

How CQC regulates:

# Specialist substance misuse services



Provider handbook

July 2015

## **The Care Quality Commission is the independent regulator of health and adult social care in England.**

### **Our purpose**

We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

### **Our role**

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

### **Our values**

Excellence – being a high-performing organisation

Caring – treating everyone with dignity and respect

Integrity – doing the right thing

Teamwork – learning from each other to be the best we can

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# Introduction

This handbook describes our approach to regulating, inspecting and rating providers of specialist substance misuse services. These services are for people who misuse alcohol and drugs and offer treatment in inpatient, community and residential settings. It explains the key principles of CQC's approach to regulating health and care providers and how it applies to independent specialist substance misuse providers. It focuses primarily on independent standalone substance misuse services and we will use this as a basis for considering our approach to specialist substance misuse services provided in other contexts, such as NHS trusts, GP practices and independent providers that also offer other services.

This document builds on our publication, [\*A fresh start for the regulation and inspection of substance misuse services\*](#), which set out our proposals to change how we regulate, inspect and monitor these providers. Our proposals included making greater use of people's views and experiences of care, and a consistent focus on people who are in vulnerable circumstances, or from specific population groups. They also included using clinical and other experts, such as inspectors with further training about substance misuse services and people with experience of receiving care (Experts by Experience), as part of inspection teams.

In *A fresh start*, we noted that the Chief Inspector of Hospitals and the Deputy Chief Inspector of Hospitals (lead for Mental Health) will oversee the regulation of hospital-based, community-based and residential treatment services for people with substance misuse problems.

As with other health and social care providers, our inspectors will use objective measures and evidence supported by professional judgement, to assess specialist substance misuse services against our five key questions:

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive to people's needs?
- Are they well-led?

We will rate services (once our regulatory powers in respect to substance misuse services are clarified) to help people compare services and highlight where care is outstanding, good, requires improvement or inadequate. We have tested our approach for providers of specialist substance misuse services. These pilots were held between January and March 2015 and included providers in the NHS and independent sector, and inpatient, community and community residential settings.

We will begin announcing comprehensive inspections of independent standalone substance misuse services from July 2015. Initially, we will inspect these services without rating them. However, our ambition is to rate these services in the future and we are working with the Department of Health to clarify our regulatory powers to do so. We will further consider the roll out of ratings to independent standalone substance misuse services once the ratings regulations are changed.

We will also continue to test the feasibility and scope of inspecting and separately rating substance misuse services offered by other providers, for example NHS trusts, GP practices and independent providers that also offer other services, with a view to rolling this out once the current inspection cycle for these providers' ends. In the interim, we will inspect substance misuse services offered by these providers if risks are identified.

For NHS trusts, as part of testing our approach ahead of the next cycle, we may also inspect and rate a substance misuse service if it represents a large proportion of a providers' activity or expenditure, if we believe the quality of care could be outstanding, where we have concerns or where the level of risk would mean it is not appropriate to not inspect it. In those circumstances we would inspect the substance misuse service and rate and report on it in the same way as a core service. This is in line with the approach we are taking for other non-core services for hospitals in the acute and community sector.

# 1. Our framework

Although we inspect and regulate different services in different ways, there are some key principles that guide our operating model across all our work.

## Our operating model

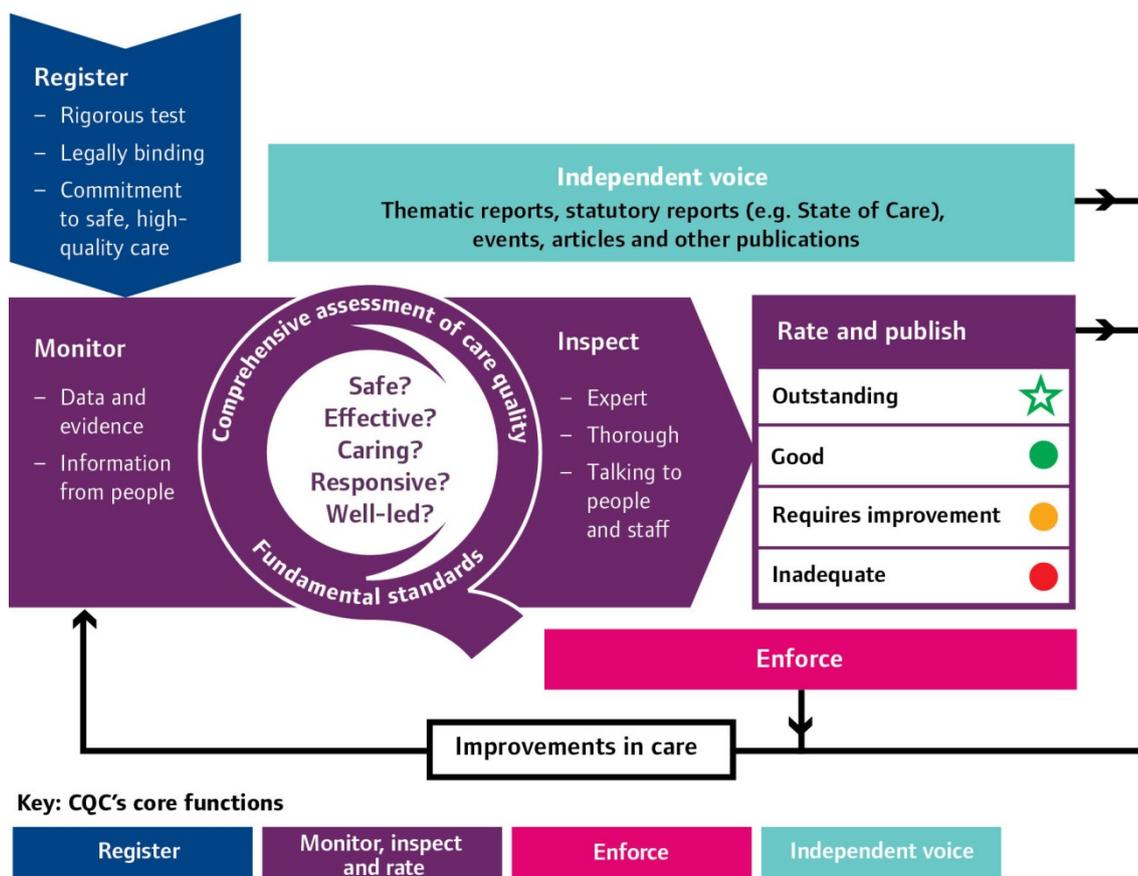
The following diagram shows an overview of our overall operating model. It covers all the steps in the process, including:

- Registering those that apply to CQC to provide services.
- Intelligent use of data, evidence and information to monitor services.
- Using feedback from people who use services and the public to inform our judgements about services.
- Inspections carried out by experts.
- Information for the public on our judgements about care quality, including a rating to help people choose services.
- The action we take to require improvements and, where necessary, the action we take to make sure those responsible for poor care are held accountable for it – our enforcement policy sets out how we will do this.

While the ratings element of the operating model will not initially apply to specialist substance misuse services, our ambition is for those services to be rated in the future.

Our model is underpinned by the fundamental standards that were introduced in April 2015. We have issued [guidance](#) to help providers understand how they can meet the regulations.

**Figure 1: CQC’s overall operating model**



## The five key questions we ask

To get to the heart of patients’ experiences of care, the focus of our inspections is on the quality and safety of services, based on the things that matter to people. We always ask the following five questions of services:

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive to people’s needs?
- Are they well-led?

For all health and social care services, we have defined these five questions as follows:

<b>Safe</b>	By safe, we mean that people are protected from abuse and avoidable harm.
<b>Effective</b>	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.
<b>Caring</b>	By caring, we mean that staff involve and treat people with compassion, kindness, dignity and respect.

<b>Responsive</b>	By responsive, we mean that services are organised so that they meet people's needs.
<b>Well-led</b>	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.

## Transitions, care pathways and joint working

We are committed to including a focus on transitions between services, care pathways and joint working as part of our inspections of specialist substance misuse services.

Transitions between services include:

- Moving between substance misuse services for young people and adults.
- Moving between providers, for example between community or inpatient services and residential services.
- Transitions from secure settings to the community.

This will mean looking at the timeliness of responses, how providers work together and share information to achieve positive outcomes for people who use services, and how people in transition between services are supported.

In terms of integrated working and care pathways, this includes how services:

- Address physical as well as mental health needs.
- Promote recovery, health and wellbeing.
- Prevent or respond appropriately to crisis.
- Enable patients to achieve a good quality of life, for example, in relation to housing, employment and social participation.

We assess transitions, care pathways and joint working through the questions that we ask and the methods that we use, including reviewing case notes.

## Key lines of enquiry

To direct the focus of their inspection, our inspection teams will use a standard set of key lines of enquiry (KLOEs) that directly relate to the five key questions – are services safe, effective, caring, responsive and well-led?

The KLOEs for specialist substance misuse services are set out in [appendix A](#).

Having a standard set of KLOEs ensures consistency of what we look at under each of the five questions and that we focus on those areas that matter most. This is vital for reaching a credible, comparable rating. To enable

inspection teams to reach a rating, they gather and record evidence to answer each KLOE.

Each KLOE is accompanied by a number of questions that we call prompts, which inspection teams will consider as part of the assessment.

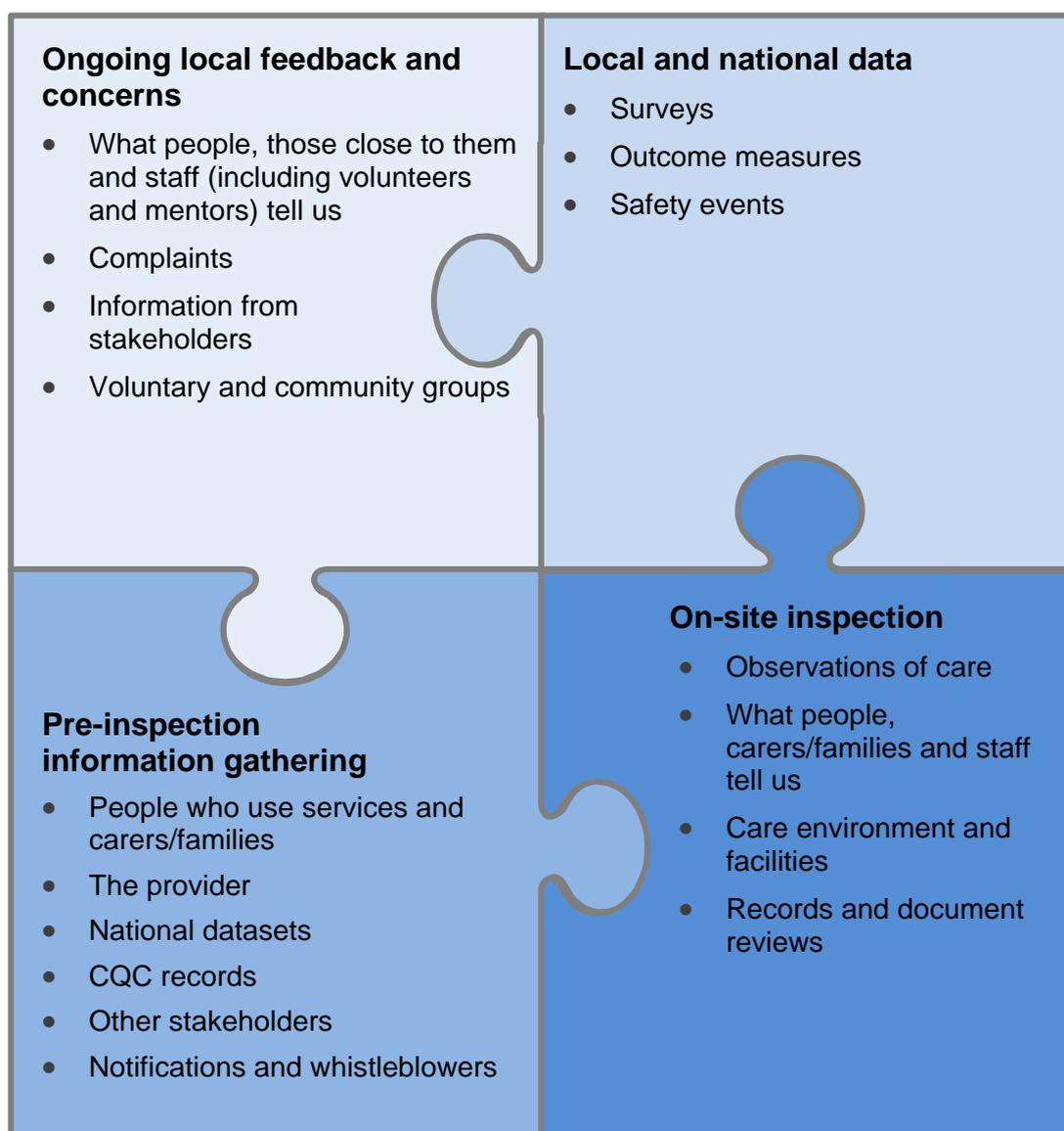
These are consistent with the KLOEs and prompts used for inspecting specialist mental health services, NHS acute hospitals and GP practices, and will therefore provide a common framework for assessing substance misuse services. However, we have made some small changes to make sure they are specifically relevant to specialist substance misuse services.

In addition to the KLOEs and prompts, our teams will also use guidance that provides detailed areas of focus for substance misuse services in different service settings. This will help to further ensure that inspection teams are able to consider issues of relevance to specialist substance misuse services. This guidance is being developed with internal and external specialists and will reflect aspects that are of particular interest to the public and professionals. It will highlight key data or audit items, specific prompts for the service, and provide guidelines on who should be interviewed and what areas should be inspected. New national priorities or policy directions will be reflected in this guidance as they emerge.

This guidance will be published on our website as it becomes available. As with other CQC inspections, we propose that inspection teams will use evidence from four main sources in order to answer the KLOEs. These are:

1. Information from the ongoing relationship management with the specialist substance misuse service provider and other stakeholders, including information from the provider on how it thinks it is performing, the processes it has in place, and the action it is taking to improve under-performance (as described in [section 4](#)).
2. Other nationally available and local information that can inform the inspection judgement. This will typically be included in data packs that will be provided to inspection teams before each inspection.
3. Information from activity carried out during the pre-inspection phase as set out in [section 6](#).
4. Information from the inspection visit itself as set out in [section 6](#).

**Figure 2: The four main sources of evidence**



## Ratings

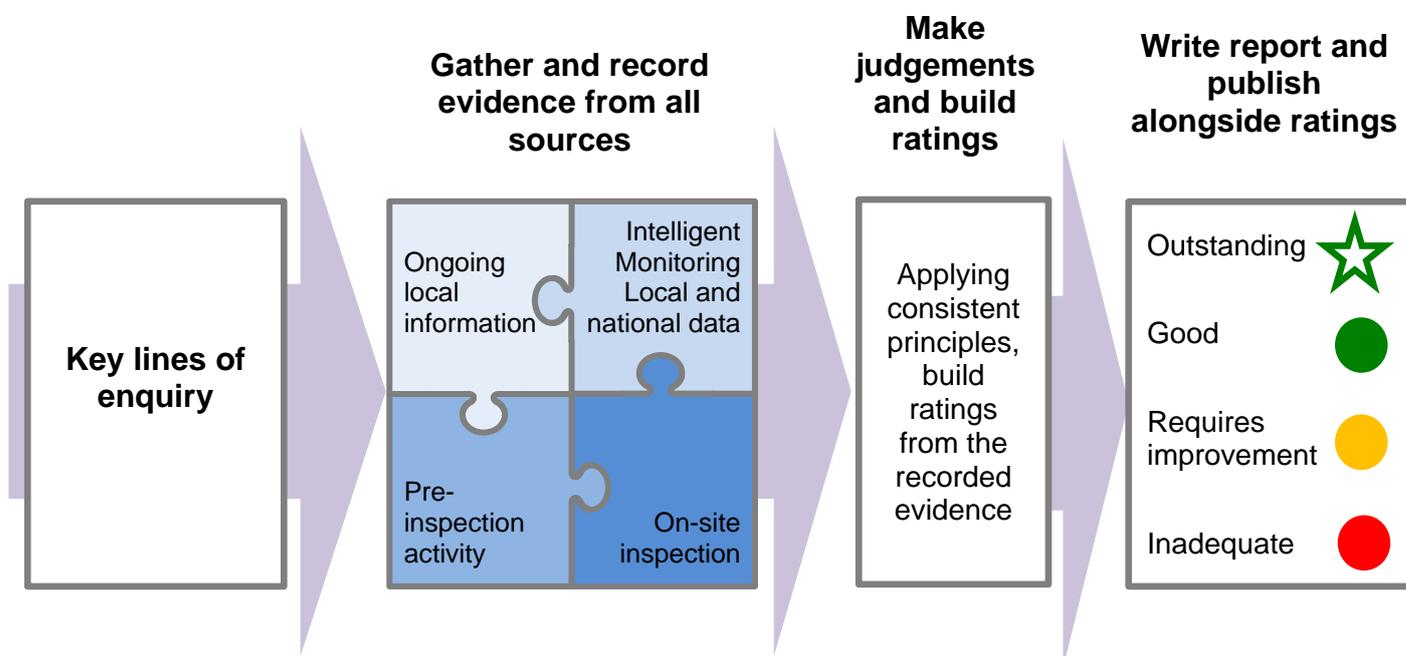
Ratings are an important element of our approach to inspection and regulation.

Initially, independent standalone substance misuse services will be inspected but not rated. However, our ambition is to rate substance misuse services in the future and we are working with the Department of Health to clarify our regulatory powers to do so. We will further consider the roll out of ratings to independent standalone substance misuse services if the ratings regulations are changed.

As set out in figure 3, our ratings would always be based on a combination of what we find at inspection, what people tell us, our Intelligent Monitoring data and information from the provider and other organisations.

We would award ratings on a four-point scale: outstanding, good, requires improvement, or inadequate.

**Figure 3: How KLOEs and evidence build towards ratings**



While we will not initially rate specialist substance misuse services, we have developed characteristics to describe what outstanding, good, requires improvement and inadequate care look like in relation to each of the five key questions in these services. The rating characteristics are set out in [appendix B](#) and will be used when we start rating independent standalone substance misuse services.

These characteristics provide a framework that, applied using professional judgement, would guide our inspection teams to award a rating to an independent standalone substance misuse service. They would not be used as a checklist or an exhaustive list. The inspection team would use their professional judgment, taking into account best practice and recognised guidelines, with the quality control process ensuring consistency.

Not every characteristic would have to be present for the corresponding rating to be given. This is particularly true at the extremes. For example, if the impact on the quality of care or on people's experience is significant, then displaying just one of the characteristics of inadequate could lead to a rating of inadequate. Even those rated as outstanding are likely to have areas where they could improve.

A service or provider would not need to display every one of the characteristics of good in order to be rated as good.

Ratings are discussed in more detail in [section 10](#).

## Equality and human rights

One of CQC's principles is to promote equality, diversity and human rights. This is a means to an end and not an end in itself. The end is good quality care for all. Respecting diversity, promoting equality and ensuring human rights will help to make sure that everyone using health and social care services receives good quality care.

To put this into practice, we have developed a human rights approach to regulation. This looks at a set of human rights principles – fairness, respect, equality, dignity, autonomy, right to life and rights for staff – in relation to the five key questions we ask. All of these principles are enshrined in the NHS Constitution.

Using a human rights approach that is based on rights that people hold, rather than what services should deliver, also helps us to look at care from the perspectives of patients. We know from talking to people that fairness, respect, equality, dignity and autonomy are very important.

This focus on human rights is integrated into our new approach to inspection and regulation. This is the best way to ensure equality and human rights are promoted in our work. We have integrated the human rights principles into our key lines of enquiry, ratings characteristics, intelligent monitoring, inspection methods, learning and development for inspection teams and our policies around judgement making and enforcement.

There are some human rights issues that are particularly relevant to specialist substance misuse services. For example, in order to provide a safe and effective service, some people who use substance misuse services can expect to receive a structured service that may include restrictions, for example to daily routines, movement and personal relationships. As set out in [section 6](#), we will look at the use of restrictions during inspections.

If people who use services are subject to the Mental Health Act 1983, we would look at how this is being applied and use this to inform our judgement of services.

## Monitoring the use of the Mental Capacity Act 2005 including the Deprivation of Liberty Safeguards

The Mental Capacity Act 2005 (MCA) is a crucial safeguard for the human rights of adults who might (or may be assumed to) lack mental capacity to make decisions, including whether or not to consent to proposed care or treatment interventions. The MCA provides the essential framework for balancing autonomy and protection when staff are assessing whether people aged 16 and over have the mental capacity to make specific decisions at the time they need to be made.

The MCA clearly applies where a service works with people who may have cognitive difficulties due to dementia, an acquired brain injury or a learning

disability. However, providers must also recognise that a person may lack mental capacity for a specific decision at the time it needs to be made for a wide range of reasons, which may be temporary, and they should know how then to proceed.

Using drugs or alcohol does not necessarily mean that the user lacks mental capacity to make a particular decision at the time it needs to be made. However, alcohol or drugs may lead to a person lacking capacity for such decision-making, either temporarily (for example, while drunk) or for a longer period of time.

Mental capacity must be assessed in accordance with the MCA: does the person have an impairment or disturbance in the functioning of the mind or brain and, if so, does it make the person unable to make a decision at the time it needs to be made?

Anyone considering making decisions about or on behalf of the person must consider whether they will regain capacity and, if so, whether this decision can wait. Conditions related to the use of drugs or alcohol, such as alcohol related brain damage (ARBD), may lead to someone having a series of assessments of their mental capacity and a range of decisions made about what is in their best interests. For example, in the case of ARBD, it may be appropriate to apply the MCA at the following stages:

- Acute physical stage (mental confusion, eye movement disorders, and poor motor coordination).
- Helping people, in a supportive environment, to abstain from alcohol in their initial period of confusion.
- Providing ongoing support and protection for people with long-term cognitive deficits.

During these stages, the provider should consider whether the person has the capacity to make decisions about where they want to be placed and abstaining from alcohol.

Any decision taken on behalf of a person lacking capacity must be made in their best interests and must be the least restrictive option to meet their needs.

We have a duty to monitor the Deprivation of Liberty Safeguards in all hospitals and care homes in England, and check on their use when we inspect places where they are used. Hospitals and care homes must tell us about the outcome of any application to deprive someone of their liberty using the Safeguards or by an order of the Court of Protection.

Where it is likely that a person lacking mental capacity to consent to the arrangements is deprived of their liberty, to be given essential care or treatment, we will look for evidence that efforts have been made to reduce any restrictions on freedom, so that the person is not deprived of their liberty. Where this is not possible we will check that the deprivation of liberty has been authorised as appropriate, by use of the Deprivation of Liberty

Safeguards, the Mental Health Act 1983, or by an order of the Court of Protection.

The importance of working within the MCA is reflected in our inspections. A specific KLOE about consent takes account of the requirements of the MCA and other relevant legislation.

During our inspections, we will assess how well providers are using the MCA to promote and protect the rights of people using their services.

In particular, we will look at how and when mental capacity is assessed, how mental capacity is maximised and, where people lack mental capacity for a specific decision, how that decision is made and recorded in compliance with the MCA.

We will look for evidence that restraint, if used to deliver necessary care or treatment, is in the best interests of someone lacking mental capacity, is proportionate, and complies with the MCA.

## **Concerns, complaints and whistleblowing**

Concerns raised by people using services, those close to them, and staff working in services, provide vital information that helps us to understand the quality of care. We will gather this information in three main ways:

- Encouraging users and staff to contact us directly through our website and phone line, and providing opportunities to share concerns with inspectors when they visit a service.
- Asking national and local partners (for example, the Ombudsmen, the local authority and Healthwatch) to share with us concerns, complaints and whistleblowing information that they hold.
- Requesting information about concerns, complaints and whistleblowing from providers themselves.

We will also look at how providers handle concerns, complaints and whistleblowing in every inspection. A service that is safe, responsive and well-led will treat every concern as an opportunity to improve, will encourage its staff to raise concerns without fear of reprisal, and will respond to complaints openly and honestly. The Parliamentary and Health Service Ombudsman, the Local Government Ombudsman and Healthwatch England have set out standard expectations for complaints handling, which are consistent with our assessment framework, and describe the good practice we will look for.

We will draw on different sources of evidence to understand how well providers encourage, listen to, respond to and learn from concerns, based on work we have undertaken with The Patients Association. Evidence sources may include complaints and whistleblowing policies, indicators such as a complaints backlog and staff survey results, speaking with users, carers, families and staff and reviewing case notes from investigations.

## 2. What specialist substance misuse services will we inspect?

We are responsible for regulating the following types of specialist substance misuse services:

1. **Hospital inpatient-based services:** These services provide assessment and stabilisation, and assisted withdrawal, for people with substance misuse problems. Services are available 24 hours a day, and are provided by a multidisciplinary clinical team with specialist training in managing addiction and withdrawal symptoms.

The clinical lead in these services is usually a consultant in addiction psychiatry, or another substance misuse medical specialist. The team may also include psychologists, nurses, occupational therapists, pharmacists and social workers. People whose use of alcohol or drugs needs to be supervised in a controlled medical environment may be admitted to an inpatient unit. Treatment may be provided on a specialist ward, or as part of their care on another ward.

2. **Community-based services:** These services provide care, treatment and support in the community for people with substance misuse problems. They may also help people who have a dual diagnosis or co-occurring disorders (COD), where the person is experiencing a mental health problem and also has a substance misuse problem.

People are primarily cared for by a doctor, nurse or social worker, but services are provided by a broad range of health and social care professionals, working in multidisciplinary teams. This could include in GP practices or other community settings, or part of health services in secure settings. The teams are also supported by community pharmacists when providing controlled drugs. Treatment is likely to involve the use of medicines, usually opioid substitution therapy, alongside psychosocial interventions.

3. **Residential rehabilitation services:** These services provide structured drug and alcohol treatment where people have to be resident at the service in order to receive treatment. This includes abstinence-based recovery services, as well as medicine-assisted recovery programmes, such as detoxification or stabilisation services. Teams vary according to the service's treatment programme, but may include psychosocial project workers, social workers, doctors and nurses.

Specialist substance misuse services are not only delivered in different settings, but also by different types of providers including NHS mental health and acute trusts, independent providers and GPs.

Recognising this diversity, we do not think that it would be appropriate to implement a 'one size fits all' model for inspecting specialist substance

misuse services. However, we want to make sure that the overall inspection approach is as consistent as possible across the range of providers that offer specialist substance misuse services.

We have already published provider [handbooks](#) that set out our approach to inspecting, rating and reporting on specialist mental health services, acute hospitals and GP practices. We will continue to consider how best to incorporate elements of our proposed approach for inspecting specialist substance misuse services into our existing inspection frameworks for these providers, with a view to rolling out our approach after the current inspection cycle is completed.

This handbook therefore focuses primarily on independent standalone substance misuse services and we will use this as a basis for developing our approach to specialist substance misuse services provided in other contexts, such as NHS trusts, GP practices and independent providers that also offer other services. Our approach will initially be rolled out to independent standalone substance misuse services, which we define as “Substance misuse services delivered by independent providers, which do not provide any other service types at location level.”

In September 2014, we published a signposting document on our initial thoughts on the regulation of health services in secure settings. We are currently developing our new framework for joint inspections with HMI Prisons in this sector and will publish this in the summer.

Substance misuse services in secure settings will be inspected in line with the new approach for prisons, young offender institutions and immigration removal centres as part of our joint inspections with HMI Prisons. We will include reference to substance misuse services in the characteristics that accompany the KLOEs for inspections of health and justice services. As we implement the new approach for prisons, young offender institutions and immigration removal centres, we will consider whether any further specific guidance is required to support our inspectors to look at substance misuse services in secure settings. We will also continue to involve relevant stakeholders in our work.

# 3. Registration

Before a provider can begin to provide a regulated activity, they must apply to CQC for registration and satisfy us that they are meeting a number of registration requirements. We have issued [guidance](#) to help providers understand how they can meet these regulations (see [section 4](#)).

Registration assesses whether all new providers, whether they are organisations, individuals or partnerships; have the capability, capacity, resources and leadership skills to meet relevant legal requirements; and are therefore likely to demonstrate that they will provide people with safe, effective, caring, responsive and high-quality care.

The assessment framework makes sure that registration inspectors gather and consider comprehensive information about proposed applicants and the services they intend to provide, including where providers are varying their existing registration, to make judgments about whether applicants are likely to meet the legal requirements of the regulations.

We make judgements about, for example, the fitness and suitability of applicants, the skills, qualifications, experience and numbers of key individuals and other staff; the size, layout and design of premises; the quality and likely effectiveness of key policies, systems and procedures; governance and decision-making arrangements; and the extent to which providers and managers understand them and use them in practice.

These judgements will not stifle innovation or discourage good providers of care services, but will make sure that those most likely to provide poor quality services are discouraged and prevented from doing so.

Not all providers of specialist substance misuse treatment services need to register with CQC. Whether a provider needs to register depends on the nature of the service being delivered and if it constitutes a regulated activity (see our [scope of registration](#) guidance for more information).

In general, providers with one or more locations that deliver residential or inpatient treatment, or where they employ listed professionals, will need to register with CQC. A service provider that provides the regulated activity of 'residential accommodation for persons who require treatment for substance misuse' must also be registered for any other regulated activities that they carry out (except the regulated activity of 'treatment of disease, disorder or injury' unless they also provide treatments that are separate from the treatment of substance misuse e.g. treating a disorder not associated with a person's substance misuse such as an eating disorder).

## 4. How we work with others

Good, ongoing relationships with stakeholders are vital to our inspection approach. These relationships allow CQC better access to qualitative, as well as quantitative, information about services, particularly local evidence about people's experience of care. Local relationships also provide opportunities to identify good practice and to work with others to push up standards.

### Working with providers

A CQC inspector will be responsible for developing and maintaining relationships with standalone specialist substance misuse services at a local level. They will be responsible for day-to-day communication, as well as exchanging information and managing our relationship with providers.

Our approach includes continuous monitoring of local data and intelligence and risk assessment. Where risks are identified, the inspector will check what the provider is doing to address the risk.

We will also make use of the information that providers routinely gather, as well as information from people who use services, the public, carers and other representatives. This may include:

- Local patient surveys or other patient experience information and feedback.
- Information about the number and types of complaints people make about their care and how these are handled.

### Working with people who use services

People's experiences of care are vital to our work; they help to inform when, where and what we inspect. We want people to tell us about their care at any time through our website, helpline and social media, and we are committed to carrying out public engagement aimed at encouraging members of the public, people who use services, their carers, those close to them and their advocates to share their views and experiences with us.

We recognise the difficulties sometimes experienced in engaging with people who use specialist substance misuse services. To ensure that we can hear from people who use these services, we will work to develop relationships with local service user groups. We will work with Public Health England and the voluntary sector to identify the networks of substance misuse service user groups that we can engage with, whether these are commissioned, established by providers, or user-led organisations.

We may also use other sources to gather and analyse information from people who use services, such as:

- **Feedback from groups representing communities, people who use services and public representatives.** This may include organisations that represent or act on behalf of people who use services, such as equality groups, community groups, voluntary groups and charities and groups for carers.
- **Comments and feedback sent to CQC from individual people who use services and those close to them.** This may include feedback on services submitted via the CQC online 'share your experience' form or through telephone calls to our national call centre, as well as engagement activity specifically designed to encourage people to share their experiences of care.
- **Nationally collated feedback from people who use services and carers.** This may include patient survey data and information from online sources where available.

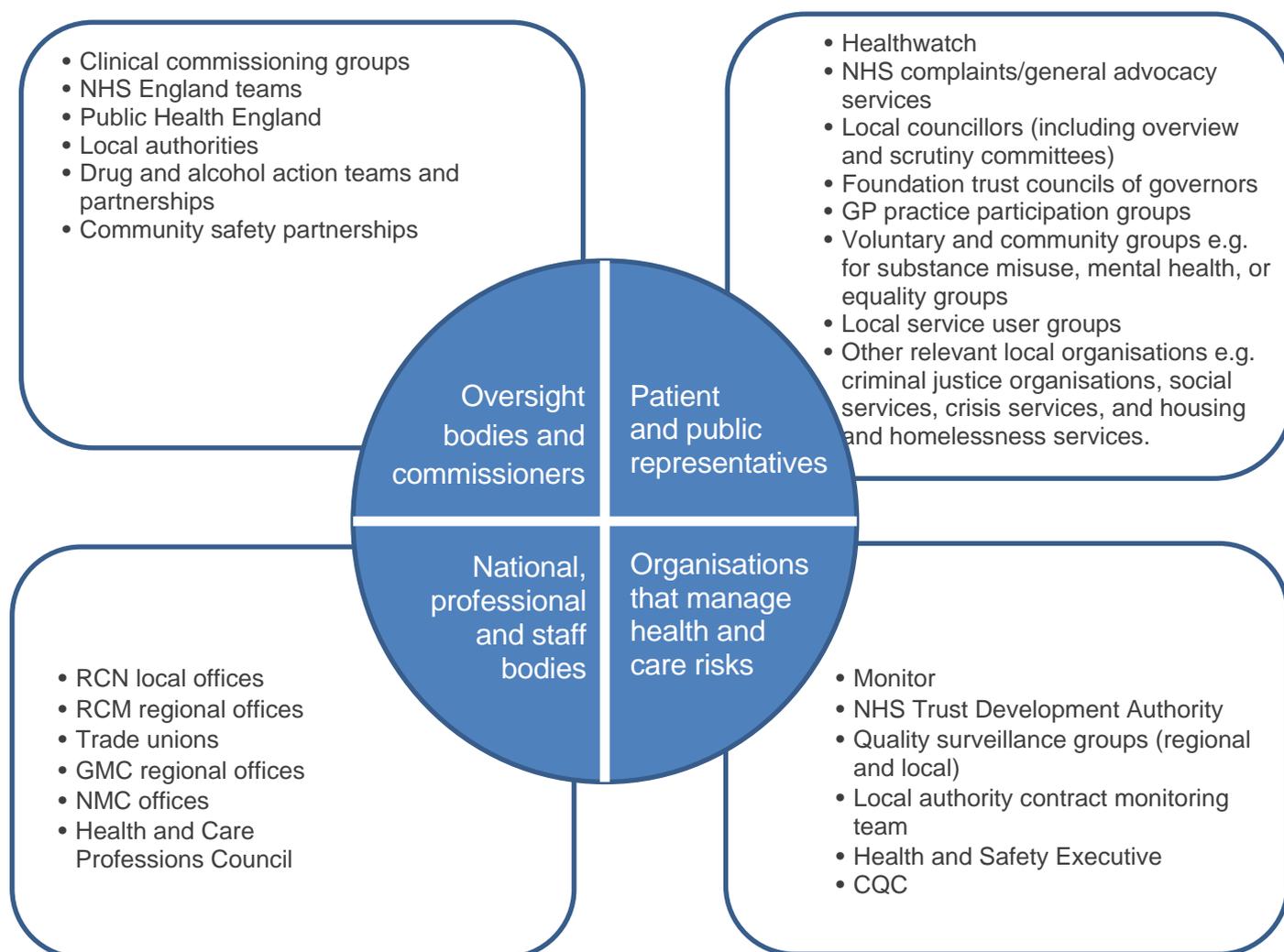
## **Working with local organisations and community groups**

It is also important to maintain good relationships with local organisations and community groups who represent people who use services and routinely gather their views. We will ask them to share with us the information that they hold. For specialist substance misuse services, these include:

- Local Healthwatch
- Local authorities
- Clinical commissioning groups
- The NHS Complaints Advocacy Service and other advocacy groups
- Drug and alcohol action teams.

Where possible, we will also engage with other local organisations and groups that may interact with substance misuse service providers and people that use these services. These may include criminal justice organisations, community mental health teams and other relevant local health services, social services, crisis services, and housing and homelessness services and other local support services.

**Figure 4: How we work with local and national partner organisations**



## **Working with partner organisations**

Many national partner organisations we work with have information about providers and about people's experiences and we want to make the best use of their evidence. It is also important that our inspectors and inspection managers have ongoing relationships with other stakeholders. This includes, for example:

- NHS England
- The Parliamentary and Health Service Ombudsman and Local Government Ombudsman
- Professional regulators, such as the Nursing and Midwifery Council, the Health and Care Professions Council and the General Medical Council
- Royal Colleges

- The NHS Trust Development Authority and Monitor (in relation to specialist substance misuse services in NHS trusts and NHS Foundation Trusts).

Public Health England holds significant information about specialist substance misuse service providers and people's experience, through its local Centre Teams and their alcohol and drug leads. It is our intention that our inspectors will develop ongoing relationships with these Public Health England Centre Teams.

## 5. Intelligent Monitoring

Intelligent Monitoring combines information from a wide range of data sources to give our inspectors a clear picture of the areas of care that may need to be followed up within a provider. Together with local insight and other factors, this information helps us to decide when, where and what to inspect. This means that we can anticipate, identify and respond more quickly to services at risk of failing.

The Intelligent Monitoring tool is built on a set of indicators that relate to the five key questions we ask of all services – are they safe, effective, caring, responsive and well-led? The tool analyses a range of information, including patient experience, staff feedback and patient outcomes.

Our approach to Intelligent Monitoring will vary for different types of services, where the amount and quality of available information may vary. For example, more information is normally available for NHS trusts compared with independent sector providers. We will develop a set of indicators that will help us to raise questions about the quality and safety of care. These will not be used on their own to make final judgements. These judgements will always be based on a combination of Intelligent Monitoring data, what we find at inspection and local information from the provider and other organisations.

Where our Intelligent Monitoring identifies risks we will follow these up as part of our inspection process.

We are continuing to work with Public Health England to develop our indicators for Intelligent Monitoring of specialist substance misuse services and to enable us to access appropriate data on an ongoing basis. Indicators are likely to be related to treatment outcomes and safety events, information from the public (such as complaints) and information about staff.

**Table 1: Example indicators for specialist substance misuse services**

<b>Outcome measures and safety events</b>	<b>Information from patients and the public</b>	<b>Information from and about staff</b>
<ul style="list-style-type: none"> <li>• Completion of treatment</li> <li>• Return to treatment</li> <li>• Abstinence rates</li> <li>• Patient safety incidents</li> <li>• Safeguarding alerts</li> </ul>	<ul style="list-style-type: none"> <li>• People’s experiences shared with CQC</li> <li>• Feedback from people’s experiences of care posted on social media</li> <li>• Complaints</li> </ul>	<ul style="list-style-type: none"> <li>• Concerns raised by staff to CQC</li> <li>• Staffing indicators – turnover, stability, sickness rates</li> </ul>

## 6. Inspection

Our inspections are at the heart of our regulatory model and focus on the things that matter to people. We have developed a tailored approach to inspecting different types of health and adult social care services, including specialist substance misuse services.

We will announce inspections for independent standalone substance misuse services from July 2015. Initially, we will inspect but not rate standalone independent substance misuse services, but our ambition is to rate them in the future. We will continue to test the feasibility and scope of inspecting and separately rating substance misuse services offered by other providers, for example NHS trusts, GP practices and independent providers that also offer other services, with a view to rolling this out once the current inspection cycle for these providers ends. However, we will still carry out an inspection of substance misuse services delivered by these providers if risks are identified.

Within our new approach we have two types of inspection: comprehensive and focused.

Type of inspection	Description
<b>Comprehensive</b> <a href="#">(section 8)</a>	<ul style="list-style-type: none"><li>• Review the provider in relation to the five key questions – if ratings are introduced, this will lead to a rating on each on a four-point scale.</li><li>• Inspection team of a size to cover all key services provided.</li><li>• Typically one to three days announced site visit plus potential unannounced visits.</li><li>• At least once every three years.</li></ul>
<b>Focused</b> <a href="#">(section 9)</a>	<ul style="list-style-type: none"><li>• Follow up a previous inspection or respond to a particular issue or concern.</li><li>• Team size and composition dependent on the focus of the inspection.</li><li>• Length of site visit and whether it is announced or unannounced is flexed.</li><li>• As frequent as required.</li></ul>

[Section 8](#) looks at our approach to comprehensive inspections but the principles apply to other inspections, for example, follow-up or themed inspections. We will adapt the detail and scope of the inspection as appropriate.

## **Services provided by third party providers**

It is often the case that a provider will have an arrangement in place whereby a third party organisation provides part or all of a regulated service, often on the provider's premises. Where this is the case, it is essential that the services provided work effectively with those provided by the third party.

The inspection team will not inspect or rate the third party service as part of the provider's inspection. However, they will consider the care pathways between the service and the provider's own services as part of their inspection. Our reports will explain where a third party provider is delivering part or all of a service and who that third party provider is.

When planning the inspection we will consider whether it is helpful, for the public and people using services, if an inspection of the third party services is carried out at (or close to) the same time.

# 7. Planning the inspection

To make the most of the time that we are on site for an inspection, we must make sure that we have the right information to help us focus on what matters most to people. This will influence what we look at, who we will talk to and how we will configure our team. The information that we gather during this time before the inspection would also be used as evidence when we make our ratings judgements.

As described in sections [4](#) and [5](#), we will analyse data from a range of sources, including people who use services, information from stakeholders and information sent to us by providers.

We collate our analysis into data packs to be used by the inspection team. Our inspectors use this information along with their knowledge of the service and their professional judgement to plan the inspection.

The provider may be able to access the data pack and have an opportunity to review it for accuracy.

## Gathering information from people who use services and stakeholders

A key principle of our approach to inspecting services is to seek out and listen to the experiences of the public, service users and those close to them. In the period leading up to an announced inspection we will seek to gather people's experiences of care and the views of their carers and families.

For specialist substance misuse services this may include:

- Promoting inspections through Public Health England, other relevant partner organisations, local organisations and service user groups and encouraging these networks to invite people who have experience of the service, and people who are close to them, to tell us about the care that they or those they support have received.
- Promoting inspections through local media.
- Focus groups with people who use services.
- Gathering individual feedback from people use services, such as through CQC's 'Share Your Experience' form or written or electronic questionnaires that people can complete in their own time.
- Using comment cards placed in reception areas and other busy areas to gather feedback from people who use services and those close to them.

In addition, we may use social media to promote opportunities for people who use services to give feedback to CQC on their care. This may involve working with voluntary and community sector organisations to promote CQC

inspections through their own social media routes. We may also use other online options for engaging with people who use services.

Before an inspection we will also analyse information from other stakeholders about the quality and safety of a provider. We will engage with and ask for information from commissioners, Public Health England, and if relevant, Monitor or the NHS Trust Development Authority. Where possible, we will also contact other appropriate stakeholders to ask for information, as set out in [section 4](#).

## Gathering information from the provider

Before an inspection, we will also ask the provider for information.

We will ask the provider to tell us about their performance against each of the five key questions (are they safe, effective, caring, responsive and well-led?). The specific information we will request from a provider will vary depending on the service, but is likely to include requests for information about:

- Staffing and governance
- Safety and effectiveness, including serious incidents Deprivation of Liberty Safeguards applications and medicines management
- Complaints
- Equality and diversity
- Current actions and planned improvements
- Key stakeholders and any shared contracting relationships that may exist with other providers.

We will ask the provider to tell us about its performance against each of the five key questions. In doing so, providers are expected to highlight areas of good and outstanding practice, as well as telling us about where the quality of services is less good, and in these cases, what action they are taking. This will allow us to assess how providers view themselves in terms of quality against the five key questions and to understand how their quality improvement plans reflect this, ahead of an inspection. The chief executive (or equivalent, such as the registered manager or nominated individual) should provide assurance to CQC that the information given is accurate and comprehensive in setting out the provider's view of its own performance.

Following the initial request, we may ask providers to submit additional information, particularly if the initial submission highlights areas that need to be clarified before the inspection site visit.

We expect providers to be open and honest with us, sharing all appropriate information. A lack of openness and transparency will be taken into account when we assess the well-led question.

We will advise providers about the timescales for submitting information, and will give them a point of contact so they can liaise with us if they have any questions.

We will ask providers to only send the information we have requested and to discuss with their point of contact any difficulties in sending the information, or where they believe they have extra information that they think may be useful to the inspection team.

## **Other information gathering activity**

Throughout the year, and particularly in the weeks leading up to an inspection, we will gather information to give us insight into the provider's quality performance. This may involve looking at:

- Case tracking service users with complex needs or those who are in vulnerable circumstances. Reviewing case notes of selected people who use services helps us to build a picture of how well providers care for people with more complex needs, with particular vulnerabilities or from different groups in society.
- Quality governance. Information on quality governance will enable us to see what systems and processes a provider has in place and understand how effective they are at ensuring organisation-wide learning, so that improvements are embedded where necessary. We will also look at how well information is used to assess and monitor the quality of care being delivered and to identify, assess and manage risks by board and sub-committees.
- Safety alerts and serious incidents requiring investigation. This enables us to explore how well a provider reports, investigates and learns from serious incidents requiring investigation (including never events) and implements the improvements needed to prevent such incidents happening again. It also tests how a provider disseminates and acts on the requirements and supporting information published in selected safety alerts.
- Information flows. These determine what key information flows there are in an organisation and how effective they are, to help us understand whether clinicians have access to the right data at the right time to make informed clinical decisions, and also to understand whether managers have access to the right data to make sure that quality care is provided.

## **The inspection team**

The size and composition of our inspection team for independent standalone substance misuse services will vary depending on the type and size of service being inspected, but will generally include:

- A CQC inspector with further training about substance misuse services.

- A relevant Expert by Experience (people with experience of using specialist substance misuse services) where possible.
- A specialist advisor with expertise in substance misuse where necessary.

A chair will not routinely be used for independent standalone substance misuse service inspections unless the inspection is of a large, complex location and independent scrutiny and challenge is needed.

## **Planning for the focus of the inspection**

The planning of the inspection involves:

- Considering how to best engage with the public, people who use the service and specific communities to get a range of views and experiences about the services.
- Deciding on the areas of focus, which are informed by the data pack and information we have gathered before the site visit.
- Meeting with a senior representative of the provider to identify any specific aspects of the quality of care that should be reviewed as part of the inspection
- Identifying members of the inspection team based on the specific skills, knowledge and experience needed.
- Ensuring that we follow up any outstanding improvement action such as requirement notices and warning notices and any improvement plans for organisations in special measures.
- Making the outline plan for the site visit.

## **Making arrangements for the inspection**

The inspector will be the main point of contact for the service and will liaise with them on all logistical requirements, for example room bookings, arranging interviews, parking and security passes.

We will contact the service where we need local information in helping us to arrange engagement activities, for example where best to hold them, and for information on local groups and service user panels and representatives who may be able to support us with this activity.

## 8. Site visit

Site visits are a key part of our regulatory framework, giving us an opportunity to talk to people using services, staff and other professionals to find out their experiences. They allow us to observe care being delivered and to review people's records to see how their needs are managed, both within and between services.

### Site visit timetable

The site visit will generally include the following stages:

- Briefing and planning session for inspection team
- Announced site visits (one to three days)
- Possible unannounced visits
- Closing the inspection visit
- Potential additional unannounced site visits.

### Briefing and planning session

Before the site visit there is a briefing and planning session for the inspection team lead.

#### Provider presentation

The registered person is invited to give a 30-minute presentation at the start of the inspection at the location. The format of the presentation will vary depending on the service being inspected but should always set out:

- Background to the organisation
- Its approach to ensuring good quality care
- What is working well or is outstanding
- The areas of concern or risk.

### Gathering evidence

The inspection team use the key lines of enquiry (KLOEs) and any concerns identified through the preparation work to structure their site visit and focus on specific areas of concern or potential areas of outstanding practice. The team will also use specific guidance being developed for different substance misuse service settings. They will collect evidence against the KLOEs using the methods described below.

## Gathering the views of people who use services

A key principle of the approach to inspecting substance misuse services is to seek out and listen to the experiences of the public, people who use services and those close to them. The specific methods will vary depending on the service type but may include:

- Speaking individually and in groups with people who use services, including by attending drop-in sessions or other discussion groups organised by the service or through telephone interviews.
- Holding drop-in sessions for people who use services.
- Using comment cards placed in reception areas and other busy areas to gather feedback from people who use services and those close to them.
- Using posters to advertise the inspection and give an opportunity to speak to the inspection team. These will be put in areas where people using services and others will see them.
- Where the service has peer supporters or service user representatives, asking them to assist in seeking feedback from people who use the service.
- Using the information gathered from our work looking at complaints and concerns of people using services.
- Promoting the 'share your experience' form on the CQC website through a variety of channels.

As noted in [section 7](#), we will include 'Experts by Experience' on our inspections where possible. Experts by Experience are people who use care services or care for someone who uses health and adult social care services. They may include people who have used community substance misuse services or attended community residential or hospital inpatient services. Their main role is to talk to people who use services and tell us what they say. Many people find it easier to talk to an Expert by Experience than an inspector. Experts by Experience may also talk to carers and staff, and may observe the care being provided or conduct telephone interviews. Experts by Experience may attend the site visit and/or other engagement activities. We will also consider whether there may be ways for Experts by Experience to undertake work to support the inspection remotely in the future.

We will use the methods outlined above to gather the views of people who use community-based substance misuse services, people with complex needs, people in vulnerable circumstances, young people who use services and the views of families and carers. However, we will continue to consider whether alternative methods may be needed to engage with these groups.

## Gathering the views of staff

The inspection team will interview individual staff at all levels. The type of staff will vary depending on the type of service being inspected and may include the following people (or equivalent roles):

- Registered manager or senior person in charge
- Consultants/senior doctors (associates)
- Junior doctors
- General practitioner
- Registered general nurses
- Registered mental health nurses
- Unqualified nurses
- Key workers
- Psychologists
- Non-medical prescribers
- Administrative and other staff
- Volunteers and peer mentors
- Complaints lead
- Human resources lead.

The inspection team may also speak to other staff as appropriate. This would include board members and other senior management, where relevant. The team will speak with staff either in focus groups or individually. We may also seek the views of staff through an electronic survey or email.

When inspecting smaller providers we recognise that our approach to focus groups may not be an appropriate method to gather staff views, given the small number of staff and the possible disruption to care of people who use services. In these cases we will gather staff views in other ways, such as interviews.

## **Other inspection methods/information gathering**

During our inspections, we will review the cases of selected people who use services. This will help inspectors to build a picture of how well providers care for people who use services who may have more complex needs, those in vulnerable circumstances or from different groups in society. This will involve both reviewing care records and speaking with staff involved in a person's care as well as the person themselves if they are willing to do so.

The service users may vary depending on the demographics of the local area but may include:

- Pregnant women
- Young people, including those in transition to adult services
- Lesbian, gay, bisexual and transgender people
- People with complex needs, for example, a dual diagnosis
- Homeless people
- Older people

- Victims of domestic abuse
- Offenders returning to the community
- Sex workers
- Black and minority ethnic communities.

Inspectors may also request to review the cases of people at different points in treatment to understand their experiences at various stages of their care.

As set out in [section 2](#), sometimes people who use specialist substance misuse services may be subject to certain restrictions on their movement and interaction with others. Where restrictions are used by a substance misuse service provider, we will look at records to consider whether restrictions are:

- Based on specialist need and risk and/or are required by a treatment programme.
- Agreed with people at the time of assessment.
- Reviewed as they progress through treatment.

Other ways of gathering evidence may include:

- Observing care including using the SOFI 2 (Short Observational Framework for Inspection) tool. Observing care remains an important way for our inspectors to judge the quality of care, particularly for people who cannot express themselves verbally or who lack capacity to make decisions about their care or consent.
- Observing meetings.
- Reviewing records, policies and other relevant documents.
- Inspecting care environments.

## Continual evidence evaluation

Throughout the inspection, the inspector will continually review the emerging findings with the inspection team. This keeps the team up to date with all issues and enables the focus of the inspection to be shifted if new areas of concern or outstanding practice are identified. It also enables the team to identify what further evidence might be needed in relation to a line of enquiry, and which relevant facts might still be needed to corroborate a judgement or, where appropriate, a rating.

Continual evaluation is also an opportunity to make connections across different areas of inspection where there may be common themes, such as lack of audits, and which might raise questions about governance structures overall.

## Feedback on the announced visit

At the end of the inspection visit, there will usually be a feedback meeting with a senior representative from the service or provider organisation. This is

to give high-level feedback only that will be illustrated with some examples. When we start rating independent standalone substance misuse services, we will not provide indicative ratings at this stage. The meeting is likely to cover issues such as:

- Thanking the provider's staff for their support and contribution.
- Explaining findings to date, but noting that further analysis of the evidence is needed before final judgements can be reached on all issues.
- Any issues that were escalated during the visit.
- Any plans for follow-up or additional visits (unless they are unannounced).
- Reminding the provider that we may carry out unannounced visits.
- Explaining that further evidence is required before we can award ratings (when we start rating services).
- Explaining how we will make judgements against the regulations.
- Explaining the next steps, including challenging factual accuracy in the report and final report sign-off, action planning and publication.
- Answering any questions from the provider.

## **Unannounced inspection visits**

Following an announced visit, the inspection team may carry out further inspection activities.

These unannounced visits may be during the day or out of hours, and may be carried out by a subset of the inspection team. They will involve the inspection methods described above. We may go back to areas we have already visited. At the start of these visits, the team will meet with the service or provider's senior operations lead on duty at the time, and at the end will feed back if there are any immediate safety concerns.

# 9. Focused inspection

There will be circumstances when we will carry out a focused inspection rather than a comprehensive inspection. We will carry out a focused inspection for one of two reasons:

- To focus on an area of concern
- Where certain changes in the provider occur.

Focused inspections do not look at all five key questions; they focus on the areas indicated by the information that triggers the focused inspection.

## Areas of concern

We will undertake a focused inspection when we are following up on areas of concern, including:

- Concerns that were originally identified during a comprehensive inspection and have resulted in enforcement or compliance action. This is normally three months after a comprehensive inspection or soon after a provider has notified us that they have taken the action needed.
- Concerns that have been raised with us outside an inspection through other sources such as information from Intelligent Monitoring, members of the public, staff or stakeholders.

## Changes in the service provider

We may undertake a focused inspection when there is a change in a service provider, such as a takeover or merger or an acquisition of a service.

## The focused inspection process

Although they are smaller in scale, focused inspections broadly follow the same process as a comprehensive inspection.

The reason for the inspection determines many aspects, such as the scope of the inspection, when to visit, what evidence needs to be gathered, the size of the team and which specialist advisers to involve. Visits may be announced or unannounced depending on the focus of the inspection.

Although smaller in scope, the inspection may result in a change to ratings at the key question level (once we start to rate independent standalone substance misuse services). The same ratings principles apply as for a comprehensive inspection. The revised ratings resulting from a focused inspection will not necessarily lead to a change of the overall provider rating if the focused inspection was carried out more than six months after the comprehensive inspection. As a focused inspection is not an inspection of

the whole of a provider or service it will not produce ratings where they do not already exist.

When a focused inspection identifies significant concerns, it may trigger a comprehensive inspection.

# 10. Judgements and ratings

## Making judgements and ratings

As noted earlier, independent standalone substance misuse services will initially be inspected but not rated. However, our ambition is to rate these services in the future.

Inspection teams will base their judgements on the available evidence, using their professional judgement. The judgement will be made following a review of the evidence under each KLOE and this evidence will come from four sources of information: our ongoing relationship; local and national data and our Intelligent Monitoring; local feedback and concerns; pre-inspection work; and from the inspection visit itself. This link between the KLOEs, the evidence gathered under them, and the rating judgements lies at the heart of our approach to ensuring consistent and authoritative judgements on the quality of care.

When making our judgements, we will consider the weight of each piece of relevant evidence. In most cases, we will need to corroborate our evidence with other sources to support our findings and to enable us to make a robust judgement.

When we have conflicting evidence, we will consider the weight of each piece of evidence, its source, how robust it is and which is the strongest. We may conclude that we need to seek additional evidence or specialist advice in order to make a judgement.

When we have the powers to rate a service, we sometimes won't be able to award a rating. This could be because:

- The service is new, or
- We don't have enough evidence, or
- The service has recently been reconfigured, such as being taken over by a new provider.

In these cases we will use the term 'Inspected but not rated'.

We may also suspend a rating. For example, we may have identified significant concerns that, after reviewing but before a full assessment, lead us to re-consider our previous rating. In this case we would suspend our rating and then investigate the concerns.

# Ratings

## What will we give a rating to?

When we start rating independent standalone specialist substance misuse services, we would rate at two levels:

- Level 1: we use our rating methodology and professional judgement to produce separate ratings for each of the five key questions.
- Level 2: we aggregate these separate ratings up to an overall location rating using 'ratings principles'.

**Figure 5: The levels at which independent standalone services would be rated**



## How we decide on a rating

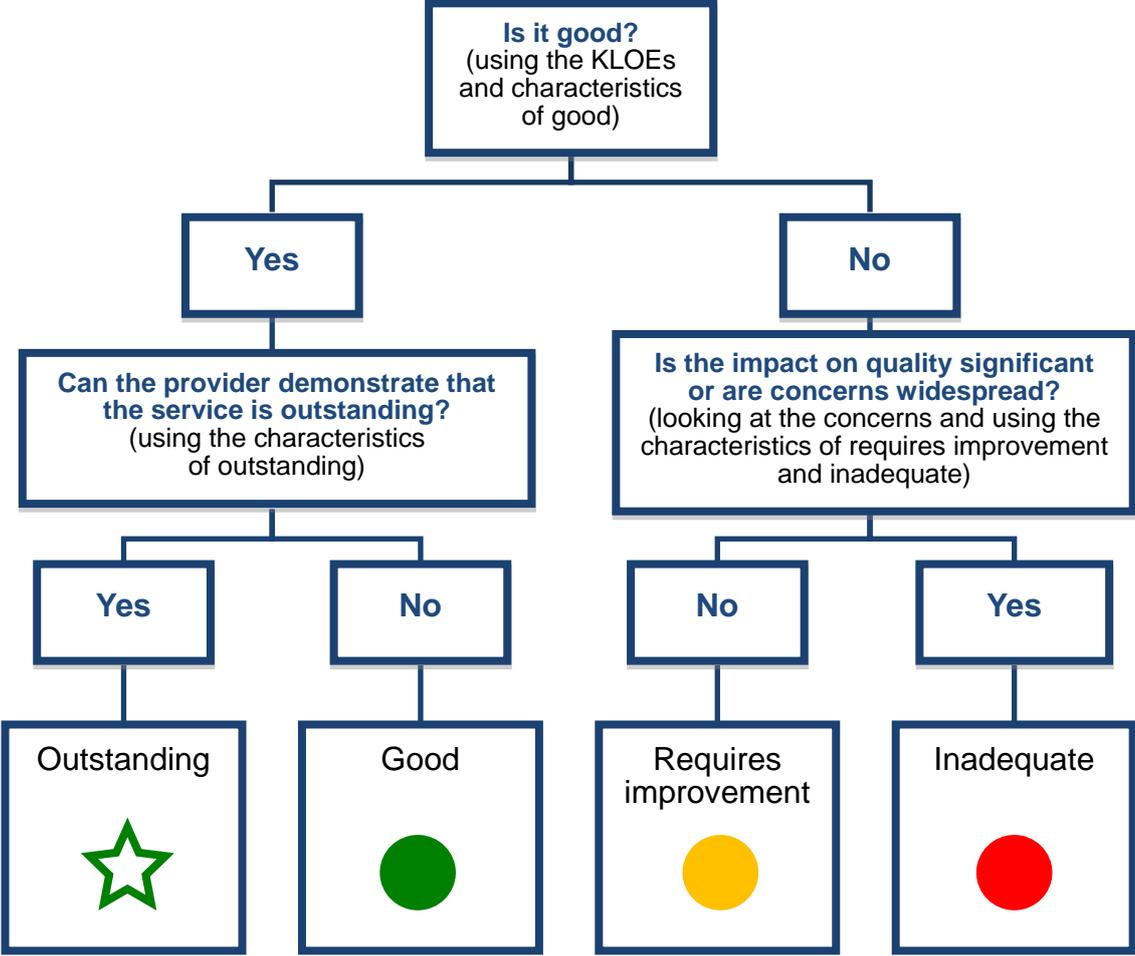
When awarding ratings of the five key questions, our inspection teams would consider the evidence gathered for each of the KLOEs and use the guidance supplied to decide on a rating.

In deciding on a rating, the inspection team would look to answer the following questions:

- Does the evidence demonstrate a potential rating of good?
- If yes – does it exceed the standard of good and could it be outstanding?
- If no – does it match the characteristics of requires improvement or inadequate?

The flowchart (figure 6) on page 40 shows how this would work.

Figure 6: How we will decide on a rating



## Aggregating ratings

When aggregating ratings for independent standalone specialist substance misuse services, our inspection teams would follow a set of principles to ensure consistent decisions. Our principles are set out in [appendix C](#).

The principles would normally apply but would be balanced by inspectors using their professional judgement. Our ratings must be proportionate to all of the available evidence and the specific facts and circumstances.

Examples of when we may use professional judgement to depart from the principles include:

- Where the concerns identified have a very low impact on people who use services.
- Where we have confidence in the service to address concerns or where action has already been taken.
- Where a single concern has been identified in a small part of a very large and wide-ranging service.

# 11. Reporting, quality control and action planning

## Reporting

An inspection report is produced following each inspection. The report is drafted in collaboration with members of the inspection team (where applicable) and is written in clear, accessible, plain English. 'Easy read' report summaries are produced to meet the needs of the people using the service where appropriate. When we start rating independent standalone substance misuse services, our reports will include our ratings judgement.

Our reports focus on our findings against the five key questions CQC asks of services. We want to help providers to continually improve, so our reports will include information about any improvement we think the provider could make, even if they meet the fundamental standards of care. We will also include information about notable practice. If we identify any breaches in the fundamental standards we will clearly set out the evidence about the breach.

## Quality control

Consistency is one of the core principles that underpin all our work. We have put in place an overall approach for CQC to embed validity and consistency in everything we do. The key elements of this are:

- A strong and agreed core purpose for CQC.
- A clear statement of our role in achieving that purpose.
- Consistent systems and processes to underpin all our work.
- High-quality and consistent training for our staff.
- Strong quality assurance processes.
- Consistent quality control procedures.

We have made a commitment to strong internal quality control and assurance mechanisms.

As part of this, we will ensure that inspection reports for specialist substance misuse services are subject to quality assurance processes. We may take a selection of reports for review by our national quality control and consistency panel, chaired by CQC's Chief Inspector of Hospitals or a nominated deputy (such as a Deputy Chief Inspector) and includes a selection of representatives from key areas including CQC legal, policy, intelligence and enforcement teams.

Following quality checks, the draft report is sent to the provider's nominated individual and chief executive, to enable them to comment on the factual accuracy.

## Action planning with local partners

We will use the inspection findings to form the basis of a discussion with the registered person – or the provider’s nominated representative – at a quality meeting. This is a meeting with the provider or their registered person, and may include partners in the local health and social care system, such as organisations that are responsible for commissioning or providing scrutiny of health and social care services in the local area.

The purpose of the quality meeting is to agree a plan of action and recommendations based on the inspection team’s finding as set out in the inspection report.

We will always hold a quality meeting with the registered person or the provider’s nominated representative.

Action planning is an important part of the post-inspection process. It considers:

- The findings of the inspection.
- Whether planned action by the provider to improve quality is adequate or whether additional steps need to be taken.
- Whether support should be made available to the provider from other stakeholders, such as commissioners, to help them improve.

The registered person or provider’s nominated representative is given an opportunity to respond to the findings of the report. The focus is then on the provider and where appropriate, the partner organisations, to identify and agree any action that needs to be taken in response to the finding of our inspection.

After the quality meeting, the recommendations for action will be captured in a high-level action plan. Further work will be needed by the provider and its partners, where appropriate, to develop detail beneath the high level plan. This should be completed within one month of the quality meeting. Action plans are owned by the provider, and it should use its own action plan template. Once agreed, action plans should be shared with the CQC Inspector to make sure that all key areas highlighted during the inspection have been appropriately addressed.

## Publication

We publish the inspection reports and data pack on our website along with ratings, where awarded, following the conclusion of the inspection process. We will coordinate this with providers and encourage them to publish their action plans on their own website.

## **Displaying ratings (where awarded)**

From April 2015, CQC ratings must be displayed at each and every premise from which a regulated activity is provided. Providers must also display ratings at their head office and on their website(s) if they have one. This is to make sure the public see them, and they are accessible to all of the people who use their services.

Full details on what and how to display are included in the guidance on our website. Providers must display their rating no later than 21 calendar days after it has been published on CQC's website.

Services regulated by CQC but which are not awarded a rating are exempt from this regulation.

We encourage providers to raise awareness of their most recent rating when they are communicating with people who use their services by letter, email or other means.

# 12. Enforcement and actions

## Types of action and enforcement

Where we have identified concerns, we decide what action is appropriate to take. The action we take is proportionate to the seriousness of the concern and whether there are multiple and persistent breaches.

Where the concern is linked to a breach in regulations, we have a wide range of enforcement powers given to us by the Health and Social Care Act 2008, as amended by the Care Act 2014.

Our published enforcement policy and decision tree on our website describes our powers in detail and our general approach to using them. We may recommend areas for improvement even though a regulation has not been breached. When we rate independent substance misuse services, this may help a provider to move to a higher rating.

We include in our report any concerns, areas for improvement or enforcement action taken, raise them at the quality meeting, and expect appropriate action to be taken by the provider and, where appropriate, local partners.

We will follow up any concerns or enforcement action. If the necessary changes and improvements are not made, we can escalate our response, gathering further information through a focused inspection. However, we always consider each case on its own merit and we do not rigidly apply the enforcement rules when another action may be more appropriate.

## Relationship with the fundamental standards regulations

We have published [guidance](#) for existing registered providers and managers, and those applying for registration, to understand what they need to do to meet the regulations introduced in April 2015. These regulations include fundamental standards, below which the provision of regulated activities and the care people receive must never fall.

The aim of the new regulations is to increase transparency about the quality of health and care services, encourage improvement, help people who use services to make choices about their care, and to hold providers to account. There are three new regulations: a statutory duty of candour (Regulation 20), a fit and proper person requirement for directors (Regulation 5), and a requirement for providers to display their CQC rating (Regulation 20A).

## **New regulations: fit and proper person requirement and the duty of candour**

Two new regulations – Regulation 5: Fit and proper persons: Directors; and Regulation 20: Duty of candour – apply to all providers from April 2015.

The intention of Regulation 5 is to ensure that people who have director level responsibility for the quality and safety of care, and for meeting the fundamental standards, are fit and proper to carry out this important role. It applies to all providers that are not individuals or partnerships. Organisations retain full responsibility for appointing directors and board members (or their equivalents). CQC may intervene where we have evidence that a provider has not met the requirement to appoint and have in place fit and proper directors, using the full range of our enforcement powers.

The intention of Regulation 20 is to ensure that providers are open and transparent with people who use services and other ‘relevant persons’ (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, and providing truthful information and an apology. This statutory duty on organisations supplements the existing professional duty of candour on individuals.

These new requirements are incorporated into our inspection assessment framework and registration processes. Where we find that providers are not conforming to these regulations we will report this and take action as appropriate. Further information is included in the guidance on our website.

## **Responding to inadequate care**

We want to ensure that services found to be providing inadequate care do not continue to do so. Therefore we have introduced special measures, which apply to providers of substance misuse services if they are rated.

The purpose of special measures is to:

- Ensure that providers found to be providing inadequate care significantly improve.
- Provide a framework within which we use our enforcement powers in response to inadequate care and work with, or signpost to, other organisations in the system to ensure improvements are made.
- Provide a clear timeframe within which providers must improve the quality of care they provide or we will seek to cancel their registration.

Special measures does not replace CQC’s existing enforcement powers: it is likely that we will take enforcement action at the same time as placing a service into special measures. And in some cases we may need to take urgent action to protect people who use the service or to bring about improvement, in accordance with our enforcement policy.

We have [published detailed guidance about our approach to special measures](#) for different types of providers, including NHS trusts, GP practices and independent health services.

## **Challenging the evidence and ratings**

We want to make sure that providers can raise legitimate concerns about the evidence we have used and the way we apply our ratings process, and have a fair and open way for resolving them.

The following routes are open to providers to challenge our judgements.

### **Factual accuracy check**

When providers receive a copy of the draft report (which will include their ratings if they are rated), they are invited to provide feedback on its factual accuracy. They can challenge the accuracy and completeness of the evidence on which the ratings are based. Any factual accuracy comments that are upheld may result in a change to one or more rating.

Providers/registered persons have 10 working days to review draft reports for factual accuracy and submit their comments to CQC.

### **Warning notice representations**

If we serve a Warning Notice, it gives providers the opportunity to make representations about the matters in the Notice. The content of the Notice will be informed by evidence about the breach, which is in the inspection report. This evidence will sometimes have also contributed to decisions about ratings. Therefore, as with the factual accuracy check, representations that are upheld that also have an impact on ratings may result in relevant ratings being amended.

### **Request for a rating review**

Providers can ask for a review of ratings, where ratings are given.

The only grounds for requesting a review is that CQC did not follow the process for making ratings decisions and aggregating them (combined inspections). Providers cannot request reviews on the basis that they disagree with the judgements made by CQC, as such disagreements would have been dealt with through the factual accuracy checks and any warning notice representations if a Warning Notice was served.

Where a provider thinks that we have not followed the published process properly and wants to request a review of one or more of their ratings, they must tell us of their intention to do so within 5 working days of publication of the report. Providers will be sent instructions for submitting their request for review, which must be received within 15 working days of the publication of the report.

Providers will have a single opportunity to request a review of their inspection ratings. In the request for review form, providers must say which rating(s) they want to be reviewed and all relevant grounds. Where we do not uphold a request for review, providers cannot request a subsequent review of the ratings from the same inspection report.

When we receive a request for review we will explain on our website that the ratings in a published report are being reviewed.

The request for review process will be led by CQC staff who were not involved in the original inspection, with access to an independent reviewer.

We will send the outcome of the review to the provider following the final decision. Where a rating is changed as a result of a review, the report and ratings will be updated on our website as soon as possible. It should be noted that following the conclusion of the review, ratings can go down as well as up.

The review process is the final CQC process for challenging a rating. Providers can challenge our decisions elsewhere – for example by complaining to the Parliamentary and Health Services Ombudsman or by applying for judicial review.

## **Complaints about CQC**

We aim to deal with all complaints about how we carry out our work, including complaints about members of our staff or people working for us, promptly and efficiently.

Complaints should be made to the person that the provider has been dealing with, because they will usually be the best person to resolve the matter. If the complainant feels unable to do this, or they have tried and were unsuccessful, they can call, email or write to us. Our contact details are on our website.

We will write back within three working days to say who will handle the complaint.

We'll try to resolve the complaint. The complainant will receive a response from us in writing within 15 working days saying what we have done, or plan to do, to put things right.

If the complainant is not happy with how we responded to the complaint, they must contact our Corporate Complaints Team within 20 days and tell us why they were unhappy with our response and what outcome they would like. They can call, email or write to our Corporate Complaints Team. The contact details are on [our website](#).

The team will review the information about the complaint and the way we have dealt with it. In some cases we may ask another member of CQC staff or someone who is independent of CQC to investigate it further. If there is a

more appropriate way to resolve the complaint, we will discuss and agree it with the complainant.

We will send the outcome of the review within 20 working days. If we need more time, we will write to explain the reason for the delay.

If the complainant is still unhappy with the outcome of the complaint, they can contact the Parliamentary and Health Service Ombudsman. Details of how to do this are on the Parliamentary and Health Service Ombudsman website.

**Note:**

Please also see the separate appendix document to this handbook, which contains important information:

Appendix A: Key lines of enquiry

Appendix B: Characteristics of each rating level

Appendix C: Ratings principles for independent standalone specialist substance misuse services