaints, response times, people who use services' satisfaction
☐Complaints and concerns policy and procedures. Are there accessible options? Evidence that learning from complaints is used when planning services

☐ Accessible information is provided in a way that takes account of people with complex needs. Will/does the service comply with the Accessible Information Standard? ☐Evidence that information is provided to people who use services, i.e. in waiting areas, on the website, in newsletters, meetings? ☐Evidence that there is clear record keeping for those with complex needs, e.g. dementia, vulnerable adults, children, and those with a long term condition	

R1	How will people receive personalised care that is responsive to their needs?

All health

Relevant regulation: 9,12

Also consider: 10, 13, 15, 17

Prompt		Notes
R1.1	How will the services provided reflect the needs of the population served and ensure flexibility, choice and continuity of care?	
R1.2	Where people's needs and choices are not being met, how will this be identified and used to inform how services will be improved and developed?	
R1.3	How will the facilities and premises be appropriate for the services that are delivered?	
R1.4	How will the service identify and meet the information and communication needs of people with a disability or sensory loss? How will it record, highlight and share this information with others when required, and gain people's consent to do so?	

R2	How will services take account of the particular needs and choices of different people?

All health- *except see service specific inspection KLOES

R2.6 and R2.7 Community health services, specialist mental health services, specialist substance misuse services

R2.8 Acute and community health services only where the health service includes end of life care

R2.9 NOT: NHS 111, specialist mental health services. Acute and community health services only where the health service includes end of life care

R2.10 NOT: NHS 111, specialist mental health services. Acute and community health services only where the health service includes end of life care

Relevant regulation: 16

Also consider: 9, 12, 17, 20

Prompt		Notes
R2.2	How will services be delivered and coordinated to be accessible and responsive to people with complex needs?	
R2.3	How will people be supported during referral, transfer between services and discharge?	
R2.4	How will reasonable adjustments be made so that people with a disability can access and use services on an equal basis to others?	
R2.5	How will key staff work across services to coordinate people's involvement with families and carers, particularly for those with multiple long-term conditions?	
R2.6	Where the service is responsible, how will people be encouraged to develop and maintain relationships with people that matter to them, both within the service and the wider community?	

R2.7	Where the service is responsible, how will people be supported to follow their interests and take part in activities that are socially and culturally relevant and appropriate to them, including in the wider community and, where appropriate, to have access to education and work opportunities?	
R2.8	How will services be delivered and coordinated to ensure that people who may be approaching the end of their life are identified, including those with a protected equality characteristic and people whose circumstances may make them vulnerable, and that this information is shared?	
R2.9	How will people who may be approaching the end of their life be supported to make informed choices about their care? How will people's decisions be documented and delivered through a personalised care plan and shared with others who may need to be informed?	
R2.10	If any treatment is changed or withdrawn, what will the processes be to ensure that this is managed openly and sensitively so that people have a comfortable and dignified death?	

R3	How will people be able to access care and treatment in a timely way?
All health - *except see service specific inspection KLOES* R3.2 NOT: ambulance services, NHS 111 R3.5 NOT: NHS 111 R3.8 NOT: ambulance services	

Relevant regulation: 9	
Also consider: 10, 17	
Prompt	**Notes**
R3.1	How will people have timely access to initial assessment, test results, diagnosis or treatment?	
R3.2	How will people be able to access care and treatment at a time to suit them?	
R3.3	What action will be taken to minimise the length of time people have to wait for care, treatment or advice?	
R3.4	How will people with the most urgent needs have their care and treatment prioritised?	
R3.5	How will appointment systems be easy to use and support people to access appointments?	
R3.6	How will appointments, care and treatment only be cancelled or delayed when absolutely necessary? How will delays or cancellations be explained to people, and people supported to access care and treatment again as soon as possible?	
R3.7	How will services run on time, and people kept informed about any disruption?	
R3.8	How will technology be used to support timely access to care and treatment? How will the technology (including telephone systems and online/digital services) be easy to use?	

R4	How will people's concerns and complaints be listened and responded to and used to improve the quality of care?

All health

Relevant regulation: 16

Also consider: 12, 17, 20

Prompt		Notes
R4.1	How will people who use the service know how to make a complaint or raise concerns and how will they be made to feel comfortable doing so in their own way? How will people be encouraged to make a complaint, and confident to speak up?	
R4.2	How easy will it be for people to use the complaints process or raise a concern? How will people be treated compassionately and given help and support, by using accessible information or protection measures, if they need to make a complaint?	
R4.3	How effectively will complaints be handled, including ensuring openness and transparency, confidentiality, regular updates for the complainant, a timely response and explanation of the outcome, and a formal record?	
R4.4	How will people who raise concerns or complaints be protected from discrimination, harassment or disadvantage?	
R4.5	To what extent will concerns and complaints be used as an opportunity to learn and drive continuous improvement?	

Well-led

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

Potential sources of evidence

Records and policies– where applicable and for existing providers

People
- ☐ Experiences of assessments, care planning and outcomes
- ☐ Experiences of how technology is used
- ☐ Patient survey results

Staff
- ☐ Leadership development and training programmes
- ☐ FPPR policies and files
- ☐ Succession planning and talent management documents
- ☐ Staff surveys – what do they say about the leadership?
- ☐ Workforce Race Equality Standard report for organisations providing NHS funded care – data and action plan for board
- ☐ Equality Delivery System 2 report for organisations providing NHS funded care – leadership domain
- ☐ Equality and diversity policies, including training / support about issues facing LGBT people using the provider.
- ☐ Recruitment policies
- ☐ Competence and value based recruitment
- ☐ Management of behaviour and performance

Observation – where applicable and for existing providers
- ☐ Visibility and approachability of leaders
- ☐ Staff understanding of vision, values, strategy and roles
- ☐ Honest and open culture with positive relationships
- ☐ Staff safety and well-being
- ☐ Person-centred care

Service
- ☐ Vision, values and strategy
- ☐ Business plans
- ☐ Annual report
- ☐ Quality strategy
- ☐ Quality accounts
- ☐ Financial plan and budget
- ☐ Cost Improvement and Sustainability Plans
- ☐ Stakeholder information e.g. NHSI, CCG and minutes of meetings with stakeholders, e.g. STP meetings, CCG meetings, relevant boards
- ☐ Minutes of contract meetings
- ☐ Learning from external developmental reviews of leadership and governance
- ☐ Duty of Candour policy
- ☐ Complaints information including policy and promotion
- ☐ Governance frameworks:
  - Board of Directors and Committees/Senior leadership team
  - Legal and Regulatory Framework
  - Policies and Procedures
  - Monitoring and Internal controls
  - Accountabilities
  - Learning and innovation
  - Assurance framework
  - Scheme of delegation
- ☐ Are the management structures and governance framework set up to ensure that the RM meets their regulatory responsibilities?
- ☐ Board/Senior Leadership team Code of Conduct
- ☐ Roles and responsibilities for Board NEDs/Senior Leadership team
- ☐ Risk management strategy
- ☐ Risk registers

	☐Audit plans and reports ☐Business continuity plans and arrangements ☐Corporate strategy milestones, targets and outcomes ☐Corporate performance management framework ☐Corporate performance dashboards / balance score card ☐Key performance indicators (KPIs) ☐Arrangements in place to monitor systems/procedures ☐Information strategy and governance arrangements ☐Information governance breaches and lessons learnt ☐Governance and management arrangements for sub-contracts ☐Requirements of Data Security and Protection Toolkit met ☐Patient experience and Engagement strategy ☐Consultation processes/strategy ☐Patient and staff engagement forums ☐Minutes of meetings with stakeholders, e.g. STP meetings, CCG meetings, relevant boards ☐Evidence of innovative projects/programmes ☐Participation in accreditation schemes ☐Evidence of participation in research projects (independent health only) ☐governance of practicing privileges (independent health only) ☐responsibility and role of Medical Advisory Committee (independent health only) ☐data submissions to Private Healthcare Information Network (independent health only) ☐compliance with Competitions and Markets Authority order (independent health only)

W1	How will there be the leadership capacity and capability to deliver high-quality, sustainable care?

All health

Relevant regulation: 17

Also consider: 4, 5, 6, 7

Prompt		Notes
W1.1	How will leaders have the skills, knowledge, experience and integrity that they need – both when they are appointed and on an ongoing basis?	
W1.2	How will leaders understand the challenges to quality and sustainability, and can they identify the actions needed to address them?	
W1.3	How will leaders be visible and approachable?	
W1.4	How will there be clear priorities for ensuring sustainable, compassionate, inclusive and effective leadership, and will there be a leadership strategy or development programme, which includes succession planning?	

W2	How will there be a clear vision and credible strategy to deliver high-quality sustainable care to people, and robust plans to deliver?

All health

Relevant regulation: 12, 17

Also consider: 4, 5, 6, 7 13 Registration regulations 2009 – Notifications 12, 14, 15, 16, 17, 18.
H&SC Act 2008: S10, S11, S13, S14, S29, S33, S34, S36, S63

Prompt		Notes
W2.1	How will there be a clear vision and a set of values, with quality and sustainability as the top priorities?	
W2.2	How will there be a robust, realistic strategy for achieving the priorities and delivering good quality sustainable care?	
W2.3	How will the vision, values and strategy be developed using a structured planning process in collaboration with staff, people who use services, and external partners?	
W2.4	How will staff know and understand what the vision, values and strategy are, and their role in achieving them?	
W2.5	How will the strategy be aligned to local plans in the wider health and social care economy, and how will services be planned to meet the needs of the relevant population?	
W2.6	How will progress against delivery of the strategy and local plans be monitored and reviewed, and what evidence will there be to show this?	

W3	How will there be a culture of high-quality, sustainable care?
All health	

Relevant regulation: 9, 17

Also consider: 10, 20

Prompt		Notes
W3.1	How will staff feel supported, respected and valued?	
W3.2	How will the culture be centred on the needs and experience of people who use services?	
W3.3	How will staff feel positive and proud to work in the organisation?	
W3.4	How will action be taken to address behaviour and performance that is inconsistent with the vision and values, regardless of seniority?	
W3.5	How will the culture encourage openness and honesty at all levels within the organisation, including with people who use services, in response to incidents? How will leaders and staff understand the importance of staff being able to raise concerns without fear of retribution, and will appropriate learning and action be taken as a result of concerns raised?	
W3.6	What mechanisms will there be for providing all staff at every level with the development they need, including high-quality appraisal and career development conversations?	

W3.7	How will there be a strong emphasis on the safety and wellbeing of staff?	
W3.8	How will equality and diversity be promoted within and beyond the organisation? How will all staff, including those with particular protected characteristics under the Equality Act, be made to feel they are treated equitably?	
W3.9	How will there be cooperative, supportive and appreciative relationships among staff? How will staff and teams work collaboratively, share responsibility and resolve conflict quickly and constructively?	

W4	How will there be clear responsibilities, roles and systems of accountability to support good governance and management?

All health- *except see service specific inspection KLOES*

W4.5 Specialist mental health services

Relevant regulation: 17

Also consider: 5, 6, 7, 16, 20

Prompt		Notes
W4.1	How will there be effective structures, processes and systems of accountability to support the delivery of the strategy and good quality, sustainable services? How will these be regularly reviewed and improved?	

W4.2	How will all levels of governance and management function effectively and interact with each other appropriately?	
W4.3	How will staff at all levels be clear about their roles and understand what they are accountable for, and to whom?	
W4.4	How will arrangements with partners and third-party providers be governed and managed effectively to encourage appropriate interaction and promote coordinated, person-centred care?	
W4.5	How will there be robust arrangements to make sure that hospital managers discharge their specific powers and duties according to the provisions of the Mental Health Act 1983?	

W5	How will there be clear and effective processes for managing risks, issues and performance?
All health	

Relevant regulation: 12, 17

Also consider: 9

Prompt		Notes
W5.1	How will there be comprehensive assurance systems, and performance issues escalated appropriately through clear structures and processes? How will these be regularly reviewed and improved?	

W5.2	How will there be processes to manage current and future performance? How will these be regularly reviewed and improved?	
W5.3	How will there be a systematic programme of clinical and internal audit to monitor quality, operational and financial processes, and systems to identify where action should be taken?	
W5.4	How will there be robust arrangements for identifying, recording and managing risks, issues and mitigating actions? How will there be alignment between the recorded risks and what staff say is 'on their worry list'?	
W5.5	How will potential risks be taken into account when planning services, for example seasonal or other expected or unexpected fluctuations in demand, or disruption to staffing or facilities?	
W5.6	When considering developments to services or efficiency changes, how will the impact on quality and sustainability be assessed and monitored? Are there examples of where financial pressures have compromised care?	

W6	How will appropriate and accurate information be effectively processed, challenged and acted on?
All health	
Relevant regulation: 12, 17 **Also consider: 9**	

Prompt		Notes
W6.1	How will there be a holistic understanding of performance, which sufficiently covers and integrates people's views with information on quality, operations and finances? How will information be used to measure for improvement, not just assurance?	
W6.2	How will quality and sustainability both receive sufficient coverage in relevant meetings at all levels? How will staff have sufficient access to information, and how will they be able to challenge it appropriately?	
W6.3	How will there be clear and robust service performance measures, which are reported and monitored?	
W6.4	How will there be effective arrangements to ensure that the information used to monitor, manage and report on quality and performance is accurate, valid, reliable, timely and relevant? What action will be taken when issues are identified?	
W6.5	How will information technology systems be used effectively to monitor and improve the quality of care?	
W6.6	How will there be effective arrangements to ensure that data or notifications are submitted to external bodies as required?	
W6.7	How will there be robust arrangements (including appropriate internal and external validation) to ensure the availability, integrity and confidentiality of identifiable data, records and data management systems, in line with data security standards? How will lessons be learned when there are data security breaches?	

W7	How will the people who use the services, the public, staff and external partners be engaged and involved to support high-quality sustainable services??

All health

Relevant regulation: 9, 17

Also consider: 10, 20

Prompt		Notes
W7.1	How will people who use services, those close to them and their representatives be actively engaged and involved in decision-making to shape services and culture? How will this include people in a range of equality groups? How will people's views and experiences be gathered and acted on to shape and improve the services and culture? How will this include people in a range of equality groups?	
W7.2	How will staff be actively engaged so that their views are reflected in the planning and delivery of services and in shaping the culture? How will this include those with a protected equality characteristic?	
W7.3	How will there be positive and collaborative relationships with external partners to build a shared understanding of challenges within the system and the needs of the relevant population, and to deliver services to meet those needs?	
W7.4	How will there be transparency and openness with all stakeholders about performance?	

W8	How will there be robust systems and processes for learning, continuous improvement and innovation?

All health

Relevant regulation: 17

Also consider: 5, 6, 7, 16, 20

Prompt		Notes
W8.1	In what ways will leaders and staff strive for continuous learning, improvement and innovation? How will this include participating in appropriate research projects and recognised accreditation schemes?	
W8.2	How will there be standardised improvement tools and methods, and how will staff have the skills to use them?	
W8.3	How will there be effective participation in and learning from internal and external reviews, including those related to mortality or the death of a person using the servicer? How will learning be shared effectively and used to make improvements?	
W8.4	How will all staff regularly take time out to work together to resolve problems and to review individual and team objectives, processes and performance? How will this lead to improvements and innovation?	
W8.5	How will there be systems to support improvement and innovation work, including objectives and rewards for staff, data systems, and processes for evaluating and sharing the results of improvement work?	