

Guidance about compliance

Essential standards of quality and safety



What providers should do to comply with the section 20
regulations of the Health and Social Care Act 2008

March 2010

About the Care Quality Commission

The Care Quality Commission is the independent regulator of health and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities, private companies or voluntary organisations, we make sure that people get better care. We do this by:

- Driving improvement across health and adult social care.
- Putting people first and championing their rights.
- Acting swiftly to remedy bad practice.
- Gathering and using knowledge and expertise, and working with others.

How to use this guide

This guide is designed to help providers of health and adult social care to comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

It has two main parts, both of which you need to read:

Part 1: Preparing to use our guidance

Step 1



Read "About this guide", which explains why we produced this guide, who it is for and how the guidance in part 2 is structured

Step 2



Select the service types that apply to you

Step 3



Read our definitions of key terms that appear in the guidance in part 2

Part 2: Guidance

- Outcomes 1-28
- Prompts that all providers should consider
- Additional prompts that apply to different service types

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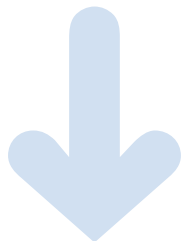


Part 1: Preparing to use our guidance

These are the steps you need to take in order to be able to use the guidance set out in part 2 of this document.



Step 1: About this guide



A new system of registration

As the regulator of health and adult social care in England, we make sure that the care that people receive meets essential standards of quality and safety and we encourage ongoing improvements by those who provide or commission care.

The new registration system for health and adult social care will make sure that people can expect services to meet essential standards of quality and safety that respect their dignity and protect their rights. The new system is focused on outcomes rather than systems and processes, and places the views and experiences of people who use services at its centre.

We will continuously monitor compliance with essential standards as part of a new, more dynamic, responsive and robust system of regulation. Our assessors and inspectors will frequently review all available information and intelligence we hold about a provider. We will seek information from patients and public representative groups, and from organisations such as other regulators and the National Patient Safety Agency.

If we have concerns that a provider is not meeting essential standards of quality and safety, we will act quickly, working closely with commissioners and others, and using our new enforcement powers if necessary.

Promoting improvement

In addition to the assurance about compliance with essential standards that registration will provide, we have an important function in promoting improvement by providing independent, reliable and timely information about the quality of care in providers above essential standards, and about the quality of care secured by commissioners for their local communities, which we describe as assessments of quality.

These assessments include: our periodic reviews of the performance of all health and adult social care providers, and of councils and primary care trusts as commissioners of care; and our special reviews and studies of particular aspects of care, on economy, efficiency and effectiveness, and information issues.

The aim of this guide

This guide is designed to help providers of health and adult social care to comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, and the Care Quality Commission (Registration) Regulations 2009. These regulations describe the essential standards of quality and safety that people who use health and adult social care services have a right to expect.

Part 2 of this guide contains the guidance – consisting of outcomes and prompts – that

we have developed to help you comply with the regulations. Our guidance is based on the outcomes that we expect people using a service will experience when the provider is meeting the essential standards.

When developing the outcomes and prompts, we have focused on people's experiences of care, and the quality of the treatment and support that they receive. People who use services tell us that this is what matters most to them, rather than the systems, policies and processes needed to deliver their care.

The guidance does not cover the standards that individual professionals should achieve in their day-to-day practice, because these standards are set and enforced by their professional registration bodies. For example, the General Medical Council and the Nursing and Midwifery Council provide such guidance for doctors and nurses.

Why we produced the guidance

Section 23(1) of the Health and Social Care Act 2008 requires us to produce guidance for providers of health and adult social care, to help them comply with the regulations within the Act that govern their activities.

The Act, the regulations and this guidance are part of a wider regulatory framework that includes regulation of professionals such as nurses, doctors and social workers. The framework is designed to ensure that people who use services are protected and receive the care, treatment and support they need.

This guidance only relates to providers of services that carry on "regulated activities". These are defined in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, which are reproduced in appendix C.

If you are a provider that carries out any regulated activities, the framework requires you to be registered with the Care Quality

Commission before you carry out these activities. The guidance in part 2 of this guide describes the outcomes that people using your services should be experiencing if you are meeting the essential standards required for us to register you.

We will use the guidance to decide whether to register individual providers, and also when we monitor their services afterwards to check that they are continuing to meet the regulations. We will also refer to the guidance when using our powers of enforcement to bring about improvement in poor services, or to prevent a provider from carrying out regulated activities.

Who this guide is for

First and foremost, this guide is for people working in those health and adult social care services that must be registered with us before they can legally operate.

Many of our own staff will also use this guide in their day-to-day work. In addition, courts and tribunals will take account of part 2 (our guidance about compliance) when making decisions about our enforcement activities.

Other groups with an interest in the quality of health and social care may find the guidance helpful – for example, people who use services, other regulators, MPs and the general public. We will also produce related information for the public about the standards that people should be able to expect from services that are registered by us.

Commissioners of services: When councils or NHS primary care trusts commission (buy) health or adult social care services for the community, this is not a "regulated activity" under the regulatory framework. This means that our guidance **does not** apply directly to councils and primary care trusts as commissioners of care services. However, because of its emphasis on outcomes for people, we hope that the guidance will help them to make decisions about which providers to buy services from.

How we developed the guide

We have developed this guide with the help of people who use health and social care services, those who provide these services, other regulators, and organisations that represent people who use services or providers, or that work in the wider system of health and social care.

We carried out a large-scale public consultation, asking people what they thought about the draft guidance, the way we explained it and the overall structure of the document.

When producing the final version of the guidance – part 2 of this document – we have:

- Continued to focus on the outcomes, experiences and human rights of people who use health and social care services.
- Used plain English wherever we can.
- Stayed within the scope of the regulations.
- Applied common standards across both health and adult social care services wherever possible.
- Provided additional prompts for certain types of providers to help them comply with aspects of the regulations that relate only to them.
- Taken account of relevant legislation and standards set by other regulators.
- Set out the standards against which we will take enforcement action to protect people from poor standards of care, treatment and support.
- Built on the progress made under the existing laws and standards governing health and social care in England.
- Applied the Government's principles for better regulation.

Following our guidance

The detailed outcomes and prompts we provide for each regulation indicate what you should be doing to meet the requirements of the regulations.

However, you are not legally bound to use these. But if you decide to follow alternative arrangements, regulation 26 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 requires you to be able to demonstrate that you have taken account of the outcomes and prompts in this document when judging your compliance with the regulations in your day-to-day activities. We must be sure that your services are meeting the essential standards of quality and safety before we can register you.

If you choose not to use the prompts, you will still need to be able to show us that you are meeting the needs of people using your services, and to the standards that the regulations require. If you do not do so, we will ask you to explain why.

If you feel you cannot follow our prompts because your services are particularly innovative and the evidence you will want to provide will be different from that which the prompts indicate, we will work with you to confirm that your services are reaching the essential standards of quality and safety.

How we have structured the guidance

Before developing the outcomes expected for compliance with each of the regulations, we grouped the regulations into six key areas. These are:

- Involvement and information
- Personalised care, treatment and support
- Safeguarding and safety
- Suitability of staffing
- Quality and management
- Suitability of management.

The guidance in part 2 contains a section for each area, containing:

- A summary of the area and the regulations that it includes.
- For each regulation:

- the text of the regulation
- what we think people who use services should experience when providers comply with the regulation (the definition of the outcome). This is what we will focus on when we check that providers are meeting essential standards
- detailed prompts to help providers achieve this outcome, divided into sub-sections to make it easier to follow. We do not expect providers to use these prompts as a checklist, but they can help providers to identify if they are meeting the outcome.

Before you read any of the detailed prompts, make sure that you have read step 2 (page 13) so that you can identify and record which ‘service types’ your regulated activities fall under. You need to follow this step because the detailed prompts are of two types:

- Prompts that apply to **all** providers.
- **In addition**, prompts that only apply to specific service types.

Do I need to read all of the outcomes?

In some instances, our expectations for an outcome may apply to a number of other outcomes. For example, Outcome 14 about supporting workers is the main part of the guidance that addresses staff training. But for providers to achieve the outcomes needed for, say, nutrition or safeguarding, they may need to meet staff training requirements in these areas.

Therefore, we strongly recommend that you read all of the outcomes relevant to you in part 2.

What type of evidence do I need to provide?

The outcomes that we set out in the guidance are the same for all providers within each service type. However, the way that providers demonstrate that they are achieving these outcomes may differ according to their size, structure and governance. Your evidence may be influenced by:

- The size of your service.
- The range and complexity of the services you provide.
- The needs and number of people who use your services.
- The range of staff you employ and how they work together to meet the needs of people who use your service.
- The systems you have to produce information, for example computer systems, audit processes or being part of a national or regional structure.

You will not routinely need to provide evidence for the prompts. These are supplied to help you comply with the regulations.

The regulations that govern your registration

When we refer to “the Act” in this document, we mean the Health and Social Care Act 2008.

The specific regulations that govern your registration are the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

Section 23 of the Act requires us to produce guidance about some of these regulations. These are called ‘section 20 regulations’ and this guidance only relates to those. However, we have reproduced all of the regulations in appendices C and D.

The table on pages 10-11 shows how the regulations and the outcomes link together in the guidance.

The legal status of our guidance for providers

Although we must take it into account when making decisions about a provider’s compliance with the regulations and in tribunals and courts, the guidance is not enforceable in its own right.

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Regulation of the requirement to prevent or control healthcare-associated infections

The Care Quality Commission is not required by the Act to produce guidance about legislation governing the prevention or control of healthcare-associated infections (regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010). This guidance is available in the Department of Health's publication: *The Code of Practice for health and adult social care on the prevention and control of infections and related guidance*.

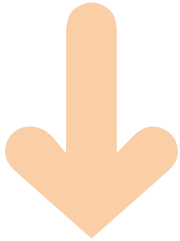
Other relevant legislation

The Act allows us to take account of a provider's compliance with any other legislation that we believe is relevant to registration. In our prompts, we specify other legislation that we consider to be of particular importance, but we have not included all relevant legislation.

As a provider of care, you are responsible for knowing what other legislation is relevant to your service and making sure that you comply with it. We may consider your compliance with such legislation as part of the way we monitor and check your services.

As well as making sure that you are aware of other relevant legislation, you should read the Schedule of Applicable Publications in appendix B.

Step 2: Select your service types



Before you can use the detailed prompts in part 2, you need to decide which of our 28 coded service types your activities fall under. You may find that your activities span a number of different service types.

Please make sure that you identify all of the service types that apply to you, and then make a record of their codes. It is important that you carry out this step accurately before reading the guidance in part 2, because the prompts include additional sections that only apply to certain service types and are coded accordingly. If you ignore or rush this step, you may miss some prompts that would have helped you comply with one or more of the regulations.

The service types and their codes are not necessarily ‘industry standard’ terms – we have simply used them to make the prompts easier for you to navigate.

You can use the following table to tick which of the service types apply to you.

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

Healthcare services

Code:

ACS

Service type:

Acute services

These services are complex and vary greatly. Generally, however, they provide medical and/or surgical investigations, diagnosis and treatment for physical illness or condition, injury or disease.

They can provide services to adults, children or both. They may provide services to a broad range of people or to a particular group of people.

They can:

- Admit people on a day case basis or as inpatients.
- Admit people at short notice or in an emergency (whether or not they have a dedicated emergency department).
- See people on an outpatient basis.

They may also provide services such as:

- Surgical operations
- Specialist medical treatments
- Emergency
- Consultations
- Diagnostics
- Maternity and neonatal
- Pathology
- Termination of pregnancy
- Complex dental procedures
- Liaison psychiatry.

People are usually admitted to the service under the care of a medical or clinical practitioner. The service may also employ a broad range of healthcare professionals to meet the needs of the people using the service.

Some services may be smaller than others and may not provide the same range of acute services than, say, a local district hospital may offer (such as an emergency department).

Code:

Service type:

ACS

Acute services (continued)

Examples of services that fit under this category

- Acute NHS hospitals
- Acute independent hospitals
- Termination of pregnancy clinics
- NHS community hospitals
- Independent sector treatment centres (ISTCs)
- Community hospitals
- Cosmetic surgery clinics
- Specialist or single specialty hospitals
- Maternity hospitals.
- IVF clinics providing surgical treatment or endoscopy
- Haemodialysis units
- Minor injuries units

HBC

Hyperbaric chamber services

These services involve the administration of oxygen (whether or not combined with one or more other gases) to a person in a sealed chamber that is gradually pressurised with compressed air. The services are carried out by, or under the supervision of, a medical practitioner.

The services help to treat a range of medical conditions including:

- Air or gas embolism
- Decompression illness
- Carbon monoxide poisoning
- Gas gangrene
- Necrotising fasciitis
- Other conditions approved by the Undersea and Hyperbaric Medical Society.

Examples of services that fit under this category

- Type 1 hyperbaric chambers
- Type 2 hyperbaric chambers

Code:
HPS

Service type:
Hospice services

These provide a range of services for conditions where curative treatment is no longer an option, and people are approaching the end of their life. They provide care, treatment and support for people and their families and carers, including respite care for people who live with friends or family at home.

Care, treatment and support can be provided in accommodation or in the community. It can be long or short-term care, on an inpatient basis or provided through day care, day therapy or outreach services.

The services will generally employ or work with a broad range of health and social care professionals to meet the needs of people using the service.

Examples of services that fit under this category

- Adult hospices
- Children’s hospices
- Day hospices
- End of life care teams
- Hospice at home

LTC

Long-term conditions services

These services provide a range of care, treatment and support to people with physical or neurological illnesses, cognitive impairments or injuries that are unlikely to improve. These conditions may have been inherited or acquired, and may not necessarily be life-limiting. This care, treatment and support is the sole or main purpose of the service.

People may be cared for by these services for many years at a time, and will be ‘admitted’ and stay at the facility over time. People using these services require the support of medical practitioners and a range of other healthcare professionals, and their care, treatment and support may involve highly technical interventions such as ventilation.

Code:

MLS

Service type:

Hospital services for people with mental health needs, and/or learning disabilities, and/or problems with substance misuse

These services are for people with **mental health needs** or **learning disabilities**, who are admitted to hospital, involving an overnight stay, for assessment or treatment when there is a need for more intensive support than would typically be provided in the community, or a need for a specialist assessment or intervention.

This usually occurs due to:

- An acute episode of a severity that requires 24-hour care.
- A need for a higher level of security.
- A need for a specialist assessment, treatment and/or rehabilitation.

This might include providing care, treatment and support for people detained under the Mental Health Act 1983.

Some people with mental health needs or a learning disability may require longer-term accommodation in hospital, while others may be admitted for short periods or treated on a day case basis.

These services **also** cover inpatient treatment for people with **problems with substance misuse**. They usually involve short periods of hospital-based treatment, including 24-hour medical cover to assess and stabilise the person, and treatment for withdrawal from drugs (legal, illegal and substitute preparations) or detoxification from alcohol.

All the hospital services above will usually comprise one or more wards in which care, treatment and support is provided. There may be a range of other facilities including occupational and arts therapies, psychological therapies, psychosocial interventions, recreational activities and services to address physical health needs.

Examples of services that fit under this category

- NHS or independent services that provide specialist hospital services for people with mental health needs, learning disabilities and problems with substance misuse
- Child and adolescent mental health services (CAMHS) tier 4

Code:

PHS

Service type:

Prison healthcare services

These services offer a primary care type of service in a prison, usually in a health centre or similar setting. They may include GP, dental, optician, chiropody, genito-urinary medicine, general medicine and physiotherapy services, as well as some outpatient clinical sessions held in the prison.

The services in prison usually consist of teams of registered nurses (RN) who are on either the adult, mental health or learning disability parts of the register and, where children are concerned (that is, mother and baby units) health visitors and midwives.

Some prison health services have inpatient facilities, which are not considered 'hospitals'. These will care for people with physical ill health or mental health needs who are not ill enough to need specialist care, treatment and support in secondary care services. If the person's condition worsens, they would be immediately sent out to external NHS hospitals and not returned to prison unless deemed clinically well enough to be discharged.

The services may also provide care, treatment and support for people with mental health needs through multi-disciplinary in-reach teams. These teams offer a similar range of specialist care, treatment and support as provided by community-based mental health services.

The services may also provide substance misuse treatment and rehabilitation services for people who misuse drugs and/or alcohol. They provide counselling, assessment, referral, advice and through-care, both pharmacological and psychosocial. They employ a broad range of health and social care professionals to meet the needs of people who use their services.

Examples of services that fit under this category

- Type 1 prison healthcare services: daytime cover, generally by part-time staff (no inpatient facilities)
- Type 2 prison healthcare services: daytime/24-hour cover, generally by full-time staff (no inpatient facilities)
- Type 3 prison healthcare services: healthcare centre with 24-hour nurse cover, usually with inpatient facilities
- Type 4 prison healthcare services: as type 3 but also serving as a national or regional assessment centre, used by other prisons
- Mental health in-reach teams
- Counselling, assessment, referral, advice and through-care (CARAT) teams
- Prison drug rehabilitation programmes
- Young offenders institutions
- Some immigration removal centres

<p>Code: RHS</p>	<p>Service type: Rehabilitation services</p> <p>These services provide, as their sole or main purpose, treatment to people following an illness or injury that impairs their physical, mental or cognitive wellbeing, but for which continued rehabilitative care is likely to bring about improvement.</p> <p>They may consist of a range of services that promote faster recovery from illness, prevent unnecessary admission to acute services, support timely discharge and maximise independent living.</p> <p>The services can be provided on a short or long-term basis, in hospital, residential, day care or domiciliary settings. They are mainly provided within healthcare settings but can also be provided in a social care setting.</p> <p>Examples of services that fit under this category</p> <ul style="list-style-type: none"> • Intermediate care schemes • Rehabilitation units
<p>RSM</p>	<p>Residential substance misuse treatment/ rehabilitation services</p> <p>These services are provided to adults and children who have problems with misusing drugs and/or alcohol. They provide care, treatment and support, both pharmacological and psychosocial, and help people to reintegrate into their communities, focusing on the coping strategies and life skills they need to do this. They employ a broad range of health and social care professionals to meet the needs of people who use their services.</p> <p>Some of these services may also provide assessment, stabilisation and treatment for withdrawal from drugs (legal, illegal and substitute preparations) or detoxification from alcohol.</p> <p>Examples of services that fit under this category</p> <ul style="list-style-type: none"> • Residential substance misuse rehabilitation services • Crisis intervention units • Care homes providing accommodation for the treatment of substance misuse

Community or integrated healthcare

Code:

CHC

Service type:

Community healthcare services

These services supply a range of healthcare staff other than doctors, for example nurses or allied health professionals, to people who need healthcare support in their own home, in community settings or in child development units.

The care provided may be short or long term, and meet acute or chronic healthcare needs. The services may help people to live independently in the community and they are directly responsible for the quality of the care and support provided by the staff they supply, and do not include employment agencies.

Examples of services that fit under this category

- District nursing
- Nurses agency
- Community physiotherapy team
- Health visiting team
- Support worker team
- Children’s community nurses
- Community paediatric therapies
- Community midwifery
- School nursing
- Family planning and sexual health clinics
- Community rehabilitation teams

DCS

Doctors consultation services

These services involve doctors working in premises, or a room, designated for medical consultation. Often the doctor will complete medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may prescribe medicines for the person to take at home.

There may be other healthcare professionals, for example nurses, supporting the work of the doctor.

Examples of services that fit under this category

- Independent doctors consulting rooms
- NHS GP practice
- Slimming clinics

<p>Code: DTS</p>	<p>Service type: Doctors treatment services</p> <p>These services involve doctors working in premises, or a room, designated for minor medical treatments as well as medical consultation. Often the doctor will complete medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may prescribe medicines for the person to take at home.</p> <p>They will also undertake minor invasive investigations or procedures, such as conscious endoscopy, in a treatment room designed for this purpose.</p> <p>There may be other healthcare professionals, for example nurses, supporting the work of the doctor.</p> <p>Examples of services that fit under this category</p> <ul style="list-style-type: none"> ● Independent doctors consulting rooms ● NHS GP practice ● Early medical abortion clinics ● Travel vaccination services ● Polyclinics
<p>DEN</p>	<p>Dental services</p> <p>These services involve registered dentists and dental care professionals usually working in premises designed for consultation and treatments, but can also be provided in a person’s place of residence. Consultations and examinations will involve discussion of the treatment options with the patient and may include dental radiography. Treatment is usually provided in a dedicated room and, in consultation with the patient, may be under local anaesthetic or use a laser. Medicines may be prescribed as part of the treatment.</p> <p>Examples of services that fit under this category</p> <ul style="list-style-type: none"> ● NHS dental practice (directly provided by a primary care trust)

Code:
DSS

Service type:

Diagnostic and/or screening services

These services provide individual health assessment and/or screening to people, using:

- Diagnostic imaging, such as:
 - X-rays
 - Computed tomography (CT)
 - Magnetic resonance imaging (MRI)
 - Ultrasound scanning
 - Gamma cameras
 - PET scanners
- Pathology
- Physiological measurement
- Genetic and screening services
- Endoscopy.

They provide, as the sole or main purpose, diagnosis or screening. They do not usually provide any other health or social care services. While large acute hospitals will have similar services, this category relates only to these dedicated, focused services.

These services undertake investigations on behalf of the person using the service or on behalf of a healthcare professional that the person is consulting (who is legally permitted to request such investigations).

They will involve a range of healthcare professionals that may include:

- Medical practitioners
- Nurses
- Radiographers
- Physiological measurement technicians.

Examples of services that fit under this category

- Health screening centres
- MRI or CT scanning services (fixed and mobile)
- Baby scanning services
- Endoscopy centres and clinics
- Stand alone or mobile urodynamic services.

<p>Code:</p> <p>LDC</p>	<p>Service type:</p> <p>Community-based services for people with a learning disability</p>
	<p>These services provide care, treatment and support in the community for people with a learning disability, through a wide range of service models. They employ a broad range of health and social care professionals mainly in multi-disciplinary teams.</p> <p>They help people to live as independently as possible, manage their condition and improve it where this is possible. People using these services may receive support over a long period of time or for short-term interventions. They may move between the various community teams to ensure that their changing needs are met.</p> <p>Examples of services that fit under this category</p> <ul style="list-style-type: none"> ● Community learning disability teams ● Challenging behaviour/outreach teams
<p>MBS</p>	<p>Mobile doctors services</p>
	<p>These services involve doctors working in premises where the person using the service is living (on a long or short-term basis). They may also provide services via an internet website where the initial consultation is with a doctor.</p> <p>The doctors provide medical consultations, including physical examination and simple physiological measurement (such as blood pressure tests). They will discuss diagnosis and treatment options and may prescribe medicines for the person to take at home.</p> <p>There may be other healthcare professionals, for example nurses, supporting the work of the doctor, but this is less likely.</p> <p>Examples of services that fit under this category</p> <ul style="list-style-type: none"> ● Independent medical agencies ● GP out-of-hours services ● Community doctor ● Internet-based diagnosis or prescription service

Code:

MHC

Service type:

Community-based services for people with mental health needs

These services provide care, treatment and support in the community for people with mental health needs, through a wide range of service models. They employ a broad range of health and social care professionals mainly in multi-disciplinary teams.

They help people to recover by providing a broad range of interventions reflecting the psychological, social and physical needs of the individual. People using these services may receive support over a long period of time or for short-term interventions. They may move between the various community teams to ensure that their changing needs are met, or be in contact with them simultaneously.

This may include providing care, treatment and support to people subject to supervised community treatment under the Mental Health Act 1983.

Examples of services that fit under this category

- Child and adolescent mental health services (CAMHS) (tiers 2, 3 and 4)
- Community-based services that provide assessment and treatment for people with mental health needs including:
 - community mental health teams
 - assertive outreach
 - early intervention teams
 - court diversity teams
 - crisis resolution home treatment teams

SMC

Community-based services for people who misuse substances

These services are provided in the community for people who misuse drugs and/or alcohol. They provide care, treatment and support, both pharmacological and psychosocial, and help with social and other needs so that people can reintegrate into their communities. They employ a broad range of health and social care professionals to meet the needs of people who use their services.

Examples of services that fit under this category

- Community drug and alcohol teams
- Criminal justice intervention teams

Code:

UCS

Service type:

Urgent care services

These services are provided in parallel with an emergency department and vary greatly from one service to another. They generally comprise a triage service, run by doctors and nurses.

They will not usually screen people whose symptoms require immediate, very urgent or emergency care. Instead, they screen standard cases where time is not of the essence, and where possible refer these for immediate consultation with an on-site primary care provider.

They may provide services such as:

- Consultations with a doctor
- Physical examinations and simple physiological testing and measurement
- Diagnosis and treatment
- Prescribing medicines
- Referrals to other primary care services.

Examples of services that fit under this category

- Primary care trust emergency triage
- Urgent care triage
- Primary care access centre
- Walk-in clinic

Residential social care

Code:

CHN

Service type:

Care home services *with* nursing

A care home is a place where personal care and accommodation are provided together. People may live in the service for short or long periods. For many people, it is their sole place of residence and so it becomes their home, although they do not legally own or rent it. Both the care that people receive and the premises are regulated.

In addition, qualified nursing care is provided, to ensure that the full needs of the person using the service are met.

Examples of services that fit under this category

- Nursing home
- Convalescent home with nursing
- Respite care with nursing
- Mental health crisis house with nursing

CHS

Care home services *without* nursing

A care home is a place where personal care and accommodation are provided together. People may live in the service for short or long periods. For many people, it is their sole place of residence and so it becomes their home, although they do not legally own or rent it. Both the care that people receive and the premises are regulated.

Examples of services that fit under this category

- Residential home
- Rest home
- Convalescent home
- Respite care
- Mental health crisis house
- Therapeutic communities

Code:

SPC

Service type:

Specialist college services

These services provide education, care and training in independence for young people with learning disabilities and/or physical disabilities. The colleges are first and foremost educational establishments and are regulated by Ofsted. The personal care and accommodation provided by a college is regulated by the Care Quality Commission where 10% or more of the students require personal care.

Community social care

Code:

DCC

Service type:

Domiciliary care services including those provided for children

These services provide personal care for people living in their own homes. The needs of people using the services may vary greatly, but packages of care are designed to meet individual circumstances.

The person is visited at various times of the day or, in some cases, care is provided over a full 24-hour period. Where care is provided intermittently throughout the day, the person may live independently of any continuous support or care between the visits.

Examples of services that fit under this category

- Domiciliary care agency

EXC

Extra Care housing services

These services cover many different arrangements. Usually, they consist of purpose built accommodation in which varying amounts of care and support can be offered, and where some services and facilities are shared. The care people receive is regulated by the Care Quality Commission, but the accommodation is not.

<p>Code: SHL</p>	<p>Service type: Shared Lives (formerly known as Adult Placement)</p>
	<p>Shared Lives is care and/or support provided by individuals, couples and families who have been approved and trained for that role by the service registered with Care Quality Commission. Care and/or support may also be provided either within or outside of the home of the carer as well as kinship support to people living in their own homes. It is the service that is regulated not the individual accommodation which is owned or rented by private residents.</p>
<p>SLS</p>	<p>Supported living services</p>
	<p>These services involve a person living in their own home and receiving care and/or support in order to promote their independence. The care they receive is regulated by the Care Quality Commission, but the accommodation is not. The support that people receive is continuous, but is tailored to their individual needs. It aims to enable the person to be as autonomous and independent as possible, and usually involves social support rather than medical care.</p>

Miscellaneous healthcare

Code:

AMB

Service type:

Ambulance services

These services include both the provision of emergency response and transport services. They may include patient transport services as well as emergency vehicles used to transport people, including ambulances. They may provide care, treatment and support and employ a range of healthcare professionals to meet the needs of the people who use the service.

Examples of services that fit under this category

- Emergency ambulance services
- Patient transport services

BTS

Blood and transplant services

The management of the supply of blood, blood-derived products and biologically derived tissues to a healthcare provider for the purposes of administering, grafting or transplantation into a human being.

Examples of services that fit under this category

- NHS Blood and Transplant

Code:

RCA

Service type:

Remote clinical advice services

These services provide, as their sole or main purpose, a range of clinical services to people from a distance in an urgent or emergency situation. The initial consultation is usually with a registered nurse. They may provide care, treatment and support to people using:

- Telephone systems
- Digital systems
- E-mail.

The services may include:

- Simple clinical advice and reassurance
- Diagnosis
- Health screening
- Prescription of medicines
- Referral to another clinical service.

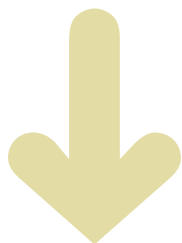
These services may provide some face-to-face support, but this is not their primary purpose.

Examples of services that fit under this category

- NHS Direct

Step 3:

Our definitions of key terms



The key terms shown below will be familiar to providers of health and social care services. However, it is important that you understand our intended meaning when we use them in our guidance. You will also need to refer to these definitions when reading and applying the guidance. In addition, the glossary in appendix A has definitions for more words and phrases.

Equality, diversity and human rights

Providers must consider equality, diversity and human rights in every aspect of their work. You should consider the needs of each person using a service against six key strands of diversity:

- Race
- Age
- Gender
- Disability
- Sexual orientation
- Religion or belief.

We sometimes refer to this as identifying a person's "diversity" or "diverse needs".

People who use services

"People" includes everyone, but sometimes the guidance only relates to certain groups of people. Where this is the case we state the group that it relates to – for example, children, people with mental health needs and people with a learning disability.

Those acting on behalf of the person using services

The outcomes and prompts refer to others acting on behalf of the person using services. They may be:

- A carer
- The next of kin
- A parent
- A friend, partner, neighbour or other relative
- An Independent Mental Capacity Advocate
- An Independent Mental Health Advocate
- A Relevant Persons Representative (DoLS)
- An Advocate
- An attorney
- The nearest relative – in relation to the Mental Health Act
- Corporate parent
- A member of staff acting informally.

To meet a person's needs, you must assess and understand when support from another person would be helpful to them. You must balance the right of the person to make decisions for themselves with the need, appropriateness or desire of the other person to be involved. However, this should never mean that the individual voice of the person using the service is lost, or that their choices are diluted when they are competent to make them.

Carers

The focus of the regulations is on the safety and wellbeing of people who use services, and therefore the outcomes and prompts do not address the specific needs of carers. However, it recognises carers acting on behalf of people who use services and where care, treatment and support is transferred to, or shared with, carers. A carer is one of the list of people above who may act on behalf of the person using the service.

We encourage you to understand, value and respect the important work that carers do, often with no recognition, and work cooperatively with carers when meeting the needs of the people who use your service.

Involvement

When the guidance refers to "involving" people who use services, we mean enabling people to get involved in the planning and delivery of their own care, treatment and support. This includes people acting on their behalf and groups of people who use services being involved together, for example through local involvement networks or a user forum.

However, in this guidance involvement does not mean the involvement of a service's community more widely and the involvement of people who may, at the time, be only potential users of services, for example the population served by an NHS acute hospital. Other legislation may place a requirement on them to do so.

“People who use services understand...”

People who use your services need to understand the care, treatment and support that they will receive. You must give them the information they need to help them understand the choices available to them, and to enable them to make informed decisions.

Sometimes, the person will not be able to ‘understand’ the choices available to them or the decisions they need to make. This may be because their ability to understand is limited by a long-term condition, their age or particular circumstances at the time. You must meet the person’s interests by making every effort to help them to understand as much as they can.

Information

Providing information to people who use services means that it must be given in a way they can understand, whatever their communication needs may be.

This does not necessarily mean that all information has to be routinely translated into different languages or formats (for example Braille, Easy Read or sign language). However, important information should be presented in any alternative formats needed to meet the different communication needs of the people who use your services. You must identify these communication needs for the people who use your services and ensure that you meet them.

Capacity and deprivation of liberty safeguards

The outcomes and prompts assume that people using your services have capacity to make their own choices and decisions independently. Where this is not the case, you must support the person in line with:

- The Human Rights Act 1998
- The Mental Health Act 1983
- The Mental Capacity Act 2005
- Deprivation of Liberty Safeguards
- The Children Act 1989 and Fraser competency.

Abuse

The outcomes and prompts describe what you need to do to safeguard children and adults. We believe that a person’s right to live a life free from abuse and neglect, and for abuse to be prevented, is as important as responding to it after it has happened. The legislation and government guidance about child abuse is different from that for adult abuse. The regulations state that you must take account of the Government’s guidance.

For **children’s** safeguarding, the definitions we use are taken from *Working Together to safeguard Children* (HM Government, 2006). We have reproduced them below:

Abuse and neglect: Abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by inflicting harm, or by failing to act to prevent harm. Children may be abused in a family or an institutional or community setting, by those known to them or, more rarely, by a stranger. They may be abused by an adult or adults, or another child or children.

Physical abuse: May involve hitting, shaking, throwing, poisoning, burning or scalding, drowning, suffocating, or otherwise causing physical harm to a child. Physical harm may also be caused when a parent or carer fabricates the symptoms of, or deliberately induces, illness in a child.

Emotional abuse: The persistent emotional maltreatment of a child such as to cause severe and persistent adverse effects on the child's emotional development.

Sexual abuse: Involves forcing or enticing a child or young person to take part in sexual activities, including prostitution, whether or not the child is aware of what is happening. The activities may involve physical contact, including penetrative or non-penetrative acts. They may include non-contact activities, such as involving children in looking at, or in the production of, sexual online images, watching sexual activities, or encouraging children to behave in sexually inappropriate ways.

Neglect: The persistent failure to meet a child's basic physical and/or psychological needs, likely to result in the serious impairment of the child's health or development.

For **adult** safeguarding, the definitions we use are taken from *No Secrets* (Department of Health and the Home Office, 2000). We have reproduced them below:

Abuse is a violation of an individual's human and civil rights by other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent. Abuse can occur in any relationship and may result in significant harm, or exploitation of, the person subjected to it.

Of particular relevance are the following descriptions of the forms that abuse may take:

Physical abuse: including hitting, slapping, pushing, kicking, misuse of medication, restraint, or inappropriate sanctions.

Sexual abuse: including rape and sexual assault or sexual acts to which the vulnerable adult has not consented, or could not consent or was pressured into consenting.

Psychological abuse: including emotional abuse, threats of harm or abandonment, deprivation of contact, humiliation, blaming, controlling, intimidation, coercion, harassment, verbal abuse, isolation or withdrawal from services or supportive networks.

Financial or material abuse: including theft, fraud, exploitation, pressure in connection with wills, property or inheritance or financial transactions, or the misuse or misappropriation of property, possessions or benefits.

Neglect and acts of omission: including ignoring medical or physical care needs, failure to provide access to appropriate health, social care or educational services, the withholding of the necessities of life, such as medication, adequate nutrition and heating.

Discriminatory abuse: including racist, sexist, that based on a person's disability, and other forms of harassment, slurs or similar treatment.

Subjective terms

We have tried not to use subjective terms such as "so far as they are able" or "wherever this is possible". Sometimes this has not been possible. This does not mean that you can make a general decision about whether the outcome is valuable or worth achieving.

Care, treatment and support

The outcomes and prompts often refer to the needs of people who use services being met through “care, treatment and support”. This is a general term that we use to refer to the things that providers do to meet people’s needs, although we realise that in some cases people may not receive actual ‘treatment’ and in others they may only receive support.

The level of care, treatment and support that each person requires will depend on their individual health and social care needs. It includes actions taken to prevent illness or disease and to promote lifestyles that maintain health.

Shared Lives

We talk about services provided under an adult placement scheme as “Shared Lives”.

Provider

There are several legal terms relating to the providers of services. These include Registered Person, Service Provider and Registered Manager. The term “provider” means anyone with a legal responsibility for ensuring the requirements of the law are met.

Fitness

The law uses the word “fit” in relation to staff and workers to mean two things. Firstly, it can mean the person is physically and mentally well enough to perform their role. Secondly, it can mean that the person is of good character, as they are honest, reliable and trustworthy, and that they have the right skills, qualifications and experience to perform their role.

For clarity and consistency in the outcomes and prompts, we use the following terms and meanings only:

Fit: this means that the person is of good character, as they are honest, reliable and trustworthy, and that they have the right skills, qualifications and experience to perform their role.

Physically and mentally able: this means that the person is physically and mentally well enough to perform their role taking into account any reasonable adjustments that may be necessary and the development of plans of support to enable them to undertake their work.

Clinical governance

Providers of healthcare services will be familiar with the term 'clinical governance'. It does not relate to providers of social care services.

We have not specifically described what a system of clinical governance should look like in this guide, as clinical governance has several purposes beyond simply establishing the essential standards of quality and safety. However, it is important for providers of healthcare to have a strong system of clinical governance in place. While the guide as a whole supports the development of an effective clinical governance system, we believe that the outcomes and prompts for the following outcomes are of particular importance:

- Outcome 1: Respecting and involving people who use services
- Outcome 2: Consent to care and treatment
- Outcome 4: Care and welfare of people who use services
- Outcome 6: Cooperating with other providers
- Outcome 7: Safeguarding people who use services from abuse
- Outcome 8: Cleanliness and infection control
- Outcome 9: Management of medicines
- Outcome 10: Safety and suitability of premises
- Outcome 11: Safety, availability and suitability of equipment
- Outcome 12: Requirements relating to workers
- Outcome 14: Supporting workers
- Outcome 16: Assessing and monitoring the quality of service provision
- Outcome 17: Complaints
- Outcome 21: Records.

Checklist before reading the guidance in part 2

You are about to start reading the detailed elements of the guidance. Before you do this, check the following:

Have you read Step 1?

This will give you a general understanding of the legislation and the framework of regulation, and how this guidance links to it.

Have you selected your service types in Step 2?

This is important as, without it, you will not be able to decide which prompts are relevant to you.

Have you understood the definitions explained in Step 3?

This is important as, without doing this, you may not fully understand the outcomes and prompts and how you need to interpret them.

Need help?

For general help and support, or to clarify elements of the guidance, you can:

- Look at our website: **www.cqc.org.uk**
- Speak to your local **assessment team** or **relationship manager**
- Contact our customer services team on **03000 616161**
- Email us at **enquiries@cqc.org.uk**
- Write to us at:
**Care Quality Commission, National Correspondence,
Citygate, Gallowgate, Newcastle upon Tyne NE1 4PA.**

Part 2: Guidance

Our guidance about compliance with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.



Involvement and information

This section looks at what providers should do to make sure that people who use services, or those acting on their behalf, are involved in making decisions about their care, treatment and support. It identifies what providers should do to ensure that the views and experiences of people who use services are taken into account when making decisions about how services are delivered and improved in order to meet the registration regulations.

It also looks at the information that providers should make available to people so that they are able to make informed choices, including information about any charges they are expected to pay for their care, treatment and support.

This section covers guidance about compliance for:

1. Respecting and involving people who use services
2. Consent to care and treatment
3. Fees.



Outcome 1: Respecting and involving people who use services

Regulation



What do the regulations say?

Respecting and involving service users

17.—(1) The registered person must, so far as reasonably practicable, make suitable arrangements to ensure—

- (a) the dignity, privacy and independence of service users; and
 - (b) that service users are enabled to make, or participate in making, decisions relating to their care or treatment.
- (2) For the purposes of paragraph (1), the registered person must—
- (a) treat service users with consideration and respect;
 - (b) provide service users with appropriate information and support in relation to their care or treatment;
 - (c) encourage service users, or those acting on their behalf, to—
 - (i) understand the care or treatment choices available to the service user, and discuss with an appropriate health care professional, or other appropriate person, the balance of risks and benefits involved in any particular course of care or treatment, and
 - (ii) express their views as to what is important to them in relation to the care or treatment;
 - (d) where necessary, assist service users, or those acting on their behalf, to express the views referred to in sub-paragraph (c)(ii) and, so far as appropriate and reasonably practicable, accommodate those views;
 - (e) where appropriate, provide opportunities for service users to manage their own care or treatment;
 - (f) where appropriate, involve service users in decisions relating to the way in which the regulated activity is carried on in so far as it relates to their care or treatment;
 - (g) provide appropriate opportunities, encouragement and support to service users in relation to promoting their autonomy, independence and community involvement; and
 - (h) take care to ensure that care and treatment is provided to service users with due regard to their age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Understand the care, treatment and support choices available to them.
- Can express their views, so far as they are able to do so, and are involved in making decisions about their care, treatment and support.
- Have their privacy, dignity and independence respected.
- Have their views and experiences taken into account in the way the service is provided and delivered.

Those acting on behalf of people who use services:

- Understand the care, treatment and support choices available to the people who use services.
- Can represent the views of the person using the service by expressing these on their behalf, and are involved appropriately in making decisions about their care, treatment and support.

This is because providers who comply with the regulations will:

- Recognise the diversity, values and human rights of people who use services.
- Uphold and maintain the privacy, dignity and independence of people who use services.
- Put people who use services at the centre of their care, treatment and support by enabling them to make decisions.
- Provide information that supports people who use services, or others acting on their behalf, to make decisions about their care, treatment and support.
- Support people who use services, or others acting on their behalf, to understand the care, treatment and support provided.
- Enable people who use services to care for themselves where this is possible.
- Encourage and enable people who use services to be involved in how the service is run.
- Encourage and enable people who use services to be an active part of their community in appropriate settings.

Prompts



Prompts for all providers to consider

Ensure personalised care, treatment and support through involvement

1A

People who use services are involved in and receive care, treatment and support that respects their right to make or influence decisions because the service:

- Explains and discusses their care, treatment and support options with them.
- Respects their right to take informed risks, while balancing the need for preference and choice with safety and effectiveness.
- Promotes and respects their privacy, dignity, independence and human rights by:
 - placing the needs, wishes, preferences and decisions of people who use services at the centre of assessment, planning and delivery of care, treatment and support
 - ensuring that the environment allows privacy in which the intimate care, treatment and support needs of the person who uses services are met
 - having clear procedures followed in practice, monitored and reviewed that ensure staff understand the concepts of privacy, dignity, independence and human rights and how they should be applied to the people who use the service
 - ensuring that the need to maintain confidentiality or disclose information is taken account of in the assessment of the individual circumstances
 - actively listening to and involving people who use services, or others acting on their behalf, in decision making.
- Provides information to help people who use services, or others acting on their behalf, to understand their care, treatment and support, including the risks and benefits, and their rights to make decisions.
- Ensures that staff recognise and respect the diversity and human rights of people who use services.
- Makes people who use services aware of independent advocacy services wherever they are available.
- Cooperates with independent advocacy services wherever a person who uses services uses one.

1B

People who use services have their care, treatment and support needs met because:

- They are listened to.
- They, or those acting on their behalf, are involved in assessing, planning and carrying out their care, treatment and support.
- The things that are important to them in relation to their care, treatment and support are established as part of the assessment, and the support to meet these needs is provided.
- Staff are respectful of the decisions made by people who use services.

Manage risk through effective procedures about involvement

1C

People who use services receive care, treatment and support where clear procedures are followed in practice, monitored and reviewed. These procedures ensure that:

- Care, treatment and support options, and the risks and benefits of those options, are explained.
- Choices and preference of the person who uses the service are expressed by them or others acting on their behalf.
- The choices of people who use services are respected and accommodated unless:
 - the choice places other people at risk of harm or injury
 - it would not be reasonable to expect the service to have the resources needed to achieve the choice
 - it is not within the provider's stated aims, objectives and purpose to meet the choice
 - the person who uses the service does not have capacity to make that decision
 - the person who uses the service is subject to a legal restriction that prohibits them making a choice.
- Individualised assessments and plans of care, treatment and support are based on their needs, choices and preferences.
- Arrangements are in place for someone to act on the behalf of the person using the service, where the person who uses services agrees to it or it is legally authorised or required.
- Any reasonable adjustments are made so that the person who uses services is enabled to be involved in decision making.

1D

People who use services benefit from a service that:

- Takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

Promote rights and choices

1E

People who use services, or others acting on their behalf, are supported to make informed choices about their care, treatment and support because they are:

- Given the information they need to make choices.
- Are able to discuss the options available to them with a person who:
 - understands their individual needs, choices and preferences
 - knows what the aims and limitations of the service are
 - understands the various choices that the person who uses the service could make
 - is aware of the consequences of the various choices that the person who uses the service could make
 - is able to present the risks and benefits of the options based on evidence, research or experience.
- Given the time they need to make their decision, taking account of the urgency of the situation.
- Given relevant information to encourage them to change lifestyle behaviours that are placing their health at risk, so they can make informed choices about whether they wish to lead a healthier life.

1F

People who use services receive care, treatment and support that is provided in a way that ensures their independence is promoted by:

- Involving them, as far as is possible, in their needs assessment, planning and setting care, treatment and support goals.
- Respecting their choice to care for themselves or manage their own treatment, wherever they can.
- Enabling people who use services, or others acting on their behalf, to make informed choices even where there are risks involved with the decision they make.

1G

People who use services receive care, treatment and support that is provided in a way that ensures their human rights and diversity are respected by:

- Discussing information about choices in a way they can understand.
- Providing information about what their rights are.
- Having staff who are aware of, understand and recognise the person's social and cultural diversity, values and beliefs that may influence their decisions and how they want to receive care, treatment and support.

1H

People who use services are provided with information about:

- The aims, objectives and purpose of the service.
- The facilities that are available for their care, treatment and support.
- How their care, treatment and support is reviewed.
- The cost of the services, where charges are applied.
- How to raise a concern or complaint about the service, and how it will be dealt with.
- Local advocacy services.

1I

People who use services, or others acting on their behalf, are given encouragement, support and opportunities to:

- Describe their holistic needs and to discuss the impact of their care, treatment and support on the person who uses the service.
- Raise specific needs or to express concerns relating to equality, diversity and human rights.

1J

People who use services can influence how the service is run as they are given opportunities to take part in decision making through:

- General discussions with the provider, on an informal basis, as the person who uses services wishes.
- Periodic surveys or gathering of their views.
- A representative user group made up of people who are using, or have used, the service or similar services.
- The cooperation with local involvement networks, where they have the right to enter and view the service.
- The cooperation with any other relevant user forums.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

1K

People who use services can be confident that:

- The outcome of diagnostic tests and assessments will be explained and discussed with them in a way which they are able to understand and which enables them to make informed choices about their care, treatment and support, where this is the role or responsibility of the service undertaking the test.

This guidance applies to the service types ticked below:

ACS ✓	AMB ✓	BTS	CHC ✓	CHN	CHS	DCC
DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC	HPS ✓
LDC ✓	LTC ✓	MBS ✓	MHC ✓	MLS ✓	PHS ✓	RCA ✓
RHS ✓	RSM	SHL	SLS	SMC	SPC	UCS ✓

1L

People using rehabilitation or treatment services for substance misuse can be confident that:

- There will be restrictions placed on them when using the service, in line with the service’s treatment approach, which may include limitations to:
 - flexibility in daily routines and freedom
 - privacy
 - choices
 - access to facilities
 - personal relationships.
- Where there are restrictions placed on them, they are:
 - based on specialist need and risk assessment, or required by their treatment programme
 - agreed with them during assessment
 - reviewed as they progress through their treatment programme
 - proportionate and in line with human rights legislation.

Outcome 1: Respecting and involving people who use services

1

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS	AMB	BTS	CHC	CHN	CHS	DCC
	DCS	DEN	DSS	DTS	EXC	HBC	HPS
	LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
	RHS	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS

1M

People who use services are enabled to:

- Participate in the activities of the local community so that they can exercise their right to be a citizen as independently as they are able to.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC ✓
	DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS
	LDC ✓	LTC ✓	MBS	MHC ✓	MLS ✓	PHS	RCA
	RHS ✓	RSM	SHL ✓	SLS ✓	SMC ✓	SPC	UCS

Outcome 2: Consent to care and treatment

Regulation →



What do the regulations say?

Consent to care and treatment

18. The registered person must have suitable arrangements in place for obtaining, and acting in accordance with, the consent of service users in relation to the care and treatment provided for them.

Regulation 18 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome →



What should people who use services experience?

People who use services:

- Where they are able, give valid consent to the examination, care, treatment and support they receive.
- Understand and know how to change any decisions about examination, care, treatment and support that has been previously agreed.
- Can be confident that their human rights are respected and taken into account.

This is because providers who comply with the regulations will:

- Have systems in place to gain and review consent from people who use services, and act on them.

Prompts



Prompts for all providers to consider

Manage risk through effective consent procedures

2A

Where they are able, people who use services receive the examination, care, treatment and support they agree to. This is because clear procedures to get valid consent are followed in practice, monitored and reviewed. Wherever consent is required these procedures include:

- Ensuring that consent is sought by a person who has sufficient knowledge about the person who uses the service, and the care, treatment and support options they are considering in order that the person who uses the service can make an informed decision.
- Ensuring that the risks, benefits and alternative options are discussed and explained in a way that the person who uses the service is able to understand.
- Ensuring where the person using the service lacks capacity, best interest meetings are held with people who know and understand the person using the service.
- Ensuring people who use services are given enough time to think about their consent decisions where requested, except in an emergency when this may not always be possible.
- Respecting confidentiality whenever this is requested by a child who is competent to make their own decision.
- The identification of who has parental responsibility in circumstances where a child is unable to give consent.
- The arrangements for seeking and obtaining consent for children.
- Respecting the right of people who use services to have an advocate to assist them in understanding their options and enable them to make an informed decision.
- Where treatment is refused, explaining the risks and benefits of refusing and the alternative options.
- Respecting and taking account of a decision by the person who uses the service to refuse or withdraw consent.
- Following any advance decision made in line with the Mental Capacity Act 2005 that the person using the service may have made, wherever this is known by the provider.

- The arrangements for taking account of restrictions authorised under the deprivation of liberty safeguards.
- The regular review of consent decisions taking into account the changing needs of the person who uses the service.
- Specific arrangements for seeking consent when a person is taking part in health and care-related research.

2B

People who use services benefit from staff who understand:

- The circumstances in which written consent must be taken.
- The way in which written consent must be documented.
- The circumstances in which verbal or implied consent can be taken.
- How to respect the cultural, social values and beliefs of the person who uses the service.
- That some people who use services may require more support than others in obtaining consent.
- How to identify when a person is not able to give valid consent at the time it is required.
- That sufficient details about the care, treatment and support options available should be provided in order for them to make an informed decision.
- That in a life threatening emergency situation, when receiving consent is not possible, decisions are made which are in the best interests of the person who uses the service.
- That consent is ongoing and can be withdrawn by the person who uses services at any time.
- How to respond to the decisions people who use services make about their care, treatment and support including:
 - respecting decisions even when they disagree
 - what to do when the wishes of the person who uses the service conflict with their care, welfare and safety needs
 - what to do when the wishes of the person who uses the service conflict with those of any other person acting on their behalf
 - how to respond to advance decisions
 - how to act so that valid consent is obtained for children while respecting their human rights and confidentiality.

2C

There are clear procedures that are followed in practice, monitored and reviewed about decision making for people who are unable to give, or choose to withhold, consent for each individual care, treatment and support activity, including:

- Meeting the requirements of the Mental Health Act 1983, the Mental Capacity Act 2005 and the Children Act 1989.
- Staff knowing the circumstances in which an advance directive or advance decision regarding the refusal of treatment by a person using services may be lawfully over-ruled.
- Where a life threatening emergency may arise and it is not possible to obtain consent.

2D

People who use services benefit from a service that:

- Takes into account relevant guidance, including that from the Care Quality Commission’s Schedule of Applicable Publications (see appendix B).

2E

People are able to make a decision about whether or not to give consent because:

- They have information about the alternative options for their care, treatment and support and the risks and benefits of each.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

2F

People who use services give valid consent because:

- Arrangements are followed to ensure that cosmetic surgery does not take place on the same day as the consultation.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
DCS ✓	DEN	DSS	DTS ✓	EXC	HBC	HPS
LDC	LTC	MBS ✓	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

2G

People who use imaging services who do not have symptoms indicating that imaging is required must:

- Receive information regarding the risks and benefits prior to the procedure being carried out including:
 - risks directly associated with the procedure
 - risks associated with unclear or incorrect results.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
DCS ✓	DEN	DSS ✓	DTS ✓	EXC	HBC	HPS
LDC	LTC	MBS ✓	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

2H

People who use services are supported to:

- Make a decision about whether or not to give consent when this is not in conflict with any restrictions set by the courts, Mental Health Act 1983, Mental Capacity Act 2005 or criminal justice system.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC ✓	LTC	MBS	MHC ✓	MLS ✓	PHS ✓	RCA
RHS	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS

Outcome 3: Fees

Regulation



What do the regulations say?

Fees etc.

19.—(1) Where a service user will be responsible for paying the costs of their care or treatment (either in full or partially), the registered person must provide a statement to the service user, or to a person acting on the service user's behalf—

- (a) specifying the terms and conditions in respect of the services to be provided to the service user, including as to the amount and method of payment of fees; and
- (b) including, where applicable, the form of contract for the provision of services by the service provider.

(2) The statement referred to in paragraph (1) must be—

- (a) in writing; and
- (b) as far as reasonably practicable, provided prior to the commencement of the services to which the statement relates.

Regulation 19 of the Care Quality Commission (Registration) Regulations 2009

Outcome



What should people who use services experience?

People who use services, or others acting on their behalf, who pay the provider for the services they receive:

- Know how much they are expected to pay, when and how.
- Know what the service will provide for the fee paid.
- Understand their obligations and responsibilities.

This is because providers who comply with the regulations will:

- Be transparent in the information they provide about any fees, contracts and terms and conditions, where people are paying either in full or in part for the cost of their care, treatment and support.

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers wherever the person using the service personally pays the provider for any part of their care, treatment and support, as part of a private or joint funding arrangement of any kind or a private medical insurance policy.

Manage risk through effective procedures about financial agreements

3A

People who use services, or others acting on their behalf, who pay the provider in full for their care, treatment and support either from private means, money received as a grant, benefit, or an insurance scheme, in order to purchase it:

- Are made aware of the requirement for them to pay for their care, treatment and support and the expected costs.
- Are given the time they need to consider whether they wish to proceed with the care, treatment and support.
- Are not placed under undue pressure to agree to sign an agreement.
- Receive a copy of the agreement they will enter into if they decide to proceed with the care, treatment and support and are given time to consider whether they wish to proceed with it in line with applicable consumer regulations.

- Are given a statement of their account at any time they request it.
- Are given terms and conditions that clarify the actions that will be taken in the event of non payment and/or late payment of fees.
- Receive a final copy of any agreement they sign.
- Are offered a receipt for money they pay to the service.

3B

People who use services whose care, treatment and support funding is paid to the service provider by a third party purchaser, but where the person or others acting on their behalf makes a contribution to the provider from their own private means:

- Are offered a receipt for money they pay to the service.

3C

People who use services who enter into a separate arrangement with a service provider because they choose to pay for additional care, treatment and support which is not contracted on their behalf by a third party purchaser:

- Have the additional services they purchase arranged so that they:
 - are made aware of the requirement for them to pay for their care, treatment and support and the expected costs
 - are given the time they need to consider whether they wish to proceed with the care, treatment and support
 - are not placed under undue pressure to agree to sign an agreement
 - receive a copy of the agreement they will enter into if they decide to proceed with the care, treatment and support
 - receive a final copy of any agreement they sign
 - are offered a receipt for money they pay to the service
 - are given a statement of their account at any time they request it, and when the account is fully paid.

3D

People who use services benefit from a service that:

- Takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

Promote rights and choices

3E

People who use services who pay the provider in full for their care, treatment and support and people who use services who enter into a separate arrangement with a service provider because they choose to pay for care, treatment and support that is not contracted on their behalf by a third party purchaser:

- Are able to discuss the terms of the agreement with someone who knows enough about it to be able to answer any questions they have, so that they can decide if they wish to proceed.
- Can make decisions about the costs and terms because information is given about these.
- Know when they or the service can cancel the agreement.
- Are told what the fee is and what it covers.
- Are given an estimate of how much it will cost if a fixed price cannot be given.
- Are told of any likely costs in addition to the price or estimate quoted.
- Are told when any unexpected additional costs need to be made, before the care, treatment and support that will lead to those additional costs is provided, wherever this is possible.
- Are notified of any planned increases in ongoing fees with sufficient time that they can consider whether they wish to continue with that service.
- Are told when payments are due and are given reasonable notice of these dates so that they have the opportunity to arrange payment without incurring a penalty of any sort, and to ensure they do not build up debt.
- Are told about how they can make payments and the payment process.

3F

People who use services whose care, treatment and support funding is paid to the service provider by a third party purchaser, but where the person makes a contribution from their own private means and which is collected by the provider on behalf of a third party purchaser:

- Are told what the fee is.
- Are told when payments are due and are given reasonable notice of these dates so that they have the opportunity to arrange payment without incurring a penalty of any sort.
- Are told about how they can make payments and the payment process.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

3G

People who use services who pay the provider in full for their care, treatment and support:

- Are told that they may become eligible for local authority social care funding support when their capital or income drops to the Government set threshold.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC ✓
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

Personalised care, treatment and support

This section looks at what providers should do to make sure that people who use services get effective, safe and appropriate care, treatment and support that meets their individual needs.

This section covers guidance about compliance for:

4. Care and welfare of people who use services
5. Meeting nutritional needs
6. Cooperating with other providers.



Outcome 4: Care and welfare of people who use services

Regulation



What do the regulations say?

Care and welfare of service users

9.—(1) The registered person must take proper steps to ensure that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe, by means of—

- (a) the carrying out of an assessment of the needs of the service user; and
- (b) the planning and delivery of care and, where appropriate, treatment in such a way as to—
 - (i) meet the service user’s individual needs,
 - (ii) ensure the welfare and safety of the service user,
 - (iii) reflect, where appropriate, published research evidence and guidance issued by the appropriate professional and expert bodies as to good practice in relation to such care and treatment, and
 - (iv) avoid unlawful discrimination including, where applicable, by providing for the making of reasonable adjustments in service provision to meet the service user’s individual needs.

(2) The registered person must have procedures in place for dealing with emergencies which are reasonably expected to arise from time to time and which would, if they arose, affect, or be likely to affect, the provision of services, in order to mitigate the risks arising from such emergencies to service users.

Regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.

This is because providers who comply with the regulations will:

- Reduce the risk of people receiving unsafe or inappropriate care, treatment and support by:
 - assessing the needs of people who use services
 - planning and delivering care, treatment and support so that people are safe, their welfare is protected and their needs are met
 - taking account of published research and guidance
 - making reasonable adjustments to reflect people's needs, values and diversity
 - having arrangements for dealing with foreseeable emergencies.

Prompts



Prompts for all providers to consider

Ensure effective, safe and appropriate, personalised care, treatment and support through coordinated assessment, planning and delivery

4A

People who use services have safe and appropriate care, treatment and support because their individual needs are established from when they are referred or begin to use the service. The assessment, planning and delivery of their care, treatment and support:

- Is centred on them as an individual and considers all aspects of their individual circumstances, and their immediate and longer-term needs.
- Is developed with them, and/or those acting on their behalf.
- Reflects their needs, preferences and diversity.
- Identifies risks, and says how these will be managed and reviewed.
- Ensures that risk assessments balance safety and effectiveness with the right of the person who uses the service to make choices, taking account of their capacity to make those choices and their right to take informed risks.

- Ensures that plans of care, treatment and support are implemented, flexible, regularly reviewed for their effectiveness, changed if found to be ineffective and kept up to date in recognition of the changing needs of the person using the service.
- Maintains their welfare and promotes their wellbeing by taking account of all their needs, including:
 - physical
 - mental
 - social
 - personal relationships
 - emotional
 - daytime activity.
- Ensures continuity in their care, treatment and support as a result of effective communication between all of those who provide it, including other providers.
- Enables people to maintain, return to, or manage changes to their health or social circumstances.
- Is undertaken to reduce the risk of deterioration in their health status.
- Encourages the prevention and early detection of ill health, including relapse, wherever there are real factors that present a risk to their health and welfare.
- Enables them to make healthy living choices concerning exercise, diet and lifestyle.

Manage risk through effective procedures

4B

People who use services benefit from a service that:

- Reflects on the findings of their service reviews.
- Learns from adverse events, incidents, errors and near misses that have occurred within the service so that the risk of these being repeated is reduced to a minimum.
- Informs them, or others acting on their behalf, if an adverse event, incident or error has occurred in their care, treatment or support that has caused, or may result in, harm and offers a full explanation of what happened along with an appropriate apology or expression of regret.
- Implements and acts upon the recommendations of safety and risk alerts and notices.

- Makes plans in advance of a foreseeable emergency, to ensure the needs of people who use the services will continue to be met before, during and after the emergency. These plans include:
 - defined roles and accountabilities
 - contingency arrangements to respond to additional demands while maintaining the essential standards of quality and safety.
- Takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B), and any other good practice guidance which relates to the care, treatment and support provided by the service and which is published by a professional or expert body that is relevant.

4C

People who use services can be confident that:

- Wherever possible, they will know the names and job titles of the people who provide their care, treatment and support and how to contact them.
- They have adequate plans in place for when they leave the service and are fully involved in this planning, where they have capacity and the wish to do so.

4D

People who use services can be confident that:

- Staff will quickly recognise when a person who uses services becomes seriously ill, physically and/or mentally, and requires treatment, and immediately respond to meet their needs.
- In these circumstances staff will ensure that where the person who uses services needs to be transferred to another service, or within the service, this is done as quickly and safely as possible.

Promote rights and choices

4E

People who use services:

- Are involved in identifying their care, treatment and support options and the alternatives, risks and benefits of each are explained.
- Are supported to make informed decisions where they are unable to do this by themselves.
- Have sufficient information to enable them, or a person acting on their behalf, to make informed choices and decisions about the service.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

4F

People who use services know that:

- They will receive care, treatment and support in single sex accommodation wherever it is available.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
	DCS	DEN	DSS	DTS	EXC	HBC	HPS ✓
	LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
	RHS	RSM	SHL	SLS	SMC	SPC	UCS

4G

People who use services know that:

- Their length of stay will be as short as possible in order to meet their needs, or as required by legal restrictions.
- Their accommodation will not limit their freedom any further than is agreed in their plan of care.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
	DCS	DEN	DSS	DTS	EXC	HBC	HPS
	LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
	RHS	RSM	SHL	SLS	SMC	SPC	UCS

4H

People who use services can be confident that:

- Analysis of diagnostic tests and assessments are undertaken by qualified staff in a way which follows guidelines from relevant expert and professional bodies.
- Where the provider uses telemedicine diagnostic services from outside England those services meet the same standards as they would have had they been located in England and subject to registration under the Health and Social Care Act 2008.

This guidance applies to the service types ticked below:

ACS ✓	AMB ✓	BTS	CHC ✓	CHN	CHS	DCC
DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC	HPS ✓
LDC	LTC ✓	MBS ✓	MHC ✓	MLS ✓	PHS ✓	RCA ✓
RHS ✓	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS ✓

4I

Children who use services are:

- Fully informed of their care, treatment and support.
- Able to take part in decision making to the fullest extent that is possible.
- Asked if they agree for their parents or guardians to be involved in decisions they need to make.
- Able to benefit from an environment that is appropriate to their age and individual needs.

This guidance applies to the service types ticked below:

ACS ✓	AMB ✓	BTS	CHC ✓	CHN	CHS	DCC ✓
DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC	HPS ✓
LDC	LTC ✓	MBS ✓	MHC ✓	MLS ✓	PHS ✓	RCA ✓
RHS	RSM	SHL	SLS	SMC	SPC	UCS ✓

4J

Women undergoing a termination of pregnancy know that:

- The correct referral procedures are followed by a medical practitioner or approved pregnancy advice bureau.
- A 24-hour telephone advice is available to provide support after they leave the service.
- They are able to express their preferences for the disposal of foetal tissue.
- They are able to discuss their choices and decisions with a trained counsellor.
- Where services are provided to children or people with a learning disability, the counsellor available has relevant expertise in discussing termination of pregnancy with them.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS ✓	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

4K

People who use services who are at the end of their life will have their care, treatment and support needs met because, wherever possible:

- They are involved in the assessment and planning for their end of life care and are able to make choices and decisions about their preferred options, particularly those relating to pain management.
- There are systems in place to ensure further assessments by specialist palliative care services and other specialists, where needed.
- They have information relating to death and dying available to them, their families or those close to them.
- There are arrangements to minimise unnecessary disruption to the care, treatment, support and accommodation of the person who uses the service, their family and those close to them.
- They are able to have those people who are important to them, with them at the end of their life.
- They have a dignified death, because staff are respectful of their needs for privacy, dignity and comfort.
- The plan of care records their wishes with regards to how their body and possessions are handled after their death and staff respect their values and beliefs.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC ✓	CHN ✓	CHS ✓	DCC ✓
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS ✓
LDC ✓	LTC ✓	MBS	MHC	MLS ✓	PHS	RCA
RHS	RSM ✓	SHL ✓	SLS ✓	SMC	SPC ✓	UCS ✓

4L

People who use services who are thought to present a risk of suicide and homicide or harm to themselves or others have an ongoing, multi-disciplinary assessment and plan of care made:

- To determine whether they have a history of harm to themselves or others.
- To establish any risk of suicide and homicide or harm to themselves or others, including environmental risks, and how these can be minimised.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
	DCS	DEN	DSS	DTS	EXC	HBC	HPS
	LDC ✓	LTC	MBS	MHC ✓	MLS ✓	PHS ✓	RCA
	RHS	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS

4M

People who use services benefit from a service that:

- Ensures that patient safety alerts, rapid response reports and patient safety recommendations issued by the National Patient Safety Agency (NPSA) and which require action are acted upon within required timescales.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB ✓	BTS ✓	CHC ✓	CHN ✓	CHS ✓	DCC ✓
	DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC ✓	HPS ✓
	LDC ✓	LTC ✓	MBS ✓	MHC ✓	MLS ✓	PHS ✓	RCA ✓
	RHS ✓	RSM ✓	SHL	SLS ✓	SMC ✓	SPC ✓	UCS ✓

4N

People using rehabilitation or treatment services for substance misuse have:

- Their care, treatment and support options explained before they start to use the service. These include any restrictions identified, and the alternatives, risks and benefits.
- A risk assessment completed that includes the risk of drug-related death.

4O

People using rehabilitation or treatment services for substance misuse benefit from clear procedures followed in practice, monitored and reviewed, for when they leave the service, in a planned or unplanned way, that specify:

- Informing the referrer.
- An assessment of the risks associated with either planned or unplanned discharge which includes:
 - provision of harm reduction advice
 - assessment of the risk of overdose
 - informing services and those acting on their behalf if the person poses a risk to themselves or others
 - informing services locally if the person is likely to stay and use services in the area.

The guidance in 4N and 4O applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
RHS	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS

4P

People with a learning disability who use services:

- Are supported to have a health action plan developed by their primary care trust.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC ✓	CHN ✓	CHS ✓	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC ✓	LTC ✓	MBS	MHC	MLS ✓	PHS ✓	RCA
RHS	RSM ✓	SHL ✓	SLS ✓	SMC	SPC	UCS

4Q

People who use services are only put in to seclusion if it is:

- In line with the National Institute for Health and Clinical Excellence's clinical guideline on *Violence: the short term management of disturbed or violent behaviour in in-patient psychiatric settings and emergency departments* (2005).
- Carried out following clear procedures that are monitored, reviewed and in line with the Mental Health Act 1983 Code of Practice.
- In an environment that complies with the Mental Health Act 1983 Code of Practice.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC ✓	MBS	MHC	MLS ✓	PHS ✓	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

4R

People who use services have their needs met through the care programme approach:

- If they meet the criteria set out in *Refocusing the Care Programme Approach: policy and positive practice guidance 2008*.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC ✓	CHN ✓	CHS ✓	DCC ✓
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS ✓
LDC ✓	LTC ✓	MBS	MHC ✓	MLS ✓	PHS ✓	RCA
RHS	RSM ✓	SHL	SLS ✓	SMC ✓	SPC	UCS

4S

People who use services have care, treatment and support that:

- Follows clear procedures, that are monitored and reviewed and are prepared by a person who has sufficient experience of hyperbaric oxygen chambers, that describe:
 - the potential hazards of using a hyperbaric oxygen chamber
 - the potential hazards of using electrical devices in a hyperbaric oxygen chamber
 - how staff should work safely
 - the safety checks that must be completed for the preparation and use of the chamber and for anyone entering it
 - how the machine should be operated safely
 - how the staff should respond to an emergency situation
 - the treatment of level 1 or level 2 critical care patients, where the service treats such people.
- Is provided in a service that is under the direction of a medical practitioner with sufficient experience and expertise in the hyperbaric oxygen chamber treatments to ensure the risks of the treatment are minimised.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC ✓	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

4T

People who use services receive care, treatment and support that is developed carefully and systematically where protocols or processes require rapid development in response to an unexpected public health event by ensuring that:

- There are clear procedures followed in practice, monitored and reviewed for the governance arrangements for this urgent development.
- There are advice protocols available that can be used as a starting point in readiness for such situations.
- The competency limits of staff who will be using the urgently developed protocols, and the points at which they will need to pass an individual case to a more experienced member of the team, are understood and fully considered when developing the protocol.
- The capacity of the service to manage the possible increase in demand as a result of the event is understood and fully considered when developing the protocol.
- People with the necessary skills and knowledge to safely develop the protocol are involved in the development, regardless of the time limitations.

4U

People who use services are supported by:

- Adequate arrangements to rapidly identify information submitted electronically or over the phone that suggests the person using the service may require emergency care, treatment or support.
- Such information, where it is identified, being passed to a more appropriate service, or practitioner within the same service, without delay so that the care, treatment and support the person using the service may need is provided as soon as possible.
- When first accessing the service, clear information is given to people accessing the service, including the type of support provided.
- Staff who understand what to do where:
 - a person in prison, detained under immigration restrictions or whose liberty is restricted under the Mental Health Act 1983 or the Mental Capacity Act 2005 contacts the service
 - another person contacts the service to discuss their needs.

The guidance in 4T and 4U applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA ✓
RHS	RSM	SHL	SLS	SMC	SPC	UCS

4V

People who use services can be confident that:

- Blood, blood products and human tissue donated for transplantation are only taken from donors who do not present an unacceptable risk to the person because of:
 - their previous medical history
 - their lifestyle
 - any medicines they may or may have previously taken
 - recent travel abroad
 - their age.

This guidance applies to the service types ticked below:

ACS	AMB	BTS ✓	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

4W

People who use services:

- Are able to visit the service prior to using it so that they can decide whether or not they wish to use it, or to allow them to become familiar with it in order to allay anxiety or fear. This is made available wherever it is practical or appropriate to do so, and there is potential for the person who uses the service to substantially benefit from the visit.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC
	DCS	DEN	DSS	DTS	EXC	HBC	HPS ✓
	LDC	LTC ✓	MBS	MHC	MLS	PHS	RCA
	RHS	RSM	SHL ✓	SLS ✓	SMC	SPC	UCS

4X

People who use services can be confident that:

- Searches are conducted in line with nationally recommended practice.
- The service will prevent and rapidly respond to incidents of illicit drug use and supply on or near the premises.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS	AMB	BTS	CHC	CHN	CHS	DCC
	DCS	DEN	DSS	DTS	EXC	HBC	HPS
	LDC	LTC	MBS	MHC	MLS ✓	PHS ✓	RCA
	RHS	RSM ✓	SHL	SLS	SMC	SPC	UCS

Outcome 5: Meeting nutritional needs

Regulation



What do the regulations say?

Meeting nutritional needs

14.—(1) Where food and hydration are provided to service users as a component of the carrying on of the regulated activity, the registered person must ensure that service users are protected from the risks of inadequate nutrition and dehydration, by means of the provision of—

- (a) a choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs;
- (b) food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background; and
- (c) support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.

(2) For the purposes of this regulation, "food and hydration" includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.

Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Are supported to have adequate nutrition and hydration.

This is because providers who comply with the regulations will:

- Reduce the risk of poor nutrition and dehydration by encouraging and supporting people to receive adequate nutrition and hydration.
- Provide choices of food and drink for people to meet their diverse needs, making sure the food and drink they provide is nutritionally balanced and supports their health.

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers where they prepare, or support people who use services to prepare, food and drink. The term 'provide' means the preparation of food and drink and includes where the service gives support to people to eat and drink. The food and drink used may be purchased either by the provider or by the person using the service. These prompts do not cover the administration of artificial hydration which may be essential to maintain hydration.

Ensure personalised care by providing adequate nutrition, hydration and support

5A

Where the service provides food and drink, people who use services have their care, treatment and support needs met because:

- Staff identify where the person who uses services is at risk of poor nutrition, dehydration or has swallowing difficulties, when they first begin to use the service and as their needs change.
- Action is taken where any risk of poor nutrition or dehydration is identified including any difficulty in swallowing or the impact of any medicines, and a referral is made to appropriate services.
- They know that their medical dietary and hydration requirements are identified and reviewed.
- Their plan of care includes how any identified risks will be managed.
- Relevant staff know what a balanced diet is.
- Staff involved in food preparation produce food to help facilitate a healthy, balanced diet.

- They have food and drink that:
 - are handled, stored, prepared and delivered in a way that meets the requirements of the Food Safety Act 1990
 - are presented in an appetising way to encourage enjoyment
 - are provided in an environment that respects their dignity
 - meet the requirements of their diverse needs
 - take account of any dietary intolerances they may have.
- They can be confident that staff will support them to meet their eating and drinking needs with sensitivity and respect for their dignity and ability.
- They are enabled to eat their food and drink as independently as possible.
- All assistance necessary is provided to ensure they actually eat and drink, where they want to but are unable to do so independently.
- They have supportive equipment available to them that allows them to eat and drink independently, wherever needed.
- They are helped into an appropriate position that allows them to eat and drink safely, wherever needed.
- They are not interrupted during mealtimes unless they wish to be or an emergency situation arises.
- They will have any special diets or dietary supplements that their needs require arranged on the advice of an appropriately qualified or experienced person.
- They have access to specialist advice and techniques for receiving nutrition where their needs require it.
- The service takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

5B

Where the service provides food and drink, but not when this is in the person's own home or Shared Lives arrangement, people have their care, treatment and support needs met because:

- A nutritional screening is carried out to identify where they are at risk of poor nutrition or dehydration when they first begin to use the service and at regular intervals.
- Where a full nutritional assessment is necessary because the nutritional screening identified risk of poor nutrition and dehydration, this is carried out by staff with the appropriate skills, qualifications and experience.
- They have their food and drink intake monitored when they are at risk of poor nutrition or dehydration and action is taken as necessary.

- They are not expected to wait for the next meal if their care, treatment and support means they missed a planned mealtime.
- The person can choose a balanced diet that is relevant to them as an individual, taking account of their nutritional status and previous wishes.

Promote rights and choices

5C

Where the service provides food and drink, people who use services can make decisions about their food and drink because they:

- Have accessible information about meals and the arrangements for mealtimes.
- Have a choice for each meal that takes account of their individual preferences and needs, including their religious and cultural requirements.
- Have access to snacks and drinks throughout the day and night.
- Have mealtimes that are reasonably spaced and at appropriate times, taking account of reasonable requests including their religious or cultural requirements.
- Have information on what constitutes a balanced diet to help them make an informed decision about the type, and amount, of food they need to address any risk of poor nutrition and/or dehydration.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

5D

People who use services benefit from clear procedures followed in practice, monitored and reviewed to ensure they:

- Are only subject to fasting (for example before an operation or procedure) for the minimum possible period, and the service will ensure they have adequate hydration as soon as possible afterwards. Nutrition should be provided as soon as possible where facilities exist, or appropriate advice and opportunity is offered where those facilities do not exist.
- Can be confident that consideration is given to the duration of fasting for each person (including specific consideration for children) prior to the scheduling of operations or procedures.
- Are given nutrition as soon as possible after procedures requiring fasting are cancelled.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC ✓	CHN	CHS	DCC
DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC ✓	HPS ✓
LDC	LTC ✓	MBS	MHC	MLS ✓	PHS ✓	RCA
RHS ✓	RSM	SHL	SLS	SMC	SPC	UCS ✓

5E

People who use services:

- Have access to facilities for infant feeding, including facilities to support breastfeeding.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC ✓	CHN	CHS	DCC
DCS	DEN	DSS ✓	DTS	EXC	HBC	HPS ✓
LDC	LTC	MBS	MHC	MLS ✓	PHS ✓	RCA
RHS	RSM ✓	SHL	SLS	SMC	SPC	UCS ✓

5F

People using rehabilitation or treatment services for substance misuse, where the service provides them with food and drink, will have some limited choice about:

- When to eat.
- Where to eat.
- Whether to eat alone, or with company.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS ✓	PHS ✓	RCA
RHS	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS

5G People who use services are:

- Actively supported to plan and prepare their own meals, where this is safe and they are able to do so.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC ✓
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS
LDC ✓	LTC	MBS	MHC	MLS ✓	PHS	RCA
RHS	RSM ✓	SHL ✓	SLS ✓	SMC	SPC ✓	UCS

5H People who use services are able to make choices about:

- What to eat.
- When to eat.
- Where to eat.
- Whether to eat alone, or with company.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS ✓
LDC	LTC ✓	MBS	MHC ✓	MLS ✓	PHS ✓	RCA
RHS	RSM	SHL	SLS ✓	SMC	SPC	UCS

Outcome 6: Cooperating with other providers

Regulation



What do the regulations say?

Cooperating with other providers

24.—(1) The registered person must make suitable arrangements to protect the health, welfare and safety of service users in circumstances where responsibility for the care and treatment of service users is shared with, or transferred to, others, by means of—

- (a) so far as reasonably practicable, working in cooperation with others to ensure that appropriate care planning takes place;
- (b) subject to paragraph (2), the sharing of appropriate information in relation to—
 - (i) the admission, discharge and transfer of service users, and
 - (ii) the co-ordination of emergency procedures; and
- (c) supporting service users, or persons acting on their behalf, to obtain appropriate health and social care support.

(2) Nothing in this regulation shall require or permit any disclosure or use of information which is prohibited by or under any enactment, or by court order.

Regulation 24 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Receive safe and coordinated care, treatment and support where more than one provider is involved, or they are moved between services.

This is because providers who comply with the regulations will:

- Cooperate with others involved in the care, treatment and support of a person who uses services when the provider responsibility is shared or transferred to one or more services, individuals, teams or agencies.
- Share information in a confidential manner with all relevant services, individuals, teams or agencies to enable the care, treatment and support needs of people who uses services to be met.
- Work with other services, individuals, teams or agencies to respond to emergency situations.
- Support people who use services to access other health and social care services they need.

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers. For the purposes of this guidance, the term ‘individual’ includes carers or others acting on behalf of the person using the service. This is because the providers must cooperate on the provision of services with those other people as well as with other providers.

Ensure personalised care through adequate coordination of services

6A

People who use services can be confident that when their care, treatment or support is provided by more than one service, team, individual or agency, or is transferred from one service, team, individual or agency to another, this is organised so that:

- A lead is always identified who is responsible for coordinating the care, treatment and support of the person who uses services.
- The person who uses services is aware of who the lead is and how to contact them.
- The plan of care includes arrangements for when a person who received care, treatment or support transfers between services.

- Each of their assessed needs is met by the service, team, individual or agency that is accountable for doing so; ensuring, in total, that all those needs are met.
- All those involved in the care, treatment and support of the person who uses services:
 - cooperate with the planning and provision of care, treatment and support
 - have the documented plan of care available to them
 - have relevant information about the person who uses services available, where it has a direct bearing on the quality and safety of the care, treatment and support being delivered
 - record the key points of the care, treatment and support they have given
 - enable relevant information to be accessed in time to ensure that the needs of the person who uses services continue to be met.

6B

People who use services can be confident that when information about their care, treatment and support needs to be passed to another service, team, individual or agency, this is organised so that:

- The information includes everything the other service, individual, team or agency will need to ensure the needs of the person who uses services are met safely, even when the transfer of information is required urgently. As a minimum this includes:
 - their name
 - gender
 - date of birth
 - address
 - unique identification number where one exists
 - emergency contact details
 - any person(s) acting on behalf the person who uses services, with contact details if available
 - records of care, treatment and support provided up to the point of transfer
 - assessed needs
 - known preferences and any relevant diverse needs
 - previous medical history that is relevant to the person's current needs, including general practitioner's contact details
 - any infection that needs to be managed
 - any medicine they need to take

- any allergies they have
- key contact in the service the person is leaving
- reason for transferring to the new service
- any advance decision
- any assessed risk of suicide and homicide and harm to self and others.
- The information is transferred in time to make sure that there is no delay to the assessment of needs by the other service, team, individual or agency.
- There are no interruptions to the continuity of care, treatment and support for the person who uses services.

Lead effectively to manage risk

6C

People who use services can be confident that when more than one service, team, individual or agency is involved at the same time in their care, treatment and support, or are planned to be in the future, the services provided are organised so that:

- All those involved understand which service has the coordinating role and who is responsible for each element of care, treatment and support to be delivered.
- Each service, team, individual or agency is involved when the plan of care is reviewed or brought up to date.
- Where appropriate, all those involved discuss together the plan of care for the person who uses services.
- It takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

6D

People who use services benefit from a service that:

- Wherever it is required, has in place a planned and prepared response to major incident and emergency situations. This prepared response should include arrangements for sharing information with other providers, provision of mutual aid and arrangements for engagement with appropriate emergency planning and civil resilience partners across the local area.
- Is aware of and has arrangements in place to respond to any requirements made of the provider by the Civil Contingencies Act 2004.
- In partnership, practises, monitors and reviews all of the plans that are in place.

6E

People who use services can be confident that when more than one service, team, individual or agency is involved at the same time in their care, treatment and support or are planned to be in the future, the transfer of information is organised so that:

- The confidentiality of people who use services is protected.
- Information is transferred safely and securely.
- Where appropriate, the way in which information is documented, copied, stored and transferred to the other service has been agreed previously between the services, in line with laws that relate to the safe handling of information.
- Staff know the ways that are acceptable for transferring information.
- Information is transferred that:
 - is relevant to the continuing safe delivery of care, treatment and support
 - is factual, correct and does not include subjective opinions about the person
 - can be shared in line with the Data Protection Act 1998 and other relevant guidance.
- Staff notify their line manager if information has been lost or transferred incorrectly.
- There are clear procedures followed in practice, monitored and reviewed about the action to be taken when confidential information is inappropriately shared or stored or is lost. These procedures should include the requirement to inform the person who uses services if their information is transferred or shared inappropriately or lost.
- When information relates to a safeguarding allegation, or where disclosure is in the wider public interest for another reason, the disclosure is made in accordance with relevant legislation and guidance. As far as possible the consent of the person(s) whose information is to be disclosed should be obtained.
- Where the service cannot obtain consent, it is clear about the reasons and the necessity for sharing.

Promote rights and choices

6F

People who use services can be confident that when more than one service, team, individual or agency are involved at the same time in their care, treatment and support, or are planned to be in the future, the services provided are organised so that:

- The person who uses the service knows who to contact about their needs and if the needs are not being met.

6G

People who use services can be confident that when information about their care, treatment and support is, or needs to be, passed to another service, team, individual or agency, this is organised so that the person or others acting on their behalf:

- Are aware of the information about them that is being transferred.
- Can be provided with a copy of the information transferred if they want it.

6H

People who use services know that they:

- Can request information to be transferred to another service and that the service agrees to transfer the information requested unless there is a good reason why they cannot. If so, that reason is fully explained.

6I

People who use services are supported to access the care, treatment and support they need by a provider who:

- Makes them aware of other available health and social care services or support relevant to their care, treatment and support.
- Helps them to approach, or make a formal referral to, any other health and social care service or support they want to access, and that are relevant to their needs.
- Enables them, as far as possible, to access other health and social care services or support relevant to their care, treatment and support needs, provided that their care, treatment and support will not be compromised.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

6J

People who use rehabilitation or treatment services for substance misuse who are provided with accommodation when they use the service:

- Are able to register with a general practitioner, dentist and any other health service they may require, as far as possible of their choice depending on the length of the treatment programme.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
RHS	RSM ✓	SHL	SLS	SMC	SPC	UCS

6K

People who use services:

- Are able to register with a general practitioner, dentist and any other health service they may require, as far as possible of their choice.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL ✓	SLS	SMC	SPC ✓	UCS

6L

People with mental health needs who use services:

- Are, where necessary, supported by local multi-agency public protection arrangements to protect themselves and others from harm.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC ✓	LTC	MBS	MHC ✓	MLS ✓	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

6M

When children who use services are moving to access adult services, these are organised so that:

- All those involved in the care, treatment and support cooperate with the planning and provision to ensure that the services provided continue to be appropriate to the age and needs of the person who uses services.
- Children and those acting on their behalf are involved in and informed about the move to adult care, treatment and support.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC ✓	CHN	CHS	DCC ✓
DCS ✓	DEN ✓	DSS	DTS ✓	EXC	HBC ✓	HPS ✓
LDC ✓	LTC ✓	MBS ✓	MHC ✓	MLS ✓	PHS ✓	RCA
RHS ✓	RSM	SHL	SLS	SMC ✓	SPC ✓	UCS

6N

People who use rehabilitation or treatment services for substance misuse will benefit from teams, individuals and/or agencies who:

- Assess at an early stage of their treatment, their need for services to support their reintegration into the wider community (including housing, employment, education and training services).

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
RHS	RSM ✓	SHL	SLS	SMC	SPC	UCS

Safeguarding and safety

This section looks at what providers should do to make sure that people who use the service, workers and others who visit are as safe as they can be and that risks are managed. It looks at what the provider needs to do to ensure that the human rights and dignity of people who use services are respected and how they should identify and respond when people are in vulnerable situations.

It also looks at the things providers should do to make sure that the premises and equipment they use to provide care, treatment and support are safe and suitable.

This section covers guidance about compliance for:

7. Safeguarding people who use services from abuse
8. Cleanliness and infection control
9. Management of medicines
10. Safety and suitability of premises
11. Safety, availability and suitability of equipment.



Outcome 7: Safeguarding people who use services from abuse

Regulation



What do the regulations say?

Safeguarding service users from abuse

11.—(1) The registered person must make suitable arrangements to ensure that service users are safeguarded against the risk of abuse by means of—

- (a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
- (b) responding appropriately to any allegation of abuse.

(2) Where any form of control or restraint is used in the carrying on of the regulated activity, the registered person must have suitable arrangements in place to protect service users against the risk of such control or restraint being—

- (a) unlawful; or
- (b) otherwise excessive.

(3) For the purposes of paragraph (1), “abuse”, in relation to a service user, means—

- (a) sexual abuse;
- (b) physical or psychological ill-treatment;
- (c) theft, misuse or misappropriation of money or property; or
- (d) neglect and acts of omission which cause harm or place at risk of harm.

Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Are protected from abuse, or the risk of abuse, and their human rights are respected and upheld.

This is because providers who comply with the regulations will:

- Take action to identify and prevent abuse from happening in a service.
- Respond appropriately when it is suspected that abuse has occurred or is at risk of occurring.
- Ensure that Government and local guidance about safeguarding people from abuse is accessible to all staff and put into practice.
- Make sure that the use of restraint is always appropriate, reasonable, proportionate and justifiable to that individual.
- Only use de-escalation or restraint in a way that respects dignity and protects human rights, and where possible respects the preferences of people who use services.
- Understand how diversity, beliefs and values of people who use services may influence the identification, prevention and response to safeguarding concerns.
- Protect others from the negative effect of any behaviour by people who use services.
- Where applicable, only use Deprivation of Liberty Safeguards when it is in the best interests of the person who uses the service and in accordance with the Mental Capacity Act 2005.

Prompts



7A

Prompts for all providers to consider

Lead effectively to reduce the potential of abuse

People receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur. The provider minimises the risk and likelihood of abuse occurring by:

- Ensuring that staff and people who use services understand the aspects of the safeguarding processes that are relevant to them.
- Ensuring that staff understand the signs of abuse and raise this with the right person when those signs are noticed.

- Ensuring that people who use services are aware of how to raise concerns of abuse.
- Having effective means to monitor and review incidents, concerns and complaints that have the potential to become an abuse or safeguarding concern.
- Having effective means of receiving and acting upon feedback from people who use services and any other person.
- Taking action immediately to ensure that any abuse identified is stopped and suspected abuse is addressed by:
 - having clear procedures followed in practice, monitored and reviewed that take account of relevant legislation and guidance for the management of alleged abuse
 - separating the alleged abuser from the person who uses services and others who may be at risk or managing the risk by removing the opportunity for abuse to occur, where this is within the control of the provider
 - reporting the alleged abuse to the appropriate authority
 - reviewing the person's plan of care to ensure that they are properly supported following the alleged abuse incident.
- Using information from safeguarding concerns to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.

7B

People who use services benefit from a service that:

- Works collaboratively with other services, teams, individuals and agencies in relation to all safeguarding matters and has safeguarding policies that link with local authority policies.
- Participate in local safeguarding children boards where required and understand their responsibilities and the responsibilities of others in line with the Children Act 2004.
- Participate in safeguarding adult boards where required.
- Has clear procedures followed in practice, monitored and reviewed in place about the use of restraint and safeguarding.
- Takes into account relevant guidance set out in the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

7C

People who use services are protected as staff and others involved in carrying on the regulated activity are not:

- Able to benefit financially or inappropriately gain from a person who uses services; unless it is in line with their service's arrangements, which should take account of other relevant professional guidance.

Outcome 7: Safeguarding people who use services from abuse

- Involved in writing wills or bequests of people who use services.
- Able to use property of people who use services for personal use.
- Able to borrow money from, or lend money to, people who use services.
- Able to sell or dispose of goods belonging to people who use services for their own gain.

Ensure personalised care

7D

People who use services receive care, treatment and support from all staff who:

- Are committed to maximising people's choice, control and inclusion and protecting their human rights as important ways of meeting their individual needs and reducing the potential for abuse.
- Recognise their personal responsibility in safeguarding people who use services.

7E

People who use services receive care, treatment and support from staff who, in relation to safeguarding:

- Know how to identify, report and respond appropriately to suspected or actual abuse because there are clear procedures that are followed in practice, monitored and reviewed.
- Recognise the impact that diversity, beliefs and values of people who use services can have.
- Are aware of and understand what abuse is, including the differences between supporting children and adults who are at risk of abuse.
- Understand the risk factors for abuse and what they must do if a person is being abused, suspected of being abused, is at risk of abuse or has been abused.
- Follow the referral process and timescales as described in all relevant local and national multi-agency procedures when responding to suspected abuse. They will take account of circumstances of the person using the service to identify and respond appropriately to other potential risk of abuse.
- Understand the roles of other organisations who may be involved in responding to suspected abuse to the extent that is appropriate to their role.
- Contribute to actions required including sharing information and attending forums.
- Work collaboratively with all relevant services, teams and agencies to safeguard and protect the welfare of people who use services.

7

- Cooperate and work collaboratively with all relevant services, teams and agencies during any investigative process.
- Take part in regular reviews of the care, treatment and support outcomes against specific plans for people who use services.
- Are confident to report any suspicions without fear that they will suffer as a result.
- Are confident to report concerns without worrying about consequences, as they are aware of their rights under the Public Interest Disclosure Act 1998.
- Follow the protection plan agreed through the multi-agency procedures in order to reduce the risk of further abuse after an actual or suspected case of abuse.

7F

People who use services receive care, treatment and support from all staff who, in relation to restraint:

- Know and understand the different forms that restraint can take.
- Understand when different types of restraint are or are not appropriate, prioritising de-escalation or positive behaviour support over restraint wherever possible.
- Understand that restraint should be used in a way that respects dignity and protects human rights wherever possible.
- Know whether and what type of restraint is permitted in the service in which they are working.
- Understand that restraint should only be used as a last resort, and that the type of restraint used should be the least restrictive and for the minimum amount of time to ensure that harm is prevented and that the person, and others around them, are safe.

7G

People who use services receive care, treatment and support from staff who, in relation to responding to behaviour that presents a risk to themselves or others:

- Understand the value of a stimulating environment, meaningful activity and effective communication in preventing behaviour that presents a risk, taking into account that over-stimulation can sometimes adversely impact the behaviour of people who use services.
- Understand what can potentially trigger behaviour that presents a risk for each person or to others.
- Have the skills and knowledge to respond at an early stage and do so to reduce the likelihood of this behaviour happening or recurring.
- Respond in a person-centred way.

Outcome 7: Safeguarding people who use services from abuse

- Have the opportunities to talk about how they prevent and manage behaviour with others so that learning is shared and the risk of further incidents is reduced.

7H

People who use services benefit from practice where the use of restraint and management of behaviour that presents a risk is:

- Always risk assessed to ensure the appropriate techniques are used.
- Practised in a way that protects the dignity and respect of people who use services and protects their human rights.
- Discussed, agreed and documented in advance, wherever possible, with the person who uses services as part of the processes for planning care.
- Identified and documented in a plan that sets out preferred measures to prevent and minimise the use of restraint, which is reviewed as the person's needs change.
- Used as a last resort and is the minimum response necessary for the shortest possible time, to make them and others as safe as possible.
- Recorded.
- Where applicable, used in line with the restraint guidelines in the Mental Capacity Act 2005 Code of Practice and the Mental Health Act 1983 Code of Practice and including a best interest assessment.
- Followed by an assessment whenever restraint is used of the person restrained and others involved in restraint for signs of injury and any emotional or psychological impact.

7I

People who use services that have been abused or are suspected of being abused (or where appropriate, people acting on their behalf) are:

- Taken seriously and treated with dignity and respect when they report abuse.
- Provided with appropriate help and support to report abuse.
- Supported by the service to take part in the safeguarding process to the extent to which they want or are able to, or to which the process allows. They are kept informed of progress.
- Made aware of, and supported to access, sources of support outside the service including local independent information advice, independent mental capacity advocacy services or independent mental health advocacy services where relevant.
- Provided with support, or given information about how they can obtain support, for as long as they need it.
- Confident that their care, treatment and support will not be compromised if they raise issues of abuse.

Promote rights and choices

7J

People who use services have access to information about:

- What abuse is and how to recognise the signs.
- What they should do if they or another person are being abused or suspect abuse, including relevant contact details under the local safeguarding procedures.
- What they might expect to happen when a referral is made under the local safeguarding procedures.

7K

People who use services:

- Can be confident that information about a safeguarding concern is appropriately shared in line with multi-agency procedures, taking into account the sensitive nature of the information.
- Can be assured that safeguarding procedures are delivered in a way that protects people's human rights, including their human rights to life and not to be treated in an inhuman or degrading way.
- Are confident that staff required to use restrictive physical interventions have received specialist training.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to "Step 2: Select your service types" on page 13, to make sure that you identify which service types apply to you.

7L

People who use services are confident:

- That where they are not covered by the Mental Health Act 2007, the service will, if allowed by legislation, only request authorisation under the Mental Capacity Act 2005 Deprivation of Liberty Safeguards, when it is in the best interests of the person who uses services and that person lacks capacity.
- The service will implement and review any subsequent authorisation in line with guidance.

Outcome 7: Safeguarding people who use services from abuse

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC
	DCS	DEN	DSS	DTS	EXC	HBC	HPS
	LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
	RHS	RSM	SHL	SLS	SMC	SPC	UCS

7M

People who use services know that where the service looks after people's money and valuables:

- Individualised records (including receipts) are kept showing details of all income received, money spent and valuables held.
- They are not used by the service for the running or management of the service.
- The manager only becomes their agent where there is no suitable person outside the service available to undertake that role.
- They can access their money and valuables in a timely way.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC
	DCS	DEN	DSS	DTS	EXC	HBC	HPS
	LDC ✓	LTC	MBS	MHC	MLS ✓	PHS	RCA
	RHS	RSM ✓	SHL	SLS	SMC	SPC ✓	UCS

7N

People who use services know that where the service looks after people's money and valuables:

- They are not used by the service for the running or the management of the service.
- The Shared Lives carer will only become their agent where there is no suitable person outside the service available to undertake that role.
- They can access their money and valuables in a timely way.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL ✓	SLS	SMC	SPC	UCS

70

People who use services can be confident that staff, and others involved in carrying on the regulated activity, will not:

- Take any person (including children) or pets into the home of the person using the service without their permission and that of the manager of the service.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC ✓
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL ✓	SLS ✓	SMC	SPC ✓	UCS

7P

People who use services can be confident that rapid tranquilisation will only be used if it is:

- Undertaken in line with evidence based guidelines including the National Institute for Health and Clinical Excellence’s clinical guideline on *Violence: The short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments* (2005).

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS ✓	PHS ✓	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

7Q

People who use services are protected from the risk and likelihood of abuse because staff:

- Assess the risk and history of abuse and the person's vulnerability to abuse, including predatory behaviour or sexual vulnerability.
- Manage any identified risks to the person using the service and others.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC ✓	LTC	MBS	MHC ✓	MLS ✓	PHS ✓	RCA
RHS	RSM ✓	SHL	SLS	SMC	SPC	UCS

Outcome 8: Cleanliness and infection control

Regulation



What do the regulations say?

Cleanliness and infection control

12.—(1) The registered person must, so far as reasonably practicable, ensure that—

- (a) service users;
- (b) persons employed for the purpose of the carrying on of the regulated activity; and
- (c) others who may be at risk of exposure to a health care associated infection arising from the carrying on of the regulated activity, are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

(2) The means referred to in paragraph (1) are—

- (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;
- (b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and
- (c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—
 - (i) premises occupied for the purpose of carrying on the regulated activity,
 - (ii) equipment and reusable medical devices used for the purpose of carrying on the regulated activity, and
 - (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection.

Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



Cleanliness and infection control

Providers of services comply with the requirements of regulation 12, with regard to the *Code of Practice for health and adult social care on the prevention and control of infections and related guidance*.

We are not required by the Act to produce guidance about the prevention or control of healthcare-associated infections. In this publication, there is no guidance about regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. The guidance is available in the Department of Health's publication: *The Code of Practice for health and adult social care on the prevention and control of infections and related guidance*.

Outcome 9: Management of medicines

Regulation →



What do the regulations say?

Management of medicines

13. The registered person must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity.

Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome →



What should people who use services experience?

People who use services:

- Will have their medicines at the times they need them, and in a safe way.
- Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

This is because providers who comply with the regulations will:

- Handle medicines safely, securely and appropriately.
- Ensure that medicines are prescribed and given by people safely.
- Follow published guidance about how to use medicines safely.

Prompts



Prompts for all providers to consider

Providing personalised care through the effective use of medicines

9A

People who use services receive care, treatment and support that:

- Ensures the medicines given are appropriate and person-centred by taking account of their:
 - age
 - choices
 - lifestyle
 - cultural and religious beliefs
 - allergies and intolerances
 - existing medical conditions and prescriptions
 - adverse drug reactions
 - recommended prescribing regimes.
- Ensures the person's prescription for medicines, for which the service is responsible, is up to date and is reviewed and changed as their needs or condition changes.
- Includes monitoring the effect of their medicines and action when necessary if their condition changes, including side effects and adverse reactions.
- Includes supporting and reminding them to self-administer their medicines independently where they are able and wish to do so by minimising the risk of incorrect administration.
- Follows clear procedures in practice, which are monitored and reviewed, which explain how up-to-date medicines information and clinical reference sources for staff are made available.

Manage risk through effective procedures about medicines handling

9B

Where people who use services receive care, treatment and support that involves medicines, the provider has:

- Clear procedures followed in practice, monitored and reviewed for medicines handling that include obtaining, safe storage, prescribing, dispensing, preparation, administration, monitoring and disposal. Wherever they are required these procedures include:
 - how medicines which are prescribed 'as required' (PRN) are handled and used

- ensuring that staff handling medicines have the competency and skills needed
- the arrangements for giving medicines covertly where this is needed in accordance with the Mental Capacity Act 2005
- the arrangements for requesting a second opinion in relation to medicines for people detained under the Mental Health Act 1983
- the arrangements for recording when it is not possible for a person to be able to self-administer their medicines
- the recording of when medicines are given to the person
- the arrangements for reporting adverse events, adverse drug reactions, incidents, errors and near misses. These should encourage local and, where applicable, national reporting, learning and promoting an open and fair culture of safety
- the arrangements to implement and act upon the recommendations of all relevant medicine-related patient safety communications issued via alert systems within the required timescales
- an up-to-date list of medicines taken by the person being produced when they begin to use the service
- the management of discharge medicine to allow for continuity of care until a new arrangement is made
- the arrangements for medicines management following death.
- Clear procedures, that are followed in practice, monitored and reviewed, for controlled drugs, unless they are taken by the person themselves in their own home, including:
 - investigations about adverse events, incidents, errors and near misses
 - sharing concerns about mishandling.
- Systems in place to reflect on the findings of their service reviews and as it does so, learns from adverse events, incidents, errors and near misses relating to medicines that have occurred within the service and elsewhere, so that the risk of them being repeated is reduced to a minimum.
- Systems in place to ensure they comply with the requirements of the Medicines Act 1968 and the Misuse of Drugs Act 1971, and their associated regulations, the Safer Management of Controlled Drugs Regulations 2006, relevant health technical memoranda and professional guidance from the Royal Pharmaceutical Society of Great Britain and other relevant professional bodies and agencies.

9C

People who use services benefit from a service that:

- Takes into account relevant guidance set out in the Care Quality Commission’s Schedule of Applicable Publications (see appendix B).

Promote rights and choices

9D

People who use services benefit from a service that:

- Ensures that wherever possible, information is available for people about the medicines they are taking, including the risks.
- Ensures information is available for people about medicines advisable for them to take for their health and wellbeing and also to prevent ill health.
- Ensures there is access for staff to up-to-date legislation and guidance related to medicines handling.
- Ensures best interest meetings are held with people who know and understand the person using the services when covert administration of medicines is being considered, to decide whether this is in the person’s best interest.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

9E

People who use services detained under the Mental Health Act 1983:

- Receive medicines that are duly authorised and administered in line with the Mental Health Act 1983 Code of Practice.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

9F People who use services receive care, treatment and support that:

- Follows clear procedures in practice, which are monitored and reviewed and that explain how staff may be permitted to administer homely remedies.

9G Where people who use services receive support with their medicines, the provider has:

- Additional clear procedures followed in practice, monitored and reviewed for medicines handling that include obtaining, administration, monitoring and disposal. Wherever they are required these procedures include:
 - how clinical trials are carried out in line with relevant laws, current guidelines and ethics committee approval
 - sharing concerns about medicines handling.
- Established arrangements for obtaining pharmaceutical information by a person who understands the care, treatment or support that is provided by the service.

9H People who use services receive care, treatment and support that:

- Ensures medicines required for resuscitation or other medical emergencies are accessible in tamper evident packaging that allows them to be administered as quickly as possible.

The guidance in 9F, 9G and 9H applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB ✓	BTS	CHC	CHN ✓	CHS ✓	DCC
	DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC ✓	HPS ✓
	LDC	LTC ✓	MBS ✓	MHC	MLS ✓	PHS ✓	RCA
	RHS ✓	RSM ✓	SHL	SLS	SMC	SPC ✓	UCS ✓

9I People who use services receive care, treatment and support from staff who:

- Ensure they make a record of any medication taken or reminded by the person using the service where this is part of the plan of care.
- Follow clear procedures, that are monitored and reviewed, that explain:
 - their role with regards to helping people take their medicines
 - what staff should do if the person using services is unable, or refuses, to take their medicines.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC ✓
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS ✓	SMC	SPC	UCS

9J

People who use services receive care, treatment and support from staff who:

- Ensure that patient safety alerts, rapid response reports and patient safety recommendations disseminated by the National Patient Safety Agency and which require action are acted upon within required timescales.

This guidance applies to the service types ticked below:

ACS ✓	AMB ✓	BTS ✓	CHC ✓	CHN	CHS	DCC
DCS ✓	DEN	DSS ✓	DTS ✓	EXC	HBC	HPS
LDC ✓	LTC	MBS ✓	MHC ✓	MLS ✓	PHS	RCA
RHS ✓	RSM	SHL	SLS	SMC ✓	SPC	UCS ✓

Outcome 10: Safety and suitability of premises

Regulation



What do the regulations say?

Safety and suitability of premises

15.—(1) The registered person must ensure that service users and others having access to premises where a regulated activity is carried on are protected against the risks associated with unsafe or unsuitable premises, by means of—

- (a) suitable design and layout;
- (b) appropriate measures in relation to the security of the premises; and
- (c) adequate maintenance and, where applicable, the proper—
 - (i) operation of the premises, and
 - (ii) use of any surrounding grounds,

which are owned or occupied by the service provider in connection with the carrying on of the regulated activity.

(2) In paragraph (1), the term “premises where a regulated activity is carried on” does not include a service user’s own home.

Regulation 15 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services and people who work in or visit the premises:

- Are in safe, accessible surroundings that promote their wellbeing.

This is because providers who comply with the regulations will:

- Make sure that people who use services, staff and others know they are protected against the risks of unsafe or unsuitable premises by:
 - the design and layout of the premises being suitable for carrying out the regulated activity
 - appropriate measures being in place to ensure the security of the premises
 - the premises and any grounds being adequately maintained
 - compliance with any legal requirements relating to the premises
- Take account of any relevant design, technical and operational standards and manage all risks in relation to the premises.

10

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers except where care, treatment and support is delivered in a person's own home.

Ensure the premises are adequate

10A

People who use services and others who work in or visit the premises can be confident that in relation to design and layout, the provider:

- Ensures the premises are suitable for the regulated activity.
- Takes account of identified risks.
- Meets the requirements of the Health and Safety at Work Act 1974 and associated regulations and the Regulatory Reform (Fire Safety) Order 2005 and other relevant legislation.
- Ensures the premises protect people's rights to privacy, dignity, choice, autonomy and safety.
- Ensures the premises have space, heating, lighting and ventilation that conform to relevant and recognised standards.

- Ensures the premises are accessible to people who need to enter the premises and meet the appropriate requirements of the Disability Discrimination Act 1995.
- Ensures the premises are free from preventable offensive odours.
- Ensures the premises are designed and operated in a way that takes account of guidance from expert bodies in relation to specific needs.
- Takes account of the safety needs of people who enter or use the premises, including the safety of children and other vulnerable people where they are permitted to enter.
- Ensures there is space for a relative, carer or friend to be able to be with a child who uses services.
- Ensures that all safety precautions are in place and tested with regard to all specialist equipment and engineering systems that are physically fixed to the premises.
- Ensures care is taken to maintain a suitable and comfortable environment for treatment having regard to the impact from equipment in use.
- Ensures the premises reflect Department of Health published guidance.

Lead effectively to manage risk about the premises

10B

People who work, visit or use services can be confident that, in relation to design and layout:

- Medical gas cylinders and pipe lines are properly installed and maintained in accordance with manufacturers' instructions and patient safety communications relating to these are followed.
- There are arrangements and licences in place for the safe collection, classification, segregation, storage, handling, transport, treatment and disposal of clinical waste in line with current waste legislation.
- Arrangements are in place to meet the Control of Substances Hazardous to Health Regulations 2002 as amended.
- Where premises are altered or their use is changed, the continued safety and suitability of the premises is assessed.

10C

People who work, visit or use services can be confident that, in relation to security of premises and grounds:

- There is a risk assessment of unauthorised access relevant to the type of premises, the services provided and the nature of people who use those services, and they implement and review procedures to take account of the risk assessment.
- Security arrangements are in place to protect people who use services and others who have access to the premises and any associated grounds.
- Measures are in place to protect the personal possessions of people who use services.

10D

People who work, visit or use services can be confident that, in relation to maintenance of premises and grounds, renewal and service continuity:

- There are clear procedures, followed in practice, monitored and reviewed, which cover:
 - how the premises are maintained
 - the identification, assessment, management and review of risks
 - where necessary the prevention, collection, storage, handling, transport, treatment and disposal of waste.
- Plans are developed and implemented for the adaptation of the premises in response to changes in:
 - the needs of people who use services
 - design, technical and operational guidance issued by appropriate expert bodies
 - how the service intends to provide regulated activities
 - relevant legislation.
- Appropriate risk assessments are undertaken regarding the safety and suitability of the premises, when the provider is not responsible for the premises in which the care, treatment and support is delivered.
- Relevant guidance is taken into account, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

10E

People who use services, and staff understand:

- What to do in the event of an emergency.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

10F

People who use services and others who work in or visit the premises can be confident that in relation to design and layout, the premises:

- Are designed and adapted so that people can move around and be as independent as possible in activities of daily living, and meet the appropriate requirements of the Disability Discrimination Act 1995.
- Have safe and secure storage facilities, including storage for the private belongings of people who use services.
- Have sufficient toilets, and where necessary bathroom and bathing facilities, that take into account people’s diverse needs and promote their privacy, dignity and independence.
- Have access to facilities for infant feeding, including facilities to support breastfeeding.
- Have call alarm systems that enable people who use services to get help when their mobility is limited for whatever reason.
- Have a system to enable staff to summon urgent assistance.
- Have somewhere private available for breaking bad news, where this is done.

10G

People who work, visit or use services can be confident that, in relation to design and layout:

- The management of electrical, heating, safety and building facilities complies with statutory requirements and manufacturers’ instructions and are managed to minimise risk.
- There are fully planned and practised fire evacuation procedures.

10H

People who work, visit or use services can be confident that, in relation to maintenance and renewal:

- There are clear procedures, followed in practice, monitored and reviewed, which cover:
 - what will happen in the event of electricity, water or gas supply failure
 - what will happen in the event of a fire or flooding
 - other emergencies that occur on the premises

Outcome 10: Safety and suitability of premises

- how the situation will be managed should IT or communication systems, which are integral to the premises, fail.
- There are systems in place to ensure that the décor of the building is maintained and refreshed.
- The management of risk includes the prevention and control of Legionella.

The guidance in 10F, 10G and 10H applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB	BTS	CHC ✓	CHN ✓	CHS ✓	DCC
	DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC ✓	HPS ✓
	LDC ✓	LTC ✓	MBS	MHC ✓	MLS ✓	PHS ✓	RCA
	RHS ✓	RSM ✓	SHL	SLS	SMC ✓	SPC ✓	UCS ✓

10I

People who use services and others who work in, or visit the premises can be confident that in relation to design and layout, the premises:

- Have space for social, therapeutic, cultural, educational and play activities that meet the needs of people who use services.
- Have space for a relative, carer or friend to be able to stay with the person using the service at the end of their life.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB	BTS	CHC ✓	CHN ✓	CHS ✓	DCC
	DCS	DEN	DSS	DTS ✓	EXC	HBC	HPS ✓
	LDC ✓	LTC ✓	MBS	MHC ✓	MLS ✓	PHS	RCA
	RHS ✓	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS

10J

People who work visit or use services can be confident that:

- Facilities exist and are maintained in line with legislation for the safe handling of radionuclides required for scanning and treatment.

This guidance applies to the service types ticked below:

<input type="checkbox"/>	ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
	DCS	DEN	DSS ✓	DTS	EXC	HBC	HPS
	LDC	LTC	MBS	MHC	MLS	PHS	RCA
	RHS	RSM	SHL	SLS	SMC	SPC	UCS

10

10K

People who use services can be confident that the staff caring for them are able to work effectively, because:

- Where they remain on the premises, staff on call have adequate facilities that ensure comfort, privacy and the ability to rest properly, and have access to a telephone connected to the premises' network.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS ✓
LDC	LTC	MBS	MHC	MLS ✓	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

10L

People who use the service have bedrooms that:

- Are single occupancy except where two people have made a positive choice to share. (Pre-existing care homes, which provided at least 80% of places in single rooms as at 16 August 2002, may continue to do so. Where they did not provide that percentage of places in single rooms as at that date, they provide at least the same percentage of places in single rooms as they provided as at 31 March 2002.)
- Are of a size and shape that supports their lifestyle, care, treatment and support needs and enables access for care, treatment and support and equipment.
- They can personalise and in which they can make choices about their environment, including temperature, furnishings and decor.
- For new build care homes and other care homes seeking to register for the first time, are no smaller than 12 square metres.
- For existing care homes, are no smaller than they were as at 31 March 2010.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

10M

People who use services have:

- Access to outdoor space; this could be outdoor areas, gardens or grounds that allow individuals to benefit from being outside.
- Access to communal rooms that are of sufficient size, and that provide opportunities to comfortably participate in social, therapeutic, cultural, daily living or educational activities, either individually or with others.
- Access to toilets, baths and showers that enable people to maintain privacy and dignity that are in close proximity to their living areas.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS ✓
LDC ✓	LTC	MBS	MHC	MLS ✓	PHS	RCA
RHS ✓	RSM ✓	SHL	SLS	SMC	SPC	UCS

10N

People who use services are able to access support from the service because:

- There are clear contingency procedures followed in practice, monitored and reviewed, should the communication systems that the service uses to enable people to access it, fail.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS ✓	MHC	MLS	PHS	RCA ✓
RHS	RSM	SHL	SLS	SMC	SPC	UCS

100

People who use services receive care, treatment and support provided in a vehicle that:

- Complies with any legal standards for safety, suitability and insurance that apply.
- Is operated and maintained in line with legislation and the manufacturer’s recommendations.

This guidance applies to the service types ticked below:

ACS	AMB ✓	BTS ✓	CHC	CHN	CHS	DCC
DCS	DEN	DSS ✓	DTS	EXC	HBC	HPS
LDC	LTC	MBS ✓	MHC	MLS	PHS	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

10P

People who use services are protected from harm because:

- Appropriate building components, such as glass alternatives, are used that reduce the risk of self-harm.
- Fixtures, fittings and furniture are designed with regard to the avoidance of ligature points.
- There is appropriate layout for observations of people who use services receiving acute mental health care, treatment and support.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC ✓	MLS ✓	PHS ✓	RCA
RHS	RSM ✓	SHL	SLS	SMC	SPC	UCS

Outcome 11: Safety, availability and suitability of equipment

Regulation



What do the regulations say?

Safety, availability and suitability of equipment

16.—(1) The registered person must make suitable arrangements to protect service users and others who may be at risk from the use of unsafe equipment by ensuring that equipment provided for the purposes of the carrying on of a regulated activity is—

- (a) properly maintained and suitable for its purpose; and
- (b) used correctly.

(2) The registered person must ensure that equipment is available in sufficient quantities in order to ensure the safety of service users and meet their assessed needs.

(3) Where equipment is provided to support service users in their day to day living, the registered person must ensure that, as far as reasonably practicable, such equipment promotes the independence and comfort of service users.

(4) For the purposes of this regulation—

- (a) “equipment” includes a medical device; and
- (b) “medical device” has the same meaning as in the Medical Devices Regulations 2002.

Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services and people who work in or visit the premises:

- Are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings).
- Benefit from equipment that is comfortable and meets their needs.

This is because providers who comply with the regulations will:

- Make sure that equipment:
 - is suitable for its purpose
 - is available
 - is properly maintained
 - is used correctly and safely
 - promotes independence
 - is comfortable.
- Follow published guidance about how to use medical devices safely.

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers unless otherwise stated. The term 'equipment' always includes 'medical devices'.

Ensure equipment is adequate

11A

People are safe because, where equipment is provided or used as part of the regulated activity, the equipment is:

- Available in sufficient quantities to meet the needs of people who use the service.
- Safe to be used.
- Suitable for its stated purpose.
- Compliant with all relevant laws.
- Installed, used and maintained correctly with reference to the specifications, manufacturer's instructions, legislation and appropriate guidance from expert bodies.

- Properly maintained, tested, serviced and renewed under a recorded programme.
- Stored safely and securely to prevent theft, damage or misuse.

11B

People's needs are met because staff using any equipment do so in a way that has regard to their dignity, comfort and safety and promotes their independence by:

- Actively listening to their preferences and thoughts about the equipment they need and how it is used.
- Supporting the person to understand how and why the equipment is being used.
- Taking care in the way they use the equipment to make sure the person is comfortable and safe.
- Using the equipment in a way that ensures the person's privacy and dignity.

Manage risk through effective procedures about equipment suitability

11C

People are safe because, where equipment is provided as part of the regulated activity, there are clear procedures followed in practice, monitored and reviewed. Wherever necessary these include:

- Identification, assessment and review of risk.
- Where risks are identified, a plan for how these are to be managed.
- How the equipment is maintained and used.
- Ensuring that all staff involved in using the equipment have the competency and skills needed, and where this is not possible, know what to do to ensure the people remain safe.
- How staff will know what to do when a person who uses services refuses to allow use of the equipment.
- The arrangements for adverse events, incidents, errors and near miss reporting. These should encourage local and, where applicable, national reporting, learning and promoting an open and fair culture of safety.
- The training of people who use services about any equipment they are given to use themselves.
- Best interest meetings with people who know and understand the person using the services to ensure that treatment and care are taken that reflect the person's best interest.
- What will happen in the event of electricity, water or gas supply failure, or other emergencies, that affect the equipment used to meet the needs of people who use services.

11D

Where people who use services receive care, treatment or support that involves the use of medical devices, the provider has:

- Clear procedures that are followed in practice, monitored and reviewed for the use of medical devices. Wherever they are required these procedures include:
 - implementing guidance issued by experts or professional bodies in relation to the medical devices used
 - acting on alerts from an expert or professional body or a product manufacturer.

11E

People who use services receive care, treatment and support from a service that:

- Takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

Providing personalised care through the effective use of medical devices

11F

People who use services receive care, treatment and support that:

- Ensures the medical devices used to meet their needs are:
 - not reused if they are manufactured for single use only
 - only modified in line with manufacturer's instructions or guidance
 - only purchased if they meet the necessary legal requirements
 - available when they are required for use
 - supplied with the necessary technical information so that the risk of using them incorrectly is minimised
 - permanently installed where appropriate, in accordance with manufacturer's requirements and published guidance
 - only used by the person, or by staff, once they know how to use and operate them correctly
 - monitored while being used and action taken if they do not appear to be working correctly
 - routinely maintained in line with the manufacturer's instructions and by people who are competent to do so
 - repaired when they break down by people who are competent to do so
 - disposed of or recycled, safely and securely.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

11G

When equipment is used in a person’s own home:

- Staff address any concerns in a timely manner where they have identified problems around the safety of the equipment.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC ✓
DCS ✓	DEN ✓	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA ✓
RHS	RSM ✓	SHL ✓	SLS ✓	SMC	SPC	UCS

11H

People who use services receive care, treatment and support that:

- Ensures equipment required for resuscitation or other medical emergencies is available and accessible for use as quickly as possible. Where the service requires it, this equipment is tamper proof.

This guidance applies to the service types ticked below:

ACS ✓	AMB ✓	BTS	CHC ✓	CHN ✓	CHS	DCC
DCS	DEN ✓	DSS ✓	DTS ✓	EXC	HBC ✓	HPS ✓
LDC	LTC ✓	MBS ✓	MHC	MLS ✓	PHS ✓	RCA
RHS ✓	RSM ✓	SHL	SLS	SMC	SPC ✓	UCS ✓

Suitability of staffing

This section looks at what providers should do to make sure that they have the right staff with the right skills, qualifications, experience and knowledge to support people. It looks at training needs for staff and how they should be supported to carry out their role, including the time they will need away from work in order to take part in learning and development opportunities.

This section covers guidance about compliance for:

12. Requirements relating to workers
13. Staffing
14. Supporting workers.



Outcome 12: Requirements relating to workers

Regulation



What do the regulations say?

Requirements relating to workers

21. The registered person must—

- (a) operate effective recruitment procedures in order to ensure that no person is employed for the purposes of carrying on a regulated activity unless that person—
 - (i) is of good character,
 - (ii) has the qualifications, skills and experience which are necessary for the work to be performed, and
 - (iii) is physically and mentally fit for that work;
- (b) ensure that information specified in Schedule 3 is available in respect of a person employed for the purposes of carrying on a regulated activity, and such other information as is appropriate;
- (c) ensure that a person employed for the purposes of carrying on a regulated activity is registered with the relevant professional body where such registration is required by, or under, any enactment in relation to—
 - (i) the work that the person is to perform, or
 - (ii) the title that the person takes or uses; and
- (d) take appropriate steps in relation to a person who is no longer fit to work for the purposes of carrying on a regulated activity including—
 - (i) where the person is a health care professional, informing the body responsible for regulation of the health care profession in question, or
 - (ii) where the person is a social care worker registered with the General Social Care Council, informing the Council.

Regulation 21 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Are safe and their health and welfare needs are met by staff who are fit, appropriately qualified and are physically and mentally able to do their job.

This is because providers who comply with the regulations will:

- Have effective recruitment and selection procedures in place.
- Carry out relevant checks when they employ staff.
- Ensure that staff are registered with the relevant professional regulator or professional body where necessary and are allowed to work by that body.
- Refer staff who are thought to be no longer fit to work in health and adult social care, and meet the requirement for referral, to the appropriate bodies.

Prompts



Prompts for all providers to consider

Manage quality by employing the right people

People who use services benefit from staff (including volunteers, students, temporary and ancillary staff and practitioners working under practising privileges) who:

12A

In relation to recruitment:

- Are honest, reliable, trustworthy and treat the people who use services with respect.
- Are not discriminated against during the application or recruitment process.
- Are qualified and competent to carry out their role and meet the needs of people who use services.
- Have been subject to the necessary checks as described in Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, so that the provider is assured that the worker is suitable for their role.
- Have been subject to a check that they are registered with the Independent Safeguarding Authority (ISA):

- where they are undertaking a Safeguarding Vulnerable Groups Act 2006 “regulated activity” or “controlled activity”; and
- are required to be registered under the Scheme’s phasing-in arrangements.
- Are only allowed to start work before a full and satisfactory Criminal Records Bureau (CRB) check has been received where the provider has received an ISA Adult First check that confirms the staff member is not barred. In these circumstances the following safeguards are put in place:
 - an appropriately qualified and experienced member of staff is appointed to supervise them
 - wherever it is possible, this supervisor is on duty at the same time as the new worker, or is available to be consulted
 - new workers do not escort people away from the premises unless accompanied by a staff member for whom a full and satisfactory CRB check has been received.

This only applies to those staff who are employed to work with adults. Those working with children must wait for a full CRB disclosure before starting work.

- Have demonstrated that they are legally entitled to work in the United Kingdom.
- Have demonstrated they meet the same standards of competency, qualification and experience for the role where they are recruited from outside the United Kingdom as they would have had they been trained in the United Kingdom.
- Are currently registered with the relevant professional regulator and/or professional body where appropriate, and only use a protected professional title where their qualifications and registration allows them to do so.
- Are aware of and adhere to any codes of professional conduct that apply to them.
- Are physically and mentally able to carry out their role, with a plan of support including reasonable adjustment where necessary. This means staff:
 - are not placed at risk by the work they will do because of an illness or medical condition they have
 - do not present a risk to people who use services because of an illness or medical condition they have.
- Are able to communicate effectively with people who use services and other staff, to ensure that the care, treatment and support of people who use services is not compromised.

- Are clear about their responsibilities because they have an up-to-date job description.
- Are clear about the roles and responsibilities of other members of their team so that they know what they can expect from other staff.

12B

In relation to qualifications, knowledge, skills and experience:

- Have relevant qualifications, knowledge, skills and experience to carry out their role.
- Where this is not possible and does not impact on the safe delivery of the service the staff member agrees to work towards gaining the skills and qualifications necessary.
- Where trainees and students are working, they are only given tasks and provide care, treatment and support that is appropriate to the stage of their training and their competence.
- Have their qualifications, knowledge and skills reviewed on a regular basis to ensure they keep up to date with current practice.
- Have an awareness and knowledge of diversity and human rights and have the competencies to support, appropriate to their role, the diverse needs and human rights of people who use services.
- Have a good understanding of the communication needs of the people who use the service.
- Can identify and respond to the changing needs of people who use services.
- Are knowledgeable of the individual needs and preferences of the people who use the service.
- Understand the physical and emotional needs of people who use services.
- Recognise and promote the independence of people who use services.
- Are aware of the services' policies, procedures, legislation and standards.
- Know who they are able to contact, and how, when expert advice is needed.

Lead effectively to ensure staff are suitable for their role

12C

People who use services receive a service from a provider that has the right staff because:

- Staff are recruited following an effective recruitment and selection procedure that complies with legislation about employment, equalities and human rights. This includes as a minimum when recruiting new staff:
 - application process including all of the necessary checks
 - interview

- references
- records of the above.
- The recruitment and selection process ensures that staff are fit and physically and mentally able to perform their role.
- Temporary, agency, bank and voluntary staff, and any practitioner working under practising privileges, are subject to the same level of checks and a similar selection criteria as staff recruited directly.
- Other people providing additional services under arrangements made with the provider are subject to the necessary checks.
- Staff provided by an agency service are known to be fit and physically and mentally able to perform their role through:
 - confirmation in writing from the agency that all necessary checks have been carried out in relation to each staff member being supplied, including registration with the ISA in line with its phasing programme.
 - the provider quality monitoring the contract they have with the agency, where the agency is used on an ongoing basis.
- There are clear procedures followed in practice, monitored and reviewed, that are implemented when staff:
 - are not well enough to work
 - behave outside the policies and procedures of the service, or professional codes of conduct or practice that apply to them
 - should be referred to their professional regulator or professional body, as appropriate
 - are subject to investigations into suspected abuse
 - are reasonably suspected to have caused harm or risk of harm to people who use services, and this includes the requirement for the person to be referred to the Independent Safeguarding Authority and/or regulatory body where the requirements for referral are met
 - who are barred but are able to work in a Safeguarding Vulnerable Groups Act 2006 “controlled activity”. This includes the staff member being subject to tough safeguards including stringent supervision
 - require specific plans of support, including any reasonable adjustments, to enable them to carry out their job
 - are at risk of, or are, being exposed to physical, psychological or emotional hazards in the workplace in the course of their duties, and providing information about how those risks can be minimised.
- They take into account relevant guidance, including that from the Care Quality Commission’s Schedule of Applicable Publications (see appendix B).

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

12D

People who use services can be confident that:

- Staff are only allowed to start work before a full and satisfactory CRB check has been received where the provider has received an ISA Adult First check that confirms the staff member is not barred. In these circumstances the following additional safeguards are put in place:
 - the provider contacts people using the service, or others acting on their behalf, at weekly intervals to monitor their satisfaction with the care provided by the new worker and any complaints that may arise
 - the provider informs people using the service, or others acting on their behalf, about the outstanding information, and tells them when it is received
 - the provider ends the new worker’s contact with people using the service where the provider considers that the outstanding information (when received) is not satisfactory.

This only applies to those staff who are employed to work with adults. Those working with children must wait for a full CRB disclosure before starting work.

- Staff are recruited with the involvement of people who use services where it is possible to do so.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC ✓
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS
LDC ✓	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM	SHL ✓	SLS ✓	SMC	SPC ✓	UCS

Outcome 13: Staffing

Regulation →



What do the regulations say?

Staffing

22. In order to safeguard the health, safety and welfare of service users, the registered person must take appropriate steps to ensure that, at all times, there are sufficient numbers of suitably qualified, skilled and experienced persons employed for the purposes of carrying on the regulated activity.

Regulation 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome →



What should people who use services experience?

People who use services:

- Are safe and their health and welfare needs are met by sufficient numbers of appropriate staff.

This is because providers who comply with the regulations will:

- Make sure that there are sufficient staff with the right knowledge, experience, qualifications and skills to support people.

Prompts



Prompts for all providers to consider

Lead effectively to ensure there are sufficient staff

13A

People who use services benefit from sufficient staff to meet their needs because the provider:

- Can demonstrate that there are sufficient numbers of staff with the right competencies, knowledge, qualifications, skills and experience to meet the needs of people who use services at all times.
- Can show that as far as possible that there are enough staff who know the needs of people using the service, meaning that people who use services can expect a consistency of care.
- Is able to demonstrate that they have carried out a needs analysis and risk assessment as the basis for deciding sufficient staffing levels.
- Has management structures, systems and clear human resources procedures followed in practice, monitored and reviewed that enable the effective maintenance of staffing levels.
- Can respond to unexpected changing circumstances in the service, for example to cover sickness, vacancies, absences and emergencies.
- Can respond to expected changing circumstances in the service, with particular regard to planned service developments, workforce changes, staff training, planned absences and changes in legislation.
- Takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 14: Supporting workers

Regulation



What do the regulations say?

Supporting workers

23.—(1) The registered person must have suitable arrangements in place in order to ensure that persons employed for the purposes of carrying on the regulated activity are appropriately supported in relation to their responsibilities, to enable them to deliver care and treatment to service users safely and to an appropriate standard, including by—

- (a) receiving appropriate training, professional development, supervision and appraisal; and
- (b) being enabled, from time to time, to obtain further qualifications appropriate to the work they perform.

(2) Where the regulated activity carried on involves the provision of health care, the registered person must (as part of a system of clinical governance and audit) ensure that healthcare professionals employed for the purposes of carrying on the regulated activity are enabled to provide evidence to their relevant professional body demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise.

(3) For the purposes of paragraph (2), “system of clinical governance and audit” means a framework through which the registered person endeavours continuously to—

- (a) evaluate and improve the quality of the services provided; and
- (b) safeguard high standards of care by creating an environment in which clinical excellence can flourish.

Regulation 23 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Are safe and their health and welfare needs are met by competent staff.

This is because providers who comply with the regulations will:

- Ensure that staff are properly supported to provide care and treatment to people who use services.
- Ensure that staff are properly trained, supervised and appraised.
- Enable staff to acquire further skills and qualifications that are relevant to the work they undertake.

Prompts



Prompts for all providers to consider

Lead effectively to support staff

14A

People who use services receive care, treatment and support from staff who are competent to carry out their roles, because:

- All staff receive a comprehensive induction that takes account of recognised standards within the sector and is relevant to their workplace and their role.
- Induction is undertaken when they start their job and is completed before they are allowed to work unsupervised.
- The induction for new staff includes at least:
 - the aims, objectives and purpose of the service
 - information on the people whose care, treatment and support the staff member will be involved in providing and any specific communication needs
 - the rights of people who use the service
 - the policies and procedures of the service
 - the action to be taken in an emergency
 - the health and safety risk assessments and any necessary health surveillance, necessary for their work
 - how to report adverse events, incidents, errors and near misses
 - the arrangements for the staff member's own support and supervision

14

- the support and the safety arrangements where they are required to work alone
- the arrangements for reporting where the service falls below essential standards of quality and safety
- An orientation to the systems, culture and terminology of the health and or social care sectors in England, where the staff member has been recruited from outside the UK.
- The learning and development needs of staff are identified based on the needs of people who use services and the skills needed from staff to ensure that the service meets essential standards of quality and safety.
- Staff have a learning and development plan in place from the point of induction based upon the needs identified and how those needs will be met. This takes account of recognised standards in the sector.
- The service has a learning and development plan which leads to the development of a programme of activity that meets mandatory, sector body and professional requirements for the designated roles and enables staff to meet their professional registration and development requirements.
- Staff are enabled to take part in learning and development that is relevant and appropriate so that they can carry out their role effectively.
- Where it applies, staff are supported to take accredited training.
- The staff learning and development programme takes account of the working patterns of staff.
- Where learning and development is delivered by a trainer, that person has demonstrated that they are competent to do so and, where an accreditation scheme applies, are accredited to act as a trainer for the course being provided.
- The programme of learning and development is supported by appropriate resources.
- Where necessary, the service works with relevant training providers to ensure the programme is delivered effectively.
- A record is kept of those attending the learning and development activities that staff attend.
- The competency of staff to provide care, treatment and support is assessed in light of their learning and development, and support is provided to them where gaps are identified.
- The learning and development plan for staff is reviewed and adjusted to meet the changing needs of the people who use the service and to ensure that the service is fully able to meet essential quality and safety standards.
- Staff receive the learning and development opportunities they need to carry out their role and keep their skills up to date.

- They take into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

14B

Children who use services can be confident that:

- They are treated by staff who are appropriately trained to provide care, treatment and support for children, including Children's Workforce Development Council Induction standards.

14C

People receive a service from a provider that supervises its staff, because:

- Staff are supported and managed at all times and are clear about their lines of accountability.
- Supervisory or peer support arrangements are in place, monitored and reviewed, for all staff involved in delivering care, treatment and support. This is in line with relevant national guidance from professional regulators and/or professional bodies, and is monitored and reviewed. These supervisory arrangements mean that:
 - staff can talk through any issues about their role, or about the people they provide care, treatment and support to, with their line manager or supervisor
 - a support structure is in place for supervision which includes one-to-one sessions or group meetings. They are undertaken at a time and frequency agreed between the line manager or supervisor and the staff member, and they are recorded.
- The development of staff is supported through a regular system of appraisal that promotes their professional development and reflects any relevant regulatory and/or professional requirements.

14D

People receive a service from a provider that supports its staff because:

- Where staff need reasonable adjustments in order to be able to carry out their role suitable plans are put in place for their ongoing support.
- Staff follow their professional codes of conduct, are supported to do so, and are not required to do anything that would mean they would fail to follow that code.
- Staff are supported to do their work in a safe working environment where risk of violence, harassment and bullying are assessed and minimised.
- There are clear procedures followed in practice, monitored and reviewed, that are implemented when staff are subjected to violence, harassment or bullying by other staff or people who use services.
- There is an open culture in the service which allows staff to feel supported to raise concerns without any fear of recrimination.

- The risk to staff from the premises, equipment, or work that they do are assessed, and the preventative and protective measures that need to be followed are implemented. This includes staff understanding and following any health surveillance measures.
- There are arrangements to identify when a member of staff develops a health problem related to their work and to support them.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

14E

People who use services receive care treatment and support from staff who have undertaken:

- Skills for Care Common Induction Standards.
- Training and qualifications that satisfy the learning outcomes as advised by Skills for Care.
- Units or qualifications relevant to job role as advised by Skills for Care.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC ✓
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM ✓	SHL ✓	SLS ✓	SMC	SPC ✓	UCS

14F

People who use services can be confident that:

- They are treated by staff who carry out sufficient levels of activity to maintain their competence, including in relation to specific anaesthetic and surgical procedures, taking account of guidance from relevant expert or professional bodies.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS ✓	DTS ✓	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS ✓	PHS ✓	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

14G

Children who use services:

- Can be confident that they are treated by staff who carry out sufficient levels of activity to maintain their competence, including in relation to specific anaesthetic and surgical procedures for children, taking account of guidance from relevant expert or professional bodies.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS ✓	DTS ✓	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS ✓	PHS ✓	RCA
RHS	RSM	SHL	SLS	SMC	SPC	UCS

14H

Children who use services:

- Receive care, treatment and support by staff registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children, or the advice of such a nurse can be accessed at any time that it is needed.

This guidance applies to the service types ticked below:

ACS ✓	AMB	BTS	CHC ✓	CHN	CHS	DCC
DCS ✓	DEN	DSS ✓	DTS ✓	EXC	HBC ✓	HPS ✓
LDC ✓	LTC ✓	MBS ✓	MHC ✓	MLS ✓	PHS ✓	RCA
RHS ✓	RSM	SHL	SLS	SMC	SPC	UCS ✓

14I People who use services:

- Are cared for by staff who have received training about the assessment of suicide and homicide risk and behaviours that challenge.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC ✓	LTC	MBS	MHC ✓	MLS ✓	PHS ✓	RCA
RHS	RSM ✓	SHL	SLS	SMC	SPC	UCS

14J People who use services:

- Are supported by healthcare professionals who are able to demonstrate to professional regulators that they continue to meet professional registration requirements because healthcare professionals are enabled by the service to collect all information required.

This guidance applies to the service types ticked below:

ACS ✓	AMB ✓	BTS ✓	CHC ✓	CHN ✓	CHS	DCC
DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC ✓	HPS ✓
LDC ✓	LTC ✓	MBS ✓	MHC ✓	MLS ✓	PHS ✓	RCA ✓
RHS ✓	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS ✓

Quality and management

This section looks at what providers should do to manage risk in order to ensure that essential standards of quality and safety are maintained, and what information they must give to the Care Quality Commission about certain important events.

This section covers guidance about compliance for:

15. Statement of purpose
16. Assessing and monitoring the quality of service provision
17. Complaints
18. Notification of death of a person who uses services
19. Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983
20. Notification of other incidents
21. Records.



Outcome 15: Statement of purpose

Regulation



What do the regulations say?

Statement of purpose

12.—(1) The registered person must give the Commission a statement of purpose containing the information listed in Schedule 3.

(2) The registered person must keep under review and, where appropriate, revise the statement of purpose.

(3) The registered person must provide written details of any revision to the statement of purpose to the Commission within 28 days of any such revision.

SCHEDULE 3

INFORMATION TO BE INCLUDED IN THE STATEMENT OF PURPOSE

1. The aims and objectives of the service provider in carrying on the regulated activity.

2. The kinds of services provided for the purposes of the carrying on of the regulated activity and the range of service users' needs which those services are intended to meet.

3. The full name of the service provider and of any registered manager, together with their business address, telephone number and, where available, electronic mail addresses.

4. The legal status of the service provider.

5. Details of the locations at which the services provided for the purposes of the regulated activity are carried on.

Regulation 12 and Schedule 3 of the Care Quality Commission (Registration) Regulations 2009

Outcome



What should people who use services experience?

People who use services:

- Will benefit from the knowledge that the Care Quality Commission is informed of the services being provided.

This is because providers who comply with the regulations will:

- Have a statement of purpose that is kept under review, and give a copy to the Care Quality Commission.
- Notify the Care Quality Commission of any changes to their statement of purpose.

Prompts



We have not produced any prompts for this regulation as the regulation is self-explanatory. Providers are reminded to read, understand and implement the full requirements of the regulation.

Outcome 16: Assessing and monitoring the quality of service provision

Regulation



What do the regulations say?

Assessing and monitoring the quality of service provision

10.—(1) The registered person must protect service users, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to—

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirements set out in this Part of these Regulations; and
- (b) identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.

(2) For the purposes of paragraph (1), the registered person must—

- (a) where appropriate, obtain relevant professional advice;
- (b) have regard to—
 - (i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by service users, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 19,
 - (ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the regulated activity,
 - (iii) the information contained in the records referred to in regulation 20,
 - (iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a)),
 - (v) reports prepared by the Commission from time to time relating to the registered person's compliance with the provisions of these Regulations, and

- (vi) periodic reviews and special reviews and investigations carried out by the Commission in relation to the provision of health or social care, where such reviews or investigations are relevant to the regulated activity carried on by the service provider;
 - (c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—
 - (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a service user, and
 - (ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;
 - (d) establish mechanisms for ensuring that—
 - (i) decisions in relation to the provision of care and treatment for service users are taken at the appropriate level and by the appropriate person (P), and
 - (ii) P is subject to an appropriate obligation to answer for a decision made by P, in relation to the provision of care and treatment for a service user, to the person responsible for supervising or managing P in relation to that decision; and
 - (e) regularly seek the views (including the descriptions of their experiences of care and treatment) of service users, persons acting on their behalf and persons who are employed for the purposes of the carrying on of the regulated activity, to enable the registered person to come to an informed view in relation to the standard of care and treatment provided to service users.
- (3) The registered person must send to the Commission, when requested to do so, a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with, together with any plans that the registered person has for improving the standard of the services provided to service users with a view to ensuring their health and welfare.

Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Benefit from safe quality care, treatment and support, due to effective decision making and the management of risks to their health, welfare and safety.

This is because providers who comply with the regulations will:

- Monitor the quality of service that people receive.
- Identify, monitor and manage risks to people who use, work in or visit the service.
- Get professional advice about how to run the service safely, where they do not have the knowledge themselves.
- Take account of:
 - comments and complaints
 - investigations into poor practice
 - records held by the service
 - advice from and reports by the Care Quality Commission.
- Improve the service by learning from adverse events, incidents, errors and near misses that happen, the outcome from comments and complaints, and the advice of other expert bodies where this information shows the service is not fully compliant.
- Have arrangements that say who can make decisions that affect the health, welfare and safety of people who use the service.

Prompts



Prompts for all providers to consider

Lead effectively to manage risk

Providers who are registered with the Care Quality Commission:

16A

In relation to monitoring the quality of services that people who use services receive:

- Have appropriate systems for gathering, recording and evaluating accurate information about the quality and safety of the care, treatment and support the service provides, and its outcomes.

- Gather information about the safety and quality of their service from all relevant sources, including:
 - feedback from people who use services or others acting on their behalf
 - observations
 - audits
 - adverse events, incidents, errors and near misses
 - investigations into the misconduct of a person employed
 - comments and complaints
 - claims
 - relevant expert and or professional bodies, including the findings of research projects they undertake
 - other comments received.
- Submit, where appropriate, information to be collected as part of a mandatory national data collection system.
- Use the findings from clinical and other audits, including those undertaken at a national level, and national service reviews to ensure that action is taken to protect people who use services from risks associated with unsafe care, treatment and support.
- Analyse and use the information gathered to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
- Reduce the risks identified in order to prevent the service becoming non-compliant with the regulations.

16B

In relation to making sure people who use services are not harmed as a result of unsafe care, treatment and support:

- Gather information about the risks to people's health, welfare and safety. This includes people who use the service, the service's staff, and anyone else involved in the regulated activities provided by the service.
- Make the necessary changes to the plan of care of a person who uses the service where the information gathered identifies a risk of inappropriate or unsafe care, treatment and support.
- Have a system to continuously identify, analyse and review risks, adverse events, incidents, errors and near misses. Information about this is used to develop solutions and risk reduction actions to ensure any non-compliance, or any risk of non-compliance, with the regulations is resolved as quickly as possible.
- Identify and analyse adverse events, incidents, errors and near misses to establish what caused them.

- Make sure there is a confidential way for staff to raise concerns about risks to people, poor practice and adverse events. Staff understand the reporting system and feel confident to use it, without fear that they will be treated unfairly as a result of raising a concern.
- Involve people who use the service, others acting on their behalf, staff and all those who provide support in decisions about taking appropriate risks in a way that complies with relevant legislation.
- Provide people who use services with information about:
 - risks to their health, welfare and safety
 - any preventative or protective measures they should follow or use
 - their own responsibilities for contributing to safety.

16C

In relation to reporting on quality, risk, and improvement plans to ensure compliance with the regulations:

- Continually review their practice and take into account adverse events, incidents, errors and near misses that have occurred including the outcomes of complaints investigations within the service so that future lapses are minimised.
- Use information about the quality of experiences of people who use services, or others acting on their behalf, the views of staff and the risks they are exposed to, including the outcomes of comments, complaints and investigations, to understand where improvements are needed.
- Make information that may be produced about the quality of the service available to people who use services or are considering using it.
- Make, implement and review plans on quality, risk and improvement.

16D

In relation to decision-making arrangements:

- Ensure that important decisions about care, treatment and support involve the person who uses the service and are supported by a written description of:
 - the names or job roles of people who can take each kind of decision or action
 - the names or job roles of people who must be consulted about, or agree to, particular decisions or actions.
- Set out the types of decision that require people who use services to be consulted and involved with.
- Set out what happens about decisions when the people who must be consulted are not available.
- Set out how and where the decisions, and the actions taken to make those decisions, are recorded.

16E

Providers who are registered with the Care Quality Commission:

- Have a continuous quality improvement system that is used to protect people who use services and others who may be at risk.
- Have an up-to-date description of the systems and methods the continuous quality improvement system uses to identify, assess, manage, monitor and record risks.
- Send this description to the Care Quality Commission when it is requested by the Commission.
- Take into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 17: Complaints

Regulation



What do the regulations say?

Complaints

19.—(1) For the purposes of assessing, and preventing or reducing the impact of, unsafe or inappropriate care or treatment, the registered person must have an effective system in place (referred to in this regulation as “the complaints system”) for identifying, receiving, handling and responding appropriately to complaints and comments made by service users, or persons acting on their behalf, in relation to the carrying on of the regulated activity.

(2) In particular, the registered person must—

- (a) bring the complaints system to the attention of service users and persons acting on their behalf in a suitable manner and format;
- (b) provide service users and those acting on their behalf with support to bring a complaint or make a comment, where such assistance is necessary;
- (c) ensure that any complaint made is fully investigated and, so far as reasonably practicable, resolved to the satisfaction of the service user, or the person acting on the service user’s behalf; and
- (d) take appropriate steps to coordinate a response to a complaint where that complaint relates to care or treatment provided to a service user in circumstances where the provision of such care or treatment has been shared with, or transferred to, others.

(3) The registered person must send to the Commission, when requested to do so, a summary of the—

- (a) complaints made pursuant to paragraph (1); and
- (b) responses made by the registered person to such complaints.

Regulation 19 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services or others acting on their behalf:

- Are sure that their comments and complaints are listened to and acted on effectively.
- Know that they will not be discriminated against for making a complaint.

This is because providers who comply with the regulations will:

- Have systems in place to deal with comments and complaints, including providing people who use services with information about that system.
- Support people who use services or others acting on their behalf to make comments and complaints.
- Consider fully, respond appropriately and resolve, where possible, any comments and complaints.

Prompts



Prompts for all providers to consider

Lead effectively to manage complaints

17A

People who use services and those acting on their behalf can be confident that their comments and complaints are listened to and dealt with effectively because:

- There are clear procedures followed in practice, monitored and reviewed, for receiving, handling, considering and responding to comments and complaints, and a named contact who is accountable for doing so.
- The complaints process is available, understood and well-publicised, and reflects established principles of good complaint handling. The process will ensure:
 - that the details of the complaint, and the desired outcome, have been properly understood
 - that advice and advocacy support is available to those who wish or need such support
 - that what is required to resolve the complaint, and the likely timescale, is explained.
- Investigations are both proportionate and sufficiently thorough.

17

- A documented audit trail of the steps taken and the decisions reached is kept.
- Consideration of the complaint is undertaken by staff who are competent to address the issues raised, provide honest explanations that are based on facts and include the reasons for the decisions made.
- Whenever possible complaints are reviewed by someone not involved in the events leading to the complaint.
- Comments and complaints are investigated and resolved to the satisfaction of the person raising the complaint unless:
 - the complaint falls outside the remit of the provider's responsibility
 - the complaint cannot be upheld.
- The service has clear procedures followed in practice, monitored and reviewed for dealing with unreasonably persistent complainants in a fair and consistent manner, but ensures that the point they make is properly considered.
- The service encourages and supports a culture of openness that ensures any comment or complaint is listened to and acted on.
- The organisation ensures that a full record of the complaint is logged in line with the service's procedures.
- The information from complaints is used to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
- The person knows how to contact the Care Quality Commission in order to inform the Commission of concerns they may have about the carrying on of the regulated activity.

17B

People who use services whose care, treatment and support is shared with more than one provider, or has been transferred to another provider, know that their comments and complaints are listened to because:

- The provider has agreed protocols in place to ensure that the services cooperate to provide one complete and coordinated response.

17C

Providers who are registered with the Care Quality Commission:

- Will produce a summary of complaints at a time and in a format set out by the Care Quality Commission and then send the summary within the time frame specified.

17D

People who use services benefit from a service that:

- Takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

Promote rights and choices

17E

People who use services or those acting on their behalf are able to use the comments and complaints process because:

- They are treated in a manner that respects their human rights and diversity in a fair and equal way.
- They know how to obtain or access information about the complaints system.
- Any comments and complaints are dealt with in a sensitive and timely manner by taking into account the individual circumstances.
- Their comments and complaints can be made either verbally, through sign language or in writing.
- Where they lack confidence or capacity to make a complaint, staff help them through the means the person who uses services finds most supportive. Alternatively, the provider accepts comments and complaints made by others acting on their behalf.
- Making a complaint will not cause them to be discriminated against or have any negative effect on their care, treatment or support.
- They are informed of the timescales and process that the provider will follow in responding to their complaint and be kept informed of progress.
- That they can ask the adult social services customer care manager to assist them in making a complaint where this applies.
- That they can use the NHS complaint process where their care, treatment and support was funded by the NHS, whether or not that care, treatment and support was provided in an NHS facility.
- They know the steps they can take if they are not satisfied with the findings or outcome once the complaint has been responded to, and are advised of their right to refer the matter to the next stage of the complaints system, including the Health Service Ombudsman, Local Government Ombudsman or Independent Sector Complaints Adjudication Service, where these options apply.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 18: Notification of death of a person who uses services

Regulation



What do the regulations say?

Notification of death of service user

16.—(1) Except where paragraph (2) applies, the registered person must notify the Commission without delay of the death of a service user—

- (a) whilst services were being provided in the carrying on of a regulated activity; or
- (b) as a consequence of the carrying on of a regulated activity.

(2) Subject to paragraph (4), where the service provider is a health service body, the registered person must notify the Commission of the death of a service user where the death—

- (a) occurred—
 - (i) whilst services were being provided in the carrying on of a regulated activity, or
 - (ii) as a consequence of the carrying on of a regulated activity; and
- (b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care or treatment.

(3) Notification of the death of a service user must include a description of the circumstances of the death.

(4) Paragraph (2) does not apply if, and to the extent that, the registered person has reported the death to the National Patient Safety Agency.

(5) This regulation does not apply where regulation 17 applies.

Regulation 16 of the Care Quality Commission (Registration) Regulations 2009

Outcome



What should people who use services experience?

People who use services:

- Can be confident that deaths of people who use services are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because:

- Providers notify the Care Quality Commission about the death of a person who uses the service.

Prompts



Prompts for all providers to consider

Informing the Care Quality Commission

18A

The regulations say that a registered person (provider or manager) must send notifications about deaths to the Care Quality Commission without delay.

18B

Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 16.

18C

English NHS trusts send these notifications to the National Patient Safety Agency (NPSA), who will send them on to the Care Quality Commission. All other providers send their notifications directly to the Commission.

18D

These notifications must not identify the person they are about, or enable them to be identified. Individuals should be referred to using a code that is unique to them. Services must keep a record of these codes and who they refer to, in case the Care Quality Commission needs to make further enquiries.

18E

The death of a person who is detained, or liable to be detained, under the Mental Health Act 1983 is not notified under this outcome. Please refer to outcome 19 in these circumstances.

English NHS trusts only

18F

English NHS trusts inform the Care Quality Commission without delay of any death of a person using the service that occurred:

- While the service was being provided.
- That was a consequence of the service being provided; and
- Was not caused by an illness or condition that was being appropriately treated.

English NHS providers must submit notifications under 18F to the Care Quality Commission by sending them to the NPSA. They must not be sent to the Care Quality Commission direct.

Providers that are not English NHS trusts

18G

All providers that are NOT English NHS trusts inform the Care Quality Commission without delay of ALL deaths of a person using the service where they die while receiving, or as a result of, the care, treatment or support provided by the service.

18H

Notifications about deaths must include the following:

- A unique identifier or code for the person.
- The date they were admitted to or started using the service.
- The date and time of their death.
- The time the person was found.
- Where the person died.
- The cause of their death, where this is known.
- Whether the death was expected.
- If the death was not expected:
 - a unique identifier or code for the last person involved in providing care; and
 - details of their job title and employer if this was not the provider.
- Details of any surgical procedure being used at the time of the person's death or within the seven days before their death.
- Whether the person was being restrained at the time of their death, or within the seven days before their death.
- Whether there are concerns about the use of controlled or other drugs relating to the death.
- Whether there are concerns about the use of medical devices relating to the death.

- Relevant dates and circumstances, using unique identifiers and codes where relevant.
- Personal details about the person:
 - their date of birth
 - their gender
 - their ethnicity
 - any disability
 - any religion or belief
 - their sexual orientation.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 19: Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983

Regulation



What do the regulations say?

Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983

17.—(1) The registered person must notify the Commission without delay of the death or unauthorised absence of a service user who is liable to be detained by the registered person—

- (a) under the Mental Health Act 1983 (“the 1983 Act”); or
 - (b) pursuant to an order or direction made under another enactment (which applies in relation to England), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.
- (2) Notification of the death of a service user must include a description of the circumstances of the death.
- (3) In this regulation—
- (a) references to persons “liable to be detained” include a community patient who has been recalled to hospital in accordance with section 17E of the 1983 Act, but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42, 73 or 74 of the 1983 Act;
 - (b) “community patient” has the same meaning as in section 17A of the 1983 Act;
 - (c) “hospital” means a hospital within the meaning of Part 2 of that Act; and
 - (d) “unauthorised absence” means an unauthorised absence from a hospital.

Regulation 17 of the Care Quality Commission (Registration) Regulations 2009

Outcome



What should people who use services experience?

People using the service who are detained under the Mental Health Act 1983:

- Can be confident that important events that affect their welfare, health and safety are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because providers who comply with the regulations will:

- Notify the Care Quality Commission about the death or unauthorised absence of a person detained under the Mental Health Act 1983 who uses services.

Prompts



Prompts for all providers to consider

Informing the Care Quality Commission

19A

The regulations say that a registered person (provider or manager) must send notifications about deaths and unauthorised absences of patients detained or liable to be detained under the Mental Health Act 1983 to the Care Quality Commission without delay.

19B

Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 16.

19C

All providers send notifications in relation to Outcome 19 directly to the Care Quality Commission.

19D

These notifications must not identify the person they are about, or enable them to be identified. Individuals should be referred to using a code that is unique to them. Services must keep a record of these codes and who they refer to, in case the Care Quality Commission needs to make further enquiries.

19E

Notification about the death of a person using the service must be made where the person dies while receiving, or as a result of, the care, treatment or support provided by the service.

19F

The death of a person who is detained, or liable to be detained, under the Mental Health Act 1983 is notified under this outcome only, and not notified under outcome 18.

19G

Unauthorised absences of a person liable to be detained under the Mental Health Act 1983 become notifiable when the person is still absent after midnight on the day their absence began.

Deaths

19H

All notifications about deaths and unauthorised absences of a person detained or liable to be detained under the Mental Health Act 1983 must include the following:

- A unique identifier or code for the person.
- The date they were admitted to or started using the service.
- Relevant dates and circumstances, using unique identifiers and codes where relevant.
- Personal details about the person:
 - their date of birth
 - their gender
 - their ethnicity
 - any disability
 - any religion or belief
 - their sexual orientation.

19I

Notifications under Outcome 19 that concern a death must also include the following:

- The date and time of the death.
- The time the person was found.
- Where the person died.
- The cause of their death, where this is known.
- Whether the death was expected.
- If the death was not expected:
 - a unique identifier or code for the last person involved in providing care; and
 - details of their job title and employer if this was not the provider.
- Details of any surgical procedure being used at the time of the person's death or within the seven days before their death.
- Whether the person was being restrained at the time of their death, or within the seven days before their death.
- Whether there are concerns about the use of controlled or other drugs relating to the death.
- Whether there are concerns about the use of medical devices relating to the death.

Unauthorised absence

19J

Notifications under Outcome 19 that concern an unauthorised absence must also include the following:

- The section of the Mental Health Act 1983 under which the person is liable to be detained.
- The reasons for their detention.
- The circumstances in which they came to be absent.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 20: Notification of other incidents

Regulation



What do the regulations say?

Notification of other incidents

18.— (1) Subject to paragraphs (3) and (4), the registered person must notify the Commission without delay of the incidents specified in paragraph (2) which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity.

(2) The incidents referred to in paragraph (1) are—

- (a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—
 - (i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,
 - (ii) changes to the structure of a service user's body,
 - (iii) the service user experiencing prolonged pain or prolonged psychological harm, or
 - (iv) the shortening of the life expectancy of the service user;
- (b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—
 - (i) the death of the service user, or
 - (ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);
- (c) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation, including the result of such a request;
- (d) any application made to a court in relation to depriving a service user of their liberty pursuant to section 16(2)(a) of the 2005 Act;
- (e) any abuse or allegation of abuse in relation to a service user;
- (f) any incident which is reported to, or investigated by, the police;
- (g) any event which prevents, or appears to the service provider to be likely to threaten to prevent, the service provider's ability to continue to carry on the regulated activity safely, or in accordance with the registration requirements, including—

- (i) an insufficient number of suitably qualified, skilled and experienced persons being employed for the purposes of carrying on the regulated activity,
- (ii) an interruption in the supply to premises owned or used by the service provider for the purposes of carrying on the regulated activity of electricity, gas, water or sewerage where that interruption has lasted for longer than a continuous period of 24 hours,
- (iii) physical damage to premises owned or used by the service provider for the purposes of carrying on the regulated activity which has, or is likely to have, a detrimental effect on the treatment or care provided to service users, and
- (iv) the failure, or malfunctioning, of fire alarms or other safety devices in premises owned or used by the service provider for the purposes of carrying on the regulated activity where that failure or malfunctioning has lasted for longer than a continuous period of 24 hours.

(3) Paragraph (2)(f) does not apply where the service provider is an English NHS body.

(4) Where the service provider is a health service body, paragraph (1) does not apply if, and to the extent that, the registered person has reported the incident to the National Patient Safety Agency.

(5) In this regulation—

(a) “the 2005 Act” means the Mental Capacity Act 2005;

(b) “abuse”, in relation to a service user, means—

- (i) sexual abuse,
- (ii) physical or psychological ill-treatment,
- (iii) theft, misuse or misappropriation of money or property, or
- (iv) neglect and acts of omission which cause harm or place at risk of harm;

(c) “health care professional” means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999 applies;

(d) “registration requirements” means any requirements or conditions imposed on the registered person by or under Chapter 2 of Part 1 of the Act;

(e) “standard authorisation” has the meaning given under Part 4 of Schedule A1 to the 2005 Act;

(f) “supervisory body” has the meaning given in paragraph 180 (in relation to a hospital in England) or paragraph 182 (in relation to a care home) of Schedule A1 to the 2005 Act;

(g) for the purposes of paragraph (2)(a)—

- (i) “prolonged pain” and “prolonged psychological harm” means pain or harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days, and
- (ii) a sensory, motor or intellectual impairment is not temporary if such an impairment has lasted, or is likely to last, for a continuous period of at least 28 days.

Regulation 18 of the Care Quality Commission (Registration) Regulations 2009

Outcome



What should people who use services experience?

People who use services:

- Can be confident that important events that affect their welfare, health and safety are reported to the Care Quality Commission so that, where needed, action can be taken.

This is because providers who comply with the regulations will:

- Notify the Care Quality Commission about incidents that affect the health, safety and welfare of people who use services, including:
 - injuries to people
 - making an application to depriving someone of their liberty
 - events which stop the registered person from running the service as well as they should
 - allegations of abuse
 - a police investigation.

Prompts



Prompts for all providers to consider

Informing the Care Quality Commission

20A

The regulations say that a registered person (provider or manager) must send notifications about incidents that affect people who use services to the Care Quality Commission without delay.

20B

Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 16.

20C

English NHS trusts send **SOME** of these notifications to the National Patient Safety Agency (NPSA), who will send them on to the Care Quality Commission. This guidance says when NHS trusts should send notifications to the NPSA, and when they send them directly to the Care Quality Commission.

20D

Other providers send **ALL** notifications directly to the Care Quality Commission.

20E

These notifications must not identify individual people, or enable them to be identified. Individuals must be referred to using a code that is unique to them. Services must keep a record of these codes and who they refer to, in case the Care Quality Commission needs to make further enquiries.

20F

The two kinds of incidents and events that must be notified to the Care Quality Commission are:

Incidents affecting a person who uses the service:

- Injuries
- Applications to deprive someone of their liberty under the Mental Capacity Act
- Allegations of abuse.

Events involving the service in a way that could affect all of the people who use it:

- Incidents reported to the police
- Events that stop or may stop the service from operating safely and properly.

20G

In all cases the notifications about an incident affecting a person must include:

- A unique identifier or code for the person.
- The date they were or will be admitted to the service.
- Their date of birth.
- Their gender.
- Their ethnicity.
- Any disability.
- Any religion or belief.
- Their sexual orientation.
- All relevant dates and circumstances, using unique identifiers and codes where relevant.
- Anything you have already done about the incident.

Notifications about incidents and events affecting a person who uses the service while receiving, or as a result of, the care, treatment and support provided by the service

Injuries

20H

Providers tell the Care Quality Commission without delay about events that lead to:

- Serious injury to any person who uses the service.
- An injury requiring treatment by a healthcare professional to avoid death or serious injury.

20I

These serious injuries include:

- Injuries that lead to or are likely to lead to permanent damage – or damage that lasts or is likely to last more than 28 days – to:
 - a person’s sight, hearing, touch, smell or taste
 - any major organ of the body (including the brain and skin)
 - bones
 - muscles, tendons, joints or vessels
 - intellectual functions, such as
 - intelligence
 - speech
 - thinking
 - remembering
 - making judgments
 - solving problems.
- Injuries or events leading to psychological harm, including:
 - post traumatic stress disorder
 - other stress that requires clinical treatment or support
 - psychosis
 - clinical depression
 - clinical anxiety
 - the development after admission of a pressure sore of grade 3 or above that develops **after the person has started to use the service** (European Pressure Ulcer Advisory Panel Grading)
 - any injury or other event that causes a person pain lasting or likely to last for more than 28 days

- any injury that requires treatment by a healthcare professional in order to prevent:
 - death
 - permanent injury
 - any of the outcomes, harms or pain described above.

English NHS providers must submit notifications under 20I to the Care Quality Commission by sending them to the NPSA. They must not be sent to the Care Quality Commission direct.

Applications to Supervisory Bodies or the Court of Protection to deprive a person of their liberty

20J

Providers of hospitals, care homes or care homes with nursing tell the Care Quality Commission without delay about any application by the service to a Supervisory Body to deprive an adult of their liberty.

20K

Providers of all services tell the Care Quality Commission without delay about any application by the service to the Court of Protection to deprive an adult of their liberty.

20L

All notifications about an application to deprive an adult of their liberty must include:

- The date of the application.
- The reasons for the application.
- Whether an application to deprive the person of their liberty has been made before.
- The address of the Supervisory Body or Court

Events that stop or may stop the registered person from running the service safely and properly

20M

Providers inform the Care Quality Commission without delay about:

- A level of staff absence or vacancy, or damage to the service's premises that mean that people's assessed needs cannot be met.
- The failure of a utility for more than 24 hours.
- The failure of fire alarms, call systems or other safety-related equipment for more than 24 hours.
- Any other circumstances or events that mean the service cannot – or may not be able to – meet people's assessed needs safely.

English NHS providers must submit notifications under 20M to the Care Quality Commission by sending them to the NPSA. They must not be sent to the Care Quality Commission direct.

Allegations of abuse

20N

Providers inform the Care Quality Commission without delay of:

- Any suspicion, concern or allegation from any source that a person using the service has been or is being abused, or is abusing another person (of any age), including:
 - details of the possible victim(s), where this is known – the same information shown in paragraph 20F above
 - a unique identifier or code for the actual or possible abusers, together with, where it is known:
 - the personal information shown in paragraph 20G above
 - their relationship to the abused person
 - a unique identifier or code for any person who has or may have been abused by a person using the service, together with (where known):
 - the same personal information shown in paragraph 20G above
 - their relationship to the abused person
 - the person who originally expressed the suspicion, concern or allegation (using a unique identifier or code).
- See paragraph 20Q below in relation to English NHS trusts and allegations of abuse of children.

20O

In relation to where the alleged or possible victim of abuse is an adult the notification must include details of the allegation, including:

- Any relevant dates, witnesses (using unique identifiers or codes) and circumstances.
- Whether the allegation has been reported to local multi-agency safeguarding arrangements and/or the police.
- The type of abuse (using the categories in the Department of Health document *No Secrets*).
- Anything the registered person has done as a result of the allegation.

20P

In relation to where the alleged or possible victim of abuse is a child or young person under 18 years, the notification must include details of the allegation, including:

- Any relevant dates, witnesses (using unique identifiers or codes) and circumstances.
- The date the allegation was notified to the police, local safeguarding children board and the strategic health authority (where appropriate).
- The type of abuse (using the categories in the Department for Children, Families and Schools document *Working Together*).
- Anything the registered person has done as a result of the allegation.

20Q

Paragraphs 20N and 20P only apply to an English NHS trust where:

- The alleged abuser is a member of staff or volunteer working for the provider.
- The alleged abuser is another person who uses the service.
- The abuse is alleged to have occurred on the premises of the provider.
- English NHS trusts notify allegations of abuse of children to local multi-agency child protection arrangements.

English NHS providers must submit notifications under 20Q to the Care Quality Commission by sending them to the NPSA. They must not be sent to the Care Quality Commission direct.

Incidents reported to or investigated by the police

20R

Providers inform the Care Quality Commission without delay of:

- Any incident reported to or investigated by the police that is associated with the delivery of the service and affects or may affect the health, safety and welfare of a person using the service, its staff, or anyone who visits the service. These events include:
 - people who use services going missing
 - assault or malicious damage
 - theft of property or money belonging to people who use the service.

The above requirement does not apply to English NHS trusts.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 21: Records

Regulation



What do the regulations say?

Records

20.—(1) The registered person must ensure that service users are protected against the risks of unsafe or inappropriate care and treatment arising from a lack of proper information about them by means of the maintenance of—

- (a) an accurate record in respect of each service user which shall include appropriate information and documents in relation to the care and treatment provided to each service user; and
- (b) such other records as are appropriate in relation to—
 - (i) persons employed for the purposes of carrying on the regulated activity, and
 - (ii) the management of the regulated activity.

(2) The registered person must ensure that the records referred to in paragraph (1) (which may be in paper or electronic form) are—

- (a) kept securely and can be located promptly when required;
- (b) retained for an appropriate period of time; and
- (c) securely destroyed when it is appropriate to do so.

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services can be confident that:

- Their personal records including medical records are accurate, fit for purpose, held securely and remain confidential.
- Other records required to be kept to protect their safety and wellbeing are maintained and held securely where required.

This is because providers who comply with the regulations will:

- Keep accurate personalised care, treatment and support records secure and confidential for each person who uses the service.
- Keep those records for the correct amount of time.
- Keep any other records the Care Quality Commission asks them to in relation to the management of the regulated activity.
- Store records in a secure, accessible way that allows them to be located quickly.
- Securely destroy records taking into account any relevant retention schedules.

Prompts



Prompts for all providers to consider

Manage risk through effective procedures about records

21A

People who use services can be confident that their personal records for their care, treatment and support are properly managed because:

- The service has clear procedures that are followed in practice, monitored and reviewed, to ensure personalised records and medical records are kept and maintained for each person who uses the service.
- Records about the care, treatment and support of people who use services are updated as soon as practical.
- Verbal communications about care, treatment and support are documented within personal records as soon as is practical.
- Records about care, treatment and support are clear, factual and accurate and maintain the dignity and confidentiality of the people who use services.
- Records are securely stored and transferred internally between departments and externally to other organisations, when required.
- Protocols exist with other organisations for secure information sharing.

- Records about people who use services are used to plan appropriate care, treatment and support to ensure their rights and best interests are protected and their needs are met.
- The record of the current interaction is linked with any previous records that exist for that person, whenever the service is able to reliably identify the person.
- They, or others acting on their behalf, and relevant staff, are aware of and can access, and where appropriate, contribute to the record.
- They are assured that safe and secure records management arrangements will continue to be in place for the legally required period should the registered provider close operations.
- Where a request for access to a record is made, all legislation and guidance in respect of Freedom of Information Act 2000 and the Data Protection Act 1998 is followed by all staff.
- Wherever they are relevant to the service, the following records are kept and for the periods of time stated:
 - risk assessments; retain the latest risk assessment until a new one replaces it
 - purchasing excluding medical devices and medical equipment; 18 months
 - general operating policies and procedures; retain the current version and previous version for three years
 - any incidents, events or occurrences that require notification to the Care Quality Commission; three years
 - use of restraint or the deprivation of liberty; three years
 - detention; three years
 - maintenance of the premises; three years
 - maintenance of equipment; three years
 - electrical testing; three years
 - fire safety; three years
 - water safety; three years
 - medical gas safety, storage and transport; three years
 - money or valuables deposited for safe keeping; three years
 - staff employment; three years following date of last entry
 - duty rosters; four years after the year to which they relate
 - purchasing of medical devices and medical equipment; 11 years
 - final annual accounts; 30 years.

- Takes into account relevant guidance, including that from the Care Quality Commission’s Schedule of Applicable Publications (see appendix B).

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

21B

People who use services can be confident that:

- Their healthcare records are kept or disposed of in accordance with the Data Protection Act 1998, the Department of Health’s Records Management: NHS Code of Practice (Part 2), and other professional bodies standards where applicable to the service.

This guidance applies to the service types ticked below:

ACS ✓	AMB ✓	BTS ✓	CHC ✓	CHN	CHS	DCC
DCS ✓	DEN ✓	DSS ✓	DTS ✓	EXC	HBC ✓	HPS ✓
LDC	LTC ✓	MBS ✓	MHC	MLS ✓	PHS ✓	RCA ✓
RHS ✓	RSM ✓	SHL	SLS	SMC ✓	SPC	UCS ✓

21C

People who use services can be confident that:

- Their social care records for adults are kept or disposed of in accordance with the Data Protection Act 1998 and three years from last date of entry.
- Their social care records for children are kept or disposed of in accordance with the Data Protection Act 1998 and 80 years from last date of entry.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC ✓
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS
LDC ✓	LTC ✓	MBS	MHC	MLS	PHS	RCA
RHS ✓	RSM ✓	SHL ✓	SLS ✓	SMC ✓	SPC ✓	UCS

21D

People who use services are supported through clear procedures that are followed in practice, monitored and reviewed that:

- Record the pathway taken through an advice algorithm, as well as the outcome of the advice algorithm.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN	CHS	DCC
DCS	DEN	DSS	DTS	EXC	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA ✓
RHS	RSM	SHL	SLS	SMC	SPC	UCS

Suitability of management

This section looks at what providers and managers must do to show that they are suitable to run the service and that they keep the Care Quality Commission informed about relevant changes.

This section covers guidance about compliance for:

22. Requirements where the service provider is an individual or partnership
23. Requirement where the service provider is a body other than a partnership
24. Requirements relating to registered managers
25. Registered person: training
26. Financial position
27. Notifications – notice of absence
28. Notifications – notice of changes.



Outcome 22: Requirements where the service provider is an individual or partnership

Regulation



What do the regulations say?

Requirements where the service provider is an individual or partnership

4.—(1) This regulation applies where a service provider (P) is an individual or a partnership.

(2) P must not carry on a regulated activity unless P is fit to do so.

(3) P is not fit to carry on a regulated activity unless P is—

(a) an individual who carries on the regulated activity, otherwise than in partnership with others, and satisfies the requirements set out in paragraph (4); or

(b) a partnership and each of the partners satisfies the requirements set out in paragraph (4);

(4) The requirements referred to are that P or, where applicable, each of the partners is—

(a) of good character;

(b) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and

(c) able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.

Regulation 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Have their needs met by the service because it is provided by an appropriate person.

This is because providers who comply with the regulations will:

- Register with the Care Quality Commission the appropriate people or persons who:
 - are of good character
 - are physically and mentally able to perform their role
 - have the necessary qualifications, skills and experience to carry on the regulated activity or, where it is an organisation, supervise its management.

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers who are an individual or a partnership. These prompts do not apply where the service provider is a body other than an individual or partnership.

Lead effectively to manage risk of inappropriate providers

22A

People who use services receive care, treatment and support from a provider who has demonstrated that it:

- Is honest, reliable and trustworthy.
- Is competent to run the service.
- Is physically and mentally able to do the job, with plans of support for individuals to show what arrangements will be put in place including any reasonable adjustments to enable them to do their job, wherever necessary.
- Is appropriately skilled with the qualifications, knowledge and experience required to manage the regulated activity, where there is no separate registered manager.
- Has been subject to the necessary checks as described in Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, so that the provider is assured that the worker is suitable for their role.
- Has been subject to a check that they are registered with the Independent Safeguarding Authority where:

- they are undertaking a Safeguarding Vulnerable Groups Act 2006 “regulated activity” or “controlled activity”
- they are required to be registered under the Scheme’s phasing-in arrangements.
- Is able to respond to any registered manager requests for resources in order to meet essential standards of quality and safety.
- Is able to empower the registered manager, where one is employed, and appropriately delegate authority to them so that they can effectively run the service on a day-to-day basis.

22B

In relation to meeting the needs of people who use services, providers:

- Anticipate and understand the possible outcomes of their decisions and actions on people’s lives.
- Influence and negotiate to achieve the essential standards of quality and safety for people who use services by understanding the importance of putting them at the centre and encouraging choice and control.
- Know and understand how to safeguard people.
- Have knowledge and understanding of how equal opportunities and a respect for human rights and diversity are put in to practice when delivering the service.
- Put into practice the aims and objectives described in the statement of purpose and explain how the service will achieve these.
- Recognise when particular knowledge and skills are needed and take appropriate action.

22C

In relation to their legal responsibilities, providers:

- Inform the Care Quality Commission about any and all:
 - convictions, cautions, warnings, reprimands and bind overs they receive
 - actions taken against them by a regulatory and/or professional body
 - voluntary insolvency arrangements and circumstances made by an individual.
- Have appropriate knowledge of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (Part 3 and Part 4) and the consequences of failing to take action on set requirements.
- Make sure that the service complies with relevant laws and takes into account relevant statutory codes of practice.
- Supply all necessary information that the Care Quality Commission may request as required by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (Part 3 and Part 4).
- Co-operate effectively with any statutory agencies' investigations.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 23: Requirement where the service provider is a body other than a partnership

Regulation



What do the regulations say?

Requirement where the service provider is a body other than a partnership

5.—(1) This regulation applies where the service provider is a body other than a partnership.

(2) The body must give notice to the Commission of the name, address and position in the body of an individual (in these Regulations referred to as “the nominated individual”) who is employed as a director, manager or secretary of the body and who is responsible for supervising the management of the carrying on of the regulated activity by the body.

(3) The registered person must take all reasonable steps to ensure that the nominated individual is—

- (a) of good character;
- (b) physically and mentally fit to supervise the management of the carrying on of the regulated activity and has the necessary qualifications, skills and experience to do so; and
- (c) able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Have their needs met because the management is supervised by an appropriate person.

This is because providers who comply with the regulations will:

- Have a nominated individual who:
 - is of good character
 - is physically and mentally able to perform their role
 - has the necessary qualifications, skills and experience to supervise the management of the regulated activity.

Prompts



Prompts for all providers to consider

The following prompts relate to all providers who are a body other than an individual or a partnership. These prompts do not apply where the service provider is an individual or partnership.

Manage quality by notifying an appropriate nominated individual

23A

People who use services receive a service whose management is supervised by a nominated individual who:

- Has been notified in writing to the Care Quality Commission.
- Is of good character as they are honest, reliable and trustworthy.
- Is physically and mentally able to do the job, with a plan of support that sets out any reasonable adjustments where necessary. This means they:
 - do not present a risk to people who use services because of any illness or medical condition they have
 - are not placed at risk by the work they will do because of any illness or medical condition they have.
- Is appropriately skilled with the qualification(s), knowledge and experience to supervise the management of the regulated activity. This means the nominated individual:

- Has been subject to the necessary checks as described in Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, so that the provider is assured that the nominated individual is suitable for their role.
- Has been subject to a check that they are registered with the Independent Safeguarding Authority:
 - where they are undertaking a Safeguarding Vulnerable Groups Act 2006 “regulated activity” or “controlled activity”; and
 - are required to be registered under the Scheme’s phasing-in arrangements.
- Has their qualifications, knowledge and skills updated on a regular basis.
- Has an awareness and knowledge of diversity and human rights and applies in practice the competencies to support people’s diverse needs and human rights.
- Is aware of the services’ policies, procedures, legislation and standards.
- Knows who they are able to contact when expert advice is needed.
- Is able to respond to any registered manager requests for resources in order to meet essential standards of quality and safety.
- Is able to empower the registered manager, where one is employed, and appropriately delegate authority to them so that they can effectively run the service on a day-to-day basis.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 24: Requirements relating to registered managers

Regulation



What do the regulations say?

Requirements relating to registered managers

6.—(1) A person (M) shall not manage the carrying on of a regulated activity as a registered manager unless M is fit to do so.

(2) M is not fit to be a registered manager in respect of a regulated activity unless M is—

- (a) of good character;
- (b) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and
- (c) able to supply to the Commission, or arrange for the availability of, the information relating to themselves specified in Schedule 3.

Regulation 6 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Have their needs met because it is managed by an appropriate person.

This is because providers who comply with the regulations will:

- Have a registered manager who:
 - is of good character
 - is physically and mentally able to perform their role
 - has the necessary qualifications, skills and experience to manage the regulated activity.

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers wherever the service, or a part of the service, is managed by a Registered Manager.

This only applies to registered NHS providers where the Care Quality Commission has decided to apply a registered manager condition.

Lead effectively to manage risk of inappropriate managers

24A

People who use services receive a service from a manager who has demonstrated that they:

- Are of good character as they are honest, reliable and trustworthy.
- Are physically and mentally able to do the job, with a plan of support, showing any reasonable adjustments, where necessary. This means the manager:
 - does not present a risk to people who use services because of any illness or medical condition they have
 - is not placed at risk by the work they will do because of any illness or medical condition they have.
- Have the qualifications, knowledge and experience to manage the regulated activity.
- Are appropriately skilled, including as a minimum:
 - effective communication skills to enable good communication with their staff and the people who use their service
 - basic management skills to ensure that the service is delivered to meet essential standards of quality and safety.
- Has been subject to the necessary checks as described in Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, so that the provider is assured that the nominated individual is suitable for their role.
- Has been subject to a check that they are registered with the Independent Safeguarding Authority:
 - where they are undertaking a Safeguarding Vulnerable Groups Act 2006 “regulated activity” or “controlled activity”; and
 - are required to be registered under the Scheme’s phasing-in arrangements.
- Show that they are registered with the relevant professional regulators and/or professional bodies where appropriate, and comply with their requirements and codes of practice.

- Show qualifications and competencies recognised by the relevant sector body or, where these don't apply, are able to demonstrate relevant skills and experience.
- Have appropriate knowledge of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (Part 3 and Part 4) and the consequences of failing to take action on set requirements.
- Anticipate and understand the possible outcomes of their decisions and actions on people's lives and take appropriate action.
- Use resources effectively.
- Have delegated responsibility to make decisions where needed.
- Delegate appropriately by:
 - knowing what can or cannot be delegated
 - knowing what can be delegated to whom
 - understanding the competencies of staff and what is it appropriate for them to do
 - having clear descriptions of each member of staff's role so that it is clear what should be delegated to whom
 - ensuring that staff have the time they need to complete any newly delegated tasks.
- Ensure that people are safeguarded from abuse.
- Have knowledge and understanding of how equal opportunities and a respect for human rights and diversity are put in to practice when delivering the service.

Outcome 24: Requirements relating to registered managers

- Understand the importance of the delivery of the service in a person-centred way, by ensuring that people who use services have choice and control.
- Put into practice the statement of purpose.
- Have plans of support that will show what arrangements will be put into place and any reasonable adjustments to enable a particular person to do their job.
- Make appropriate use of resources and highlight any areas of concerns to the provider, where relevant.
- Inform the Care Quality Commission about any:
 - convictions, cautions, warnings, reprimands and bind overs they receive
 - any action taken against them by a professional body.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 25: Registered person: training

Regulation →



What do the regulations say?

Registered person: training

7.—(1) If the service provider is—

- (a) an individual, the individual must undertake;
- (b) a partnership, it must ensure that one of the partners undertakes; or
- (c) a body other than a partnership, it must ensure that the nominated individual undertakes,

from time to time such training as is reasonably practicable and appropriate to ensure that there are the necessary experience and skills available for carrying on the regulated activity.

(2) The registered manager must undertake from time to time such training as is appropriate to ensure that the manager has the experience and skills necessary for managing the carrying on of the regulated activity.

Regulation 7 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Outcome →



What should people who use services experience?

People who use services:

- Have their care, treatment and support needs met because there is a competent person leading the service.

This is because providers who comply with the regulations will:

- Undertake appropriate training.

Prompts



Prompts for all providers to consider

Manage risk through effective procedures for learning and development

25A

People who use services benefit from a service that is competently run and has effective systems to meet the requirements of the regulations. This is because the registered persons undertake the training necessary to ensure they:

- Have the relevant skills and experience and apply these in their work.
- Apply up-to-date knowledge to effectively meet the needs of people who use services, including taking into account staffing and premises requirements.
- Have a clear organisational structure with well-defined, transparent and consistent lines of responsibility.
- Have effective processes and systems to identify, manage, monitor and report risks, which must include systems to gather information from people who use services, professionals, and published audits and reports.
- Use this information to reduce unacceptable risks and keep this under review.
- Have a clear understanding of the services' policies, procedures, legislation and standards.

25B

In addition, where the registered person is in day-to-day charge of the service, people who use services benefit from effective management. This is because the registered persons:

- Have plans in place to keep their knowledge and skills up to date and participate in appropriate training and activities. This training ensures that they:
 - provide effective care, treatment and support to the people who use their service
 - uphold and promote the rights of the people who use their service
 - are able to meet the diverse needs of people who use their service and follow current legislation
 - put into practice the statement of purpose.

Additional prompts for specific service types

In addition to the prompts for all providers above, the following prompts relate to specific service types. Please refer to “Step 2: Select your service types” on page 13, to make sure that you identify which service types apply to you.

25C

People who use services benefit from a manager who:

- Has an appropriate qualification as advised by Skills for Care, or be working towards it when newly registered with the Care Quality Commission.

This guidance applies to the service types ticked below:

ACS	AMB	BTS	CHC	CHN ✓	CHS ✓	DCC ✓
DCS	DEN	DSS	DTS	EXC ✓	HBC	HPS
LDC	LTC	MBS	MHC	MLS	PHS	RCA
RHS	RSM ✓	SHL ✓	SLS ✓	SMC ✓	SPC ✓	UCS

Outcome 26: Financial position

Regulation



What do the regulations say?

Financial position

13.—(1) Subject to paragraph (2), the service provider must take all reasonable steps to carry on the regulated activity in such a manner as to ensure the financial viability of the carrying on of that activity for the purposes of—

- (a) achieving the aims and objectives set out in the statement of purpose; and
- (b) meeting the registration requirements prescribed pursuant to section 20 of the Act.

(2) This regulation does not apply where the service provider is—

- (c) an English local authority; or
- (d) a health service body.

Regulation 13 of the Care Quality Commission (Registration) Regulations 2010

Outcome



What should people who use services experience?

People who use services:

- Can be confident that the service provider is able to meet the financial demands of providing safe and appropriate services.

This is because providers who comply with the regulations will:

- Have the financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards.

Prompts



Prompts for all providers to consider

Ensure quality through adequate finances

26A

People who use services are confident that the provider has:

- The financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards.
- Wherever it is available, insurance and suitable indemnity arrangements to cover potential liabilities arising from death, injury, or other causes, loss or damage to property, and other financial risks.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 27: Notifications – notice of absence

Regulation



What do the regulations say?

Notice of absence

14.—(1) Subject to paragraphs (7) and (8), where—

- (a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or
- (b) the registered manager,

proposes to be absent from carrying on or managing the regulated activity for a continuous period of 28 days or more, the registered person must give notice in writing to the Commission of the proposed absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) must be given no later than 28 days before the proposed absence commences or within such shorter period as may be agreed with the Commission and must contain the following information in relation to the proposed absence—

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for the management of the carrying on of the regulated activity during the period of absence;
- (d) the name, address and qualifications of the person who will be responsible for the management of the carrying on of the regulated activity during that absence;
- (e) in the case of the absence of the registered manager, the arrangements that have been, or are proposed to be, made for appointing another person to manage the carrying on of the regulated activity during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence referred to in paragraph (1) arises as the result of an emergency, the registered person must give notice of the absence to the Commission within 5 working days of its occurrence specifying the matters set out in paragraph (2)(a) to (e).

(4) Where—

(a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or

(a) the registered manager,

has been absent for a continuous period of 28 days or more, and the Commission has not been given notice of the absence, the registered person shall forthwith give notice in writing to the Commission specifying the matters set out in paragraph (2)(a) to (e).

(5) The registered person must notify the Commission of the return to duty of the service provider or (as the case may be) the registered manager not later than 7 working days after the date of that return.

(6) In this regulation “working day” means any day other than a Saturday, a Sunday, Christmas Day, Good Friday or a day which is a bank holiday in England and Wales within the meaning of the Banking and Financial Dealings Act 1971.

(7) Subject to paragraph (8), this regulation does not apply where the service provider is a health service body.

(8) Where the service provider is a health service body and is subject to a registered manager condition pursuant to regulation 5 or section 12(3) or (5) of the Act, this regulation shall have effect in relation any absence, proposed absence or return to duty of that registered manager.

Regulation 14 of the Care Quality Commission (Registration) Regulations 2009

Outcome



What should people who use services experience?

People who use services:

- Can have confidence that, if the person(s) in charge of their service is absent, it will continue to be properly managed and be able to meet their needs.

This is because providers who comply with the regulations will:

- Inform the Care Quality Commission:
 - about any significant planned absences from the service
 - about any significant unplanned absences
 - how the service will be run while they are away
 - when they return from a significant absence.

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers.

The regulations say that a registered person who is an individual (provider or manager) must send these notifications to the Care Quality Commission. Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 16.

Inform the Care Quality Commission of absences of a registered person

People who use services receive a service from a provider (where the provider is an individual) and/or registered manager who has made appropriate arrangements to cover their absence:

27A

In relation to planned absences of a registered provider who is in day-to-day charge of the service or of a registered manager:

- Registered persons give the Care Quality Commission 28 days' notice if they are going to be absent from the service for 28 or more days.
- Where an absence is planned less than 28 days before it begins, registered persons inform the Care Quality Commission without delay before the absence begins.

27B

In relation to an emergency absence of a registered provider who is in day-to-day charge of the service or of a registered manager that is likely to last more than 28 days:

- Inform the Care Quality Commission of the absence within five working days after it began.

27C

In relation to all notices of absence of a registered provider who is in day-to-day charge of the service or of a registered manager:

- Tell the Care Quality Commission:
 - the reason for the absence, and how long it will last, if it is known
 - who will run the service while the registered person is away
 - the name, address and qualifications of the person who will be responsible for the service while the registered person is away.
- If the length of the absence is unknown, propose to the Care Quality Commission how long the situation will continue before a new manager will be proposed for registration.

27D

In relation to returning from an absence of a registered provider who is in day-to-day charge of the service or of a registered manager:

- Inform the Care Quality Commission that they have returned to work no later than seven days after their return.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Outcome 28: Notifications – notice of changes

Regulation



What do the regulations say?

Notice of changes

15.—(1) Subject to paragraph (2), the registered person must give notice in writing to the Commission, as soon as it is reasonably practicable to do so, if any of the following events takes place or is proposed to take place—

- (a) a person other than the registered person carries on or manages the regulated activity;
- (b) a registered person ceases to carry on or manage the regulated activity;
- (c) the name of a registered person (where that person is an individual) changes;
- (d) where the service provider is a partnership, any change in the membership of the partnership;
- (e) where the service provider is a body other than a partnership—
 - (i) a change in the name or address of the body,
 - (ii) a change of director, secretary or other similar officer of the body, or
 - (iii) a change of nominated individual;
- (f) where the service provider is—
 - (i) an individual, the appointment of a trustee in bankruptcy in relation to that individual, or
 - (ii) a company or partnership, the appointment of a receiver, manager, liquidator or provisional liquidator in relation to that company or partnership.

(2) Paragraph (1)(e)(ii) does not apply where the service provider is a health service body.

(3) In this regulation, “nominated individual” means the individual who is employed as a director, manager or secretary of the body and whose name has been notified to the Commission as being the person who is responsible for supervising the management of the carrying on of the regulated activity by that body.

Regulation 15 of the Care Quality Commission (Registration) Regulations 2009

Outcome



What should people who use services experience?

People who use services:

- Can be confident that, if there are changes to the service, its quality and safety will not be adversely affected.

This is because providers who comply with the regulations will:

- Inform the Care Quality Commission:
 - when the person who manages or carries on the service changes
 - when the registered details of the service and any individual, partnership or organisation who manage or carry it on, change
 - when the registered person becomes financially insolvent
 - when the service closes.

Prompts



Prompts for all providers to consider

The following prompts relate to all registered providers.

The regulations say that a registered person (provider or manager) must send these notifications to the Care Quality Commission. Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 1.

Inform the Care Quality Commission

People who use services receive a service from a registered provider and/or manager who has made appropriate arrangements to notify the Care Quality Commission of changes.

28A

In relation to the people who manage or carry on the service:

- Registered providers tell the Care Quality Commission of any plans for a person other than a registered person to carry on or manage the service as soon as possible before they do so.
- Where a person other than a registered person begins to carry on or manage the service and it has not been possible to tell the Care Quality Commission before they start to do so, they tell the Care Quality Commission about the planned change without delay.

28B

In relation to the registered details of the service:

- Providers tell the Care Quality Commission as soon as possible about:
 - where a registered person is an **individual**; any changes to their name
 - the appointment a new registered manager, and
 - the name of the new registered manager
 - the date they will begin work
 - where the service provider is a **partnership**; any changes to the membership of a partnership
 - where the service provider is an **organisation**; any changes to the organisation's:
 - name
 - business address
 - officers (such as to the directors or secretary)
 - nominated individual.

The requirement to notify changes to officers does not apply to English NHS trusts

28C

In relation to changes to financial solvency:

- Inform the Care Quality Commission when:
 - where the provider is an **individual or member of a partnership that is not a limited liability partnership**; they have been made bankrupt or their estate has been sequestrated; or
 - where the provider is an **organisation or limited liability partnership**; that an administrator, receiver, liquidator or provisional liquidator has been appointed.

This requirement does not apply to English NHS trusts

28D

Where a provider cannot tell the Care Quality Commission about any of these changes before they are made or take place, they do so without delay afterwards.

Additional prompts for specific service types

There are no additional prompts for this outcome.

Appendices

Appendix A: Glossary

<p>Abuse</p>	<p>Abuse is defined by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 as:</p> <ul style="list-style-type: none"> ● Sexual abuse ● Physical or psychological ill-treatment ● Theft, misuse or misappropriation of money or property, or ● Neglect and acts of omission which cause harm or place at risk of harm. <p>In addition, we have given further guidance about this term in ‘definitions of key terms’ (see page 34).</p>
<p>Adequate</p>	<p>Sufficient for a specific requirement.</p>
<p>Advance decision</p>	<p>A decision to refuse specified medical treatment, made in advance by a person who has the mental capacity to do so. In this way, people can refuse medical treatment for a time in the future when they may lack the capacity to consent to, or refuse, that treatment.</p>
<p>Adverse drug reaction</p>	<p>An unwanted or unexpected reaction to a medicine.</p>
<p>Adverse event</p>	<p>An event that is not anticipated or not known to be related to the person’s condition or the intervention being used. Adverse events include near misses.</p>
<p>Advocacy</p>	<p>The action of an advocate, or the services provided by one or more advocates. Taking action to help people to say what they want, securing their rights, representing their interests and obtaining the services they need.</p> <p>Advocacy is most effective when carried out by a person who is independent of the services being provided.</p>

<p>Advocate</p>	<p>Advocate can be used in a general sense, as one who speaks on behalf of another, or it can have special meanings derived from the Mental Health Act 1983 and the Mental Capacity Act 2005.</p> <p>There are formal and informal advocates and these can be:</p> <ul style="list-style-type: none"> ● Individuals acting informally: <ul style="list-style-type: none"> – carers – relatives – partners – neighbours or friends – staff. ● Those prescribed by legislation, such as Independent Mental Health Advocates and Independent Mental Capacity Advocates ● Those provided by schemes run by local authorities, the NHS and charities. <p>In addition, we have given further guidance about this term in ‘definitions of key terms’ (see page 33).</p>
<p>Agreement (in relation to a signed document)</p>	<p>An understanding between two or more individuals or entities about enforceable rights and duties regarding their past or future performances and consideration. While an agreement usually leads to a written contract, it can also be recorded in different ways and may also be spoken, rather than written.</p>
<p>Aids to daily living</p>	<p>Equipment or items that are crucial to the maintenance of fully independent, or partially independent, living.</p>
<p>Alert letters</p>	<p>Leaflets sent out by bodies with information about specific problems that have arisen, or to warn that there may be a problem, for example a drug recall or an alert about an equipment fault.</p>
<p>Algorithm</p>	<p>A procedure that involves a finite series of sequential steps, used to find the solution to a specific problem or to complete a specified task.</p>
<p>Balanced diet</p>	<p>A diet that contains adequate amounts of all the necessary nutrients for maintaining or improving health.</p>
<p>Behaviour that challenges</p>	<p>Unusual or out-of-character behaviour that is attributable to mental ill health or a temporary emotional disturbance.</p>

<p>Bind over</p>	<p>A person accused of an offence may be bound over to appear at a court, or to be of good behaviour, or to keep the peace. If they refuse to accept a bind over, the person may be committed to prison. A bind over is not a conviction and does not go onto a personal criminal record.</p>
<p>Capacity (including concepts of competencies)</p>	<p>The ability by someone to make a specific decision for himself or herself in a given situation. It is assumed that anyone aged 16 or over has capacity unless proven otherwise.</p> <p>There are no degrees of capacity: either a person has capacity or does not. Children under the age of 16 are assumed not to have capacity unless they have sufficient understanding and intelligence to enable them to understand fully what is proposed.</p> <p>Capacity is defined by the Mental Capacity Act 2005 as:</p> <p>“People who lack capacity:</p> <p>(1) For the purposes of this Act, a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.</p> <p>(2) It does not matter if the impairment or disturbance is permanent or temporary.</p> <p>(3) A lack of capacity cannot be established merely by reference to:</p> <p>(a) A person’s age or appearance, or</p> <p>(b) A condition of his, or an aspect of his behaviour, which might lead others to make unjustified assumptions about his capacity.”</p> <p>In addition, we have given further guidance about this term in ‘definitions of key terms’ (see page 34).</p>
<p>Care programme approach</p>	<p>The process that providers of mental health care use to coordinate the care, treatment and support for people who have mental health needs.</p>
<p>Carer</p>	<p>Carers look after family, partners or friends in need of help because they are ill, frail or have a disability. The care they provide is unpaid.</p> <p>Carers include young carers.</p> <p>The term does not include paid care workers or people who undertake voluntary work.</p> <p>In addition, we have given further guidance about this term in ‘definitions of key terms’ (see page 33).</p>

Carry on	To provide, run or manage the provision of a regulated activity.
Child/children	The Children Act 1989 and the Children Act 2004 define a child as being a person up to the age of 18 years. However, the Children Act 2004 states that safeguarding, protection and cooperation between services may, in certain circumstances, be continued through to a young person's 19th birthday or beyond.
Commissioner	A person with responsibility for buying services from service providers in either the public, private or voluntary sectors.
Commissioners of services	Organisations that buy services on behalf of the people living in the area that they cover. This may be for a population as a whole, or for individuals who need specific care, treatment and support. For the NHS, this is done by primary care trusts and for social care by local authorities.
Competency	The required level of skills and knowledge for a particular task.
Complaint	An expression of dissatisfaction with something. This can relate to any aspect of a person's care, treatment or support and can be expressed orally, in gesture or in writing.
Compliance	Agreement, assent or submission with defined requirements.
Consent	<p>A person's agreement to, or permission for, a proposed action, particularly any form of examination, care, treatment or support.</p> <p>Professionals have their own codes of practice that indicate how the consent they need from people who use services should be managed.</p> <p>In our guidance, we recognise that the consent of a person who uses services can involve another person, and that it can be obtained, given and recorded in different ways.</p>
Controlled drug	One of a group of medicines that have the potential for abuse. For this reason, they are "controlled" by the Misuse of Drugs Act 1971. Many controlled drugs are essential to modern clinical care, treatment and support. They include narcotics, such as morphine and diamorphine, that are used in a wide variety of clinical treatments, for example relieving acute pain after a heart attack or fracture, relieving chronic pain, treating drug dependence and in anaesthesia.
Culture	Learned attitudes, beliefs and values that define a group or groups of people.

<p>Dignity</p>	<p>Dignity is concerned with how people feel, think and behave in relation to the worth or value that they place on themselves and others. To treat someone with dignity is to treat them as being of worth and respect them as a valued person, taking account of their individual views and beliefs.</p>
<p>Discharge</p>	<p>The point at which a patient leaves hospital to return home or be transferred to another service, or the formal conclusion of a service provided to a person who uses services.</p>
<p>Employed</p>	<p>The employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract, including a carer agreement and the grant of practising privileges.</p> <p>It includes:</p> <ul style="list-style-type: none"> ● Contracted staff ● Temporary staff ● Bank staff ● Practitioners working under practising privileges ● Volunteers ● Students and learners ● Contractors.
<p>End of life</p>	<p>The last phase of a person’s life, when a judgement has been made by an appropriately qualified person that the person has an advanced, progressive, incurable illness, or that the person’s death is imminent.</p>
<p>End of life care</p>	<p>The care, treatment and support that is provided to enable a person with advanced, progressive, incurable illness to live as well as possible before they die. End of life care also covers the management of pain and other symptoms, and the provision of psychological, social, spiritual and practical support, and support for the family into bereavement.</p>
<p>Enforcement action</p>	<p>Action taken to cancel, prevent or control the way a service is delivered using the range of statutory powers available to the Care Quality Commission. It can include action taken in respect of services that should be, but are not, registered.</p>

Equipment	Machines and medical devices used to help, prevent, treat or monitor a person's condition or illness. The term may also be used to refer to aids that may support a person's care, treatment, support, mobility or independence, for example, a walking frame, hoist, or furniture and fittings. It excludes machinery or engineering systems that are physically affixed and integrated into the premises.
Examination	Examination includes undertaking tests such as an x-ray or taking a blood sample to determine a diagnosis and treatment plan, or whether further tests are needed, or if a person needs to be referred for more in-depth or specialist tests or treatment.
Experience	<p>Experience can refer to the broad effects that care, treatment or support can have on a person, including their thoughts and feelings about the care, treatment and support they have received, how they interact with staff and others, or any wider impact on their life and those around them.</p> <p>It can also refer to the experience a health or social care professional has of delivering a specific type of care, treatment or support. It often includes aspects of knowledge and skill, as well as taking account of the length of time they have been undertaking certain activities or the number of times they have performed an activity.</p>
Expert bodies	Professional organisations that develop, issue and design technical and operational standards relating to specialist areas.
General practitioner (GP)	A medical practitioner who provides primary care and specialises in family medicine. General practitioners treat acute and chronic illnesses and provide preventative care and health education for all ages and genders.
Handling (medicines)	The safe and secure, storage, selection, preparation, giving or administering, and safe disposal, of medicines.
Health action plan	A guide to a person's health that may be developed in any healthcare setting. It describes the person's health and the best ways to support them to get the right treatment and healthcare.
Healthcare	The preservation of mental and physical health by preventing or treating illness through services offered by the health professions, including those working in social care settings.
Healthcare-associated infection	An avoidable infection that occurs as a result of the healthcare that a person receives.

Healthcare professional	Individuals regulated and/or licensed to provide some type of healthcare.
Health status	The current state of a person's health. It includes the status of their wellness, fitness, and any underlying diseases or injuries.
Holistic	About the whole person, including all their needs and all aspects of their life.
Homely remedy	A medicine that can be bought without a prescription to treat a minor ailment.
Hospice	An organisation or agency that provides multidisciplinary and person-centred palliative care for people with an advanced, progressive, incurable disease. Care, treatment and support may be provided to the person through a range of services such as inpatient care, day care, community and social care, home care, outpatient appointments, sitting services, respite care and bereavement support, when curative treatment is no longer an option.
Human rights	<p>The basic rights and freedoms contained in the European Convention on Human Rights. The Human Rights Act 1998 means that these should be available to everyone, regardless of their age, nationality, race, ethnicity, gender or religion and beliefs. It is an offence for a public body to breach any person's human rights, and under the Health and Social Care Act 2008, "public body" includes any provider that supplies accommodation together with nursing or personal care on behalf of a local authority.</p> <p>In addition, we have given further guidance about this term in 'definitions of key terms' (see page 32).</p>
Implied consent	A form of consent that is not expressly granted by a person, but rather inferred from a person's actions and the facts and circumstances of a particular situation (or in some cases, by a person's silence or inaction). The assumed agreement is that the person would approve a course of action if asked in a given situation, but is not presently able to be asked.
Independent doctor	Medically qualified doctors who are actively practising, but who do not hold a post in the NHS.
Independent healthcare	Private, voluntary and not-for-profit healthcare organisations that are not part of the NHS.
Intimidation	To scare, frighten or coerce, especially with threats.

<p>Medical device</p>	<p>Any instrument, apparatus, appliance, material or other article (whether used alone or in combination), including the software necessary for its proper application, intended by the manufacturer to be used for people for the purpose of:</p> <ul style="list-style-type: none"> ● Diagnosis, prevention, monitoring, treatment or alleviation of disease. ● Diagnosis, monitoring, alleviation of or compensation for an injury or disability. ● Investigation, replacement or modification of the anatomy or of a physiological process. ● Control of conception, <p>and which does not achieve its physical intended action on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.</p>
<p>Medicine</p>	<p>A substance or substances administered for the purpose of modifying, controlling, treating or diagnosing a medical condition, disease or illness.</p>
<p>Nutritional assessment</p>	<p>A detailed, specific and in-depth evaluation of nutritional status, typically undertaken by a person with nutritional expertise (for example, a dietician, a clinician with a specialist interest or a nurse specialist), so that a specific dietary plan can be drawn up and implemented. It is often used for more complicated nutritional problems.</p>
<p>Nutritional screening</p>	<p>A quick, simple and general procedure used by nursing, medical, or other healthcare or social care staff, often at first contact with the person using the service, to detect those at risk of poor nutrition. This allows a clear plan of action to be developed and implemented. It should be an integral part of the initial assessment of the person using the service on their admission, or on receipt of care, treatment and support when they begin to use the service.</p>
<p>Nutritional status</p>	<p>A person's physiological state that results from the relationship between nutrient intake and requirements. and from the body's ability to digest, absorb and use these nutrients.</p>
<p>Palliative care</p>	<p>The active, holistic care of people who use services with advanced progressive illness. Management of pain and other symptoms, and provision of psychological, social and spiritual support, is paramount. The goal of palliative care is to achieve the best quality of life for people who use services and their families. Many aspects of palliative care are also applicable earlier in the course of the illness, in conjunction with other treatments.</p>

Parent	A person holding a legally recognised parental responsibility.
People who use services	<p>A person who receives services provided in the carrying on of a regulated activity. This is the definition of “service user” provided in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.</p> <p>In addition, we have given further guidance about this term in ‘definitions of key terms’ (see page 32).</p>
Personalised	Where the person using the service leads, with choice being the defining principle.
Person-centred	Putting the person who uses services at the centre of their care, treatment and support, ensuring that everything that is done is based on what is important to that person from their own perspective.
Plan of support	A written and agreed plan to provide support to a worker in the discharge of their responsibilities, and for people who use services to know what to expect of their care. A plan of support should be agreed between the worker and others involved in supporting them – these may include the employer, employee representatives, occupational health professionals and others.
Polypharmacy	The use of multiple medicines to treat a person, without appropriate review to ensure that they are all necessary for effective treatment.
Practising privileges	The right granted to a healthcare professional to practise or provide care, treatment or support to people using independent healthcare services. The right to practise is based on similar principles as an employment contract, without the two parties entering into a formal contract of employment. Practising privileges are granted after the same checks have been made on a person as on anyone that the service directly employs. By accepting practising privileges, the healthcare professional accepts to be bound by the policies, protocols, systems and governance arrangements set up by the provider of the service.
Premises	Any building or other structure, including any machinery or engineering systems that are physically affixed and integral to such building or structure, or a vehicle.
Prescribing	To order the use of a medicine or other treatment by someone authorised to prescribe.

Privacy and dignity	To respect a person's privacy is to recognise when they wish and need to be alone (or with family or friends), and protected from others looking at them or overhearing conversations that they might be having. It also means respecting their confidentiality and personal information. To treat someone with dignity is to treat them as being of worth and respect them as a valued person, taking account of their individual beliefs.
Professional body	An organisation that exists to further a profession and to protect both the public interest, by maintaining and enforcing standards of training and ethics in their profession, and the interest of its professional members.
Public interest	<p>There is no single definition of public interest. It includes, but is not confined to:</p> <ul style="list-style-type: none"> ● Exposing or detecting crime. ● Exposing significantly anti-social behaviour. ● Exposing corruption or injustice. ● Disclosing significant incompetence or negligence. ● Protecting people's health and safety. ● Preventing people from being misled by some statement or action of an individual or organisation. ● Disclosing information that allows people to make a significantly more informed decision about matters of public importance. <p>There is also a public interest in freedom of expression itself. When considering what is in the public interest, we also need to take account of information already in the public domain or about to become available to the public.</p>
Quality monitoring	A continuous system of monitoring to ensure that local quality measures are effective. Quality monitoring is part of quality assurance.

<p>Reasonable adjustments</p>	<p>The duty to make reasonable adjustments, as set out in the Disability Discrimination Act 1995, aims to ensure that people with a disability are not disadvantaged. There are three parts to the duty:</p> <ul style="list-style-type: none"> ● A duty to take reasonable steps to change a practice, policy or procedure that makes it impossible or unreasonably difficult for people with a disability to receive any benefit. ● A duty to take reasonable steps to remove, alter, or provide an alternative method to, a physical feature that makes it impossible or unreasonably difficult for people with a disability to receive any benefit. ● A duty to take reasonable steps to provide an additional aid or service where it would enable people with a disability to receive any benefit.
<p>Record</p>	<p>A formal written report or statement of facts, events or information, usually collected over a fairly long period of time. The act of maintaining individual records is called recording.</p>
<p>Resources</p>	<p>The things needed to carry out a task or a piece of work. Resources can include appropriately qualified staff, suitable buildings and sufficient equipment.</p>
<p>Restraint</p>	<p>The Mental Capacity Act 2005 defines restraint as:</p> <ul style="list-style-type: none"> ● Physical restraint – holding someone, moving a person or blocking their movement. ● Mechanical restraint – use of equipment. ● Chemical restraint – use of medication. ● Environmental restraint. ● Technological surveillance – use of tags, CCTV, door alarms or pressure pads. ● Psychological restraint – constant commands.
<p>Risk</p>	<p>The probability of an issue occurring, related to a particular condition or treatment. Also the conclusion of considering the likelihood of an adverse event occurring and, if it does occur, how severe the consequences are likely to be.</p> <p>The risk may come directly from the condition itself or indirectly from the process or method involved in the treatment or application. Risk does not mean bad things will happen. It allows people to make decisions about the world in which they live and the choices they have to make, because it is a balanced judgement of danger.</p>

Risk assessment	The process of identifying all the risks to and from an activity, and assessing the potential impact of each risk.
Safeguard	To protect and promote the welfare of people: <ul style="list-style-type: none"> ● Protecting people from abuse or neglect. ● Preventing impairment of people's health or development. ● Ensuring that people receive care, treatment and support in circumstances consistent with the provision of safe and effective care, treatment and support.
Safeguarding	Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights. Children, and adults in vulnerable situations, need to be safeguarded. For children, safeguarding work focuses more on care and development; for adults, on independence and choice.
Social and cultural values	Social and cultural values relate to a way of life. All societies have a culture, or common way of life, that includes: <ul style="list-style-type: none"> ● Language – the spoken word and other communication methods. ● Customs – rites, rituals, religion and lifestyle. ● Shared system of values – beliefs and morals. ● Social norms – patterns of behaviour that are accepted as normal and right. (These can include dress and diet.) <p>The different cultures in society reflect the richness of cultural diversity, where different people live and work together, but retain their individual identity.</p>
Social care	Social care includes all forms of personal care and other practical assistance provided for people who by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs or any other similar circumstances, are in need of such care or other assistance. <p>For the purposes of the Care Quality Commission, it only includes care provided for, or mainly for, people over 18 years' old in England. We sometimes refer to this as adult social care.</p>

Specialist techniques for nutrition	Sometimes it is not possible for people, such as those with acute swallowing problems or anorexia or those who have had abdominal surgery, to consume food orally. In these cases, it may be necessary to provide nutrition artificially by inserting a tube or other device. There are various methods of doing this, for example naso-gastric tube, percutaneous endoscopic gastrostomy (PEG) feed, and enteral and parenteral feeding. These techniques can be prescribed only by a specialist such as a dietician and undertaken by a trained healthcare professional.
Staff	The entire group of people employed for the purposes of carrying on a regulated activity.
Supervision	A process to guide, support and assist people who provide services to carry out their duties and assigned tasks, so as to achieve the planned outcome.
Third party	A person or organisation other than the principals who are involved in a transaction or direct provision of a service.
Timely	At the right, or at a suitable, moment.
Volunteer	An unpaid member of staff. A person who gives their time willingly in return for no payment in money or kind.
Welfare	A person's state or condition, taking into account their physical, social and financial situation. A person's welfare will also take account of their emotional and spiritual states.
Without delay	As soon as it is reasonably practicable to do so.

Appendix B: Schedule of Applicable Publications

In the prompts for some of the regulations, we include the following statement:

“People who use services benefit from a service that takes into account relevant guidance, including that from the Care Quality Commission’s Schedule of Applicable Publications.”

For each outcome where the above statement appears, we set out below the documents that we intend to consider. Providers should reflect the key expectations of these publications for their service, as they relate to the essential standards of quality and safety.

For some publications, these expectations are different for different types of service. For example:

NHS Information Governance: Guidance on Legal and Professional Obligations (DH, 2007)

- This publication is listed in this Schedule under outcome 21 (Records).
- It provides information about the range of legal and professional obligations that limit, prohibit or set conditions in respect of the management, use and disclosure of information. It focuses mainly on the impact of these provisions for NHS information, but also includes some social care information. It may also include useful guidance about these laws for independent healthcare providers.
- Therefore, the expectations within this publication are different for different types of provider, and providers should be aware what this publication means for them.

This Schedule does not include any acts of Parliament or underpinning regulations enacted by Parliament, as legislation is enforceable in its own right and there is provision under the Health and Social Care Act 2008 for us to take other enactments into account in our work.

Abbreviations used:

DCSF = Department for Children, Schools and Families

DH = Department of Health

MHRA = Medicines and Healthcare products Regulatory Agency

NICE = National Institute for Health and Clinical Excellence

NPSA = National Patient Safety Agency

NTA = National Treatment Agency for Substance Misuse

Outcome 1	Respecting and involving people who use services
<ul style="list-style-type: none">● The NHS Constitution (DH, 2009)● Confidentiality: NHS code of practice (DH, 2003)● Relevant national strategies, national service frameworks, and nationally agreed policy guidance and recommendations about involving people published by the Department of Health and other Government departments, including:<ul style="list-style-type: none">– Human Rights in Health Care – A Framework for Local Action (DH)– Valuing People: a new strategy for learning disability for the 21st century (HM Government, 2001)– Valuing People Now: a new three-year strategy for people with learning disabilities – Making it happen for everyone (HM Government, 2009)– Real involvement: working with people to improve services (DH, 2008)– Independence, Choice and Risk: A Framework for Supported Decision Making (DH, 2007)– Refocusing the care programme approach: Policy and positive practice guidance (DH, 2008)● Guide to the public sector equalities duties (Equality and Human Rights Commission, 2009)● Being open – communicating patient safety incidents with patients and their carers (NPSA, 2006)● Care Planning Practice Guide (NTA, 2006)	

Outcome 2	Consent to care and treatment
<ul style="list-style-type: none"> ● The NHS Constitution (DH, 2009) ● Reference guide to consent for examination or treatment (DH, 2001) ● Good practice in consent: achieving the NHS plan commitment to patient centred consent practice (Health Service Circular HSC 2001/023) ● Seeking Consent: working with children (DH, 2001) ● Research governance framework for health and social care: Second edition (DH, 2005) ● Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy (DH) ● Relevant guidance and codes of conduct relating to consent published by professional registration councils such as the General Medical Council, Nursing & Midwifery Council, General Social Care Council and the Health Professions Council ● Mental Health Act Code of Practice (2007) ● Mental Capacity Act Code of Practice (2008) 	
Outcome 3	Fees
<ul style="list-style-type: none"> ● Office of Fair Trading: Guidance on unfair terms in care home contracts ● Office of Fair Trading: Guidance on unfair contract terms ● General Medical Council code of conduct 	

Outcome 4

Care and welfare of people who use services

- The NHS Constitution (DH, 2009)
- Mental Capacity Act Code of Practice (2007)
- Research governance framework for health and social care: Second edition (DH, 2005)
- Being open – communicating patient safety incidents with patients and their carers (NPSA, 2006)
- Mental Health Act Code of Practice (2008)
- Care Planning Practice Guide (NTA, 2006)
- National strategies, national service frameworks and white papers, and nationally agreed policy guidance published by the Department of Health and other Government departments, including:
 - National Service Framework for Mental Health (DH, 1999)
 - National Service Framework for Older People (DH, 2001)
 - Valuing People: a new strategy for learning disability for the 21st century (HM Government, 2001)
 - Diabetes National Service Framework (DH, 2003)
 - National Service Framework for children, young people and maternity services (DH & Department for Education and Skills, 2004)
 - Choosing Health: Making healthy choices easier (DH, 2004)
 - National Service Framework for Renal Services (DH, 2004)
 - National Service Framework for Long Term Conditions (DH, 2005)
 - Cancer Reform Strategy (DH, 2007)
 - National Framework for NHS Continuing Health care and NHS funded Nursing Care (DH, 2007)
 - National Stroke Strategy (DH, 2008)
 - End of Life Care Strategy (DH, 2008)
 - Living well with dementia: A National Dementia Strategy (DH, 2009)
 - Healthy Lives brighter futures: The children strategy for children and young people’s health (DH, 2009)
 - Valuing People Now: a new three-year strategy for people with learning disabilities – Making it happen for everyone (HM Government, 2009)

Outcome 4 (cont)

Care and welfare of people who use services

- Relevant policy and implementation guidance and recommendations about good practice published by the Department of Health. Including:
 - Refocusing the care programme approach: Policy and positive practice guidance (DH, 2008)
 - Mental Health Policy Implementation Guide: Adult Acute Inpatient Care Provision (DH, 2002)
 - Mental Health Policy Implementation Guide: National Minimum Standards for General Adult Services in Psychiatric Intensive Care Units and Low Secure Environments (DH, 2002)
 - The acutely or critically sick or injured child in the district general hospital: A team response (DH, 2006)
 - Drug misuse and dependence: UK guidelines on clinical management (DH, 2007)
 - DH Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy
 - DH Guidance on the Establishment and Use of Diagnostic Reference Levels
 - DH IRMER Guidance and Good Practice Notes
- Relevant evidence-based guidance about good practice and alerts published by expert and professional bodies, including:
 - Equality and Human Rights Commission
 - Joint Committee on Human Rights
 - The National Treatment Agency for Substance Misuse
 - Health Service Ombudsman
 - National Institute for Health and Clinical Excellence
 - Social Care Institute for Excellence
 - National Patient Safety Agency
 - Medicines and Healthcare products Regulatory Agency
 - Health Protection Agency
 - Administration of Radioactive Substances Advisory Committee
 - Medical and other clinical royal colleges, faculties and professional associations

Outcome 5

Meeting nutritional needs

- Nutrition support in adults (CG 32, NICE, 2006)
- Nutrition Action Plan (DH and Nutrition Summit stakeholders, 2007)
- Relevant evidence-based guidance about nutrition in health and social care settings published by expert and professional bodies

Outcome 6

Cooperating with other providers

- The NHS Constitution (DH, 2009)
- Records management: NHS code of practice (DH, 2006)
- Guidance on the Health Act Section 31 partnership agreements (DH, 1999)
- Discharge from hospital pathway, process and practice (DH, 2003)
- Information security management: NHS code of practice (DH, 2007)
- Relevant national strategies, national service frameworks, white papers, and nationally agreed policy guidance and recommendations published by the Department of Health and other Government departments where they include guidance about working in partnership, including:
 - The NHS Emergency Planning Guidance (DH, 2005), and associated supplements (DH, 2005, 2007)
 - Pandemic Influenza: A National Framework for Responding to an Influenza Pandemic (DH, 2007)
 - Every Child Matters (HM Government, 2003)
 - Valuing People Now: a new three-year strategy for people with learning disabilities – Making it happen for everyone (HM Government, 2009)
 - Creating strong, safe and prosperous communities. Statutory Guidance (HM Government, 2008)
 - Green light for mental health: How good are your mental health services for people with learning disabilities; A service toolkit (DH, 2004)
 - Dual diagnosis in mental health inpatient and day hospital settings (DH, 2006)
 - Everybody's business: A service development guide (DH & Care Services Improvement Partnership, 2005)
 - DCSF guidance on information sharing

Outcome 7

Safeguarding people who use services from abuse

- No secrets: Guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse (DH and Home Office, 2000)
- Working together to safeguard children (HM Government, 2006) and supplementary guidance published by government departments
- Every Child Matters (HM Government, 2003)
- Statutory Guidance on making arrangements to safeguard and promote the welfare of children under section 11 of the Children Act 2004 (DCSF, 2007)
- Safeguarding Adults: A National Framework of Standards for good practice and outcomes in adult protection work (Association of Directors of Adult Social Services, 2005)
- Deprivation of Liberty Safeguards: A guide for hospitals and care homes (DH, 2009)
- Guidance for restrictive physical interventions: How to provide safe services for people with learning disabilities and autistic spectrum disorder (DH, 2002)
- What to do if you're worried a child is being abused (HM Government, 2006)
- Healthy Lives brighter futures: The children's strategy (DH, 2009)
- Information Sharing: Guidance for practitioners and managers (DCSF, 2008)
- Statement on the duties of doctors and other professionals in investigations of child abuse (DCSF and DH, 2007)
- Mental Health Act Code of Practice (DH, 2008)
- Mental Capacity Act Code of Practice (DH, 2007)
- Violence: The short term management of violent/disturbed behaviour in in-patient psychiatric and emergency departments (CG25, NICE, 2005)
- Guidance on when to suspect child maltreatment (CG89, NICE, 2009)
- Services for people with learning disabilities and challenging behaviour or mental health needs – Mansell report: revised edition (DH, 2007)

Outcome 9

Management of medicines

- Relevant evidence-based guidance and alerts about medicines management and good practice published by appropriate expert and professional bodies, including:
 - National Patient Safety Agency
 - National Institute for Health and Clinical Excellence
 - Medicines and Healthcare products Regulatory Agency
 - Department of Health
 - Royal Pharmaceutical Society of Great Britain (RPSGB)
 - Social Care Institute for Excellence
 - Medical and other clinical royal colleges, faculties and professional associations
- The safe and secure handling of medicines: a team approach (RPSGB, 2005)
- Safer management of controlled drugs: Guidance on strengthened governance arrangements (DH, 2007)
- Safer management of controlled drugs: Guidance on standard operating procedures for controlled drugs (DH, 2007)
- The handling of medicines in social care (RPSGB, 2007)
- Research governance framework for health and social care: Second edition (DH, 2005)

Outcome 10

Safety and suitability of premises

- All currently valid Health Technical Memoranda (HTMs) published by the Department of Health
- All currently valid Health Building Notes (HBNs) published by the Department of Health
- Legionnaires Disease: The control of legionella bacteria in water systems, approved code of practice and guidance (Health and Safety Executive, 2000)
- Controlling legionella in nursing and residential care homes (Health and Safety Executive, 1997)
- Guidance on Manual Handling operations Regulations (Health and Safety Executive, 2004)
- Alerts, rapid response reports, guidance and directives about all aspects of healthcare and social care premises published by:
 - National Patient Safety Agency
 - DH
 - Secretary of State
 - Health and Safety Executive
 - Department of Environmental Health
 - Home Office
 - National Institute for Health and Clinical Excellence
 - National Patient Safety Agency
 - NHS Estates
 - Social Care Institute for Excellence
 - Care Services Improvement Partnership
 - Professional Royal Colleges and other recognised professional bodies
- A professional approach to managing security in the NHS (NHS Security Management Service, 2003)
- Safety, privacy and dignity in mental health units. Guidance in mixed sex accommodation for mental health services (NHS Executive, 2000)
- Implementation Criteria for Recommended Specification: Adult Medium Secure Units (Quality Network for Forensic Mental Health Services, 2007)
- Environmental principles for medium secure accommodation (Health Offender Partnerships, 2008)
- The NHS constitution (DH, 2009)
- Guidance notes for Dental Practitioners on the Safe Use of X-ray Equipment published by the National Radiation Protection Board

Outcome 11

Safety, availability and suitability of equipment

- MHRA DB2008(03) Guidance on the safe use of lasers, IPL systems and LEDs
- MHRA DB 2006 (4) Single-use Medical Devices: Implications and Consequences of Reuse (MHRA, 2006)
- MHRA DB 2006(5) Managing Medical Devices: Guidance for health care and social care organisations (MHRA, 2006)
- Safety alerts, rapid response alerts, guidance and directives relating to equipment published by expert and professional bodies including:
 - National Institute of Clinical Excellence
 - National Patient Safety Agency
 - Medicines and Healthcare products Regulatory Agency
 - Royal Pharmaceutical Society of Great Britain
 - DH
 - Product manufacturers
- DH IRMER Guidance and Good Practice Notes
- Mental Health Act 1983 and Mental Health Act Code of Practice (DH, 2008 relating to seclusion facilities)

Outcome 12

Requirements relating to workers

- NHS employment check standards published by NHS Employers
- Code of practice for the international recruitment of health care professionals (DH, 2004)
- The Health care Professionals Alert Notices Directions 2006 (DH, 2006)
- Relevant guidance and codes of conduct and practice about professional registration and qualifications published by professional registration councils and professional bodies including:
 - General Medical Council
 - Nursing and Midwifery Council
 - Health Professional Council
 - General Dental council
 - General Social Care Council
 - Royal Pharmaceutical Society of Great Britain
 - Medical and other clinical royal colleges, faculties and professional associations
- CRB Code of Practice
- Safeguarding Vulnerable Groups Act 2006
- Protection of vulnerable adults scheme (POVA)
- ISA Referral Guidance (Independent Safeguarding Authority, 2009)
- DH IRMER Guidance and Good Practice Notes

Outcome 13	Staffing
<ul style="list-style-type: none"> ● Relevant guidance about staffing levels and skills mix published by professional registration councils and relevant expert and professional bodies, including: <ul style="list-style-type: none"> – Skills for Care – Skills for Health – General Medical Council – Nursing and Midwifery Council – National Health Service – British Medical Association – Royal College of Nursing – General Social Care Council – National Patient Safety Agency – Health Professional Council – General Dental Council – DH – National Institute for Health and Clinical Excellence – Social Care Institute for Excellence – NHS Employers – Health and Safety Executive – Medical and other clinical royal colleges, faculties and professional associations ● National service frameworks and national strategies published by the Department of Health and other Government departments where they include guidance about staffing levels and skills mix. ● DH – Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy 	

Outcome 14

Supporting workers

- Relevant guidance and curricula about supporting workers published by relevant expert and professional bodies, including:
 - Skills for Care
 - Skills for Health
 - NHS Employers
 - Social Care Institute for Excellence
 - National Patient Safety Agency
 - Medical and other clinical royal colleges, faculties and professional associations
 - General Medical Council
- NHS promoting safer and therapeutic services October 2005; published by the NHS Security management Service
- Assuring the Quality of Medical Appraisal July 2005; a report published by the NHS Clinical Governance Support Team
- NHS Appraisal; Appraisal for consultants working in the NHS
- Secretary of State Directions on work to tackle violence against staff and professionals who work in or provide services to the NHS (DH, 2003)
- Published guidance from the Health & Safety Executive
- DH IRMER Guidance and Good Practice Notes

Outcome 16

Assessing and monitoring the quality of service provision

- Listening, improving, responding: a guide to better customer care (DH, 2009)
- DH IRMER Guidance and Good Practice Notes
- Relevant guidance, national reports and codes of conduct about risk management, monitoring quality and audit published by expert and professional bodies, including:
 - General Medical Council
 - Nursing & Midwifery Council
 - General Social Care Council
 - General Dental Council
 - Health Professions Council
 - National Patient Safety Agency
 - National Confidential Enquiry into Patient Outcomes and Death
 - Confidential Enquiries into Maternal and Child Health
 - Medicines and Healthcare products Regulatory Agency
 - NHS Litigation Authority
 - National Institute for Health and Clinical Excellence

Outcome 17

Complaints

- NHS Constitution (DH, 2009)
- The Principles of Good Complaint Handling (Parliamentary and Health Service Ombudsman, 2008)
- Listening, improving, responding: a guide to better customer care (DH, 2009)
- NHS Litigation Authority guidance about complaints
- Being open – communicating patient safety incidents with patients and their carers (NPSA, 2009)

Outcome 21	Records
<ul style="list-style-type: none"> ● The NHS Constitution (DH, 2009) ● Confidentiality: NHS code of practice (DH, 2003) ● Caldicott Guardian Manual 2006 (DH, 2006) ● Records management: NHS code of practice (DH, 2006), ● Information security management: NHS code of practice (DH, 2007) ● NHS Information Governance: Guidance on Legal and Professional Obligations (DH, 2007) ● Relevant professional guidance and codes of conduct and practice relating to record keeping published by professional bodies and registration councils including the General Medical Council, Nursing & Midwifery Council, General Social Care Council, BMA, RCN, Health Professional Council, Royal College of Physicians and the Academy of Medical Royal Colleges ● DH – Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy ● Codes of practice published by the Information Commissioner 	

 STATUTORY INSTRUMENTS

2010 No. 781

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

The Health and Social Care Act 2008 (Regulated Activities)
Regulations 2010

<i>Made</i>	- - - -	<i>15th March 2010</i>
<i>Coming into force</i>	- -	<i>1st April 2010</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 8(1), 20(1) to (5), 35, 86(2) and (4), 87(1) and (2) and 161(3) and (4) of the Health and Social Care Act 2008(a).

In accordance with section 20(8) of the Act, the Secretary of State has consulted such persons as he considers appropriate.

A draft of these Regulations was laid before Parliament in accordance with section 162(3) of the Health and Social Care Act 2008 and approved by resolution of each House of Parliament.

PART 1

GENERAL

Citation and commencement

1. These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and come into force on 1st April 2010.

Interpretation

2. In these Regulations—

“the Act” means the Health and Social Care Act 2008;

“the 1983 Act” means the Mental Health Act 1983(b);

“the 2006 Act” means the National Health Service Act 2006(c);

(a) 2008 c. 14. “Prescribed” and “regulations” are defined in section 97(1) of the Act.
(b) 1983 c.20.
(c) 2006 c.41.

“the 2001 Order” means the Health Professions Order 2001**(a)**;

“adult placement carer” means an individual who, under the terms of a carer agreement, provides, or intends to provide, personal care for service users together with, where necessary, accommodation in the individual’s home;

“adult placement scheme” means a scheme carried on (whether or not for profit) by a local authority or other person for the purposes of—

- (a) recruiting and training adult placement carers;
- (b) making arrangements for the placing of service users with adult placement carers; and
- (c) supporting and monitoring placements;

“carer agreement” means an agreement entered into between a person carrying on an adult placement scheme and an individual for the provision, by that individual, of personal care to a service user together with, where necessary, accommodation in the individual’s home;

“chiroprapist or podiatrist” means a person registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order**(b)**;

“employment” means—

- (a) employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract (including under a carer agreement); and
- (b) the grant of practising privileges,

and “employed” and “employer” should be construed accordingly;

“employment agency” and “employment business” have the same meanings as in the Employment Agencies Act 1973**(c)**;

“health care professional” means, except in paragraph 5 of Schedule 1, a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999**(d)** applies;

“hospital”, except in paragraphs 1(3)(d) and 6 of Schedule 1, has the same meaning as in section 275 of the 2006 Act;

“institution within the further education sector” has the same meaning as in section 91 of the Further and Higher Education Act 1992**(e)**;

“local anaesthesia” means any anaesthesia other than general, spinal or epidural anaesthesia, and also excludes the administration of a regional nerve block;

“medical practitioner” means a registered medical practitioner**(f)**;

“nominated individual” must be construed in accordance with regulation 5(2);

“nurse” means a registered nurse;

“nursing care” means any services provided by a nurse and involving—

- (a) the provision of care; or
 - (b) the planning, supervision or delegation of the provision of care,
- other than any services which, having regard to their nature and the circumstances in which they are provided, do not need to be provided by a nurse;

“personal care” means—

(a) S.I. 2002/254.
(b) See the definition of “relevant professions” in Schedule 3, paragraph 1 of the 2001 Order as amended by S.I. 2004/2033, article 10(5)(b)(i).
(c) 1973 c.35. See section 13(2) and (3). Section 13(2) was amended by the Employment Relations Act 1999 (c.26), Schedule 7, paragraphs 1 and 7.
(d) 1999 c.8. Section 60(2) was amended by the Health and Social Care Act 2008, Schedule 8, paragraph 1(3) and Schedule 15, Part 2 and by S.I. 2002/253 and the 2001 Order.
(e) 1992 c.13.
(f) The definition of “registered medical practitioner” in Schedule 1 to the Interpretation Act 1978 (c.30) has been substituted by S.I. 2002/3135, Schedule 1, paragraph 10 with effect from 16th November 2009.

- (a) physical assistance given to a person in connection with—
 - (i) eating or drinking (including the administration of parenteral nutrition),
 - (ii) toileting (including in relation to the process of menstruation),
 - (iii) washing or bathing,
 - (iv) dressing,
 - (v) oral care, or
 - (vi) the care of skin, hair and nails (with the exception of nail care provided by a chiropodist or podiatrist); or
- (b) the prompting, together with supervision, of a person, in relation to the performance of any of the activities listed in paragraph (a), where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision;

“practising privileges” means the grant, by a person managing a hospital, to a medical practitioner of permission to practise as a medical practitioner in that hospital;

“premises” means—

- (a) any building or other structure, including any machinery or engineering systems which are physically affixed and integral to such building or structure; or
- (b) a vehicle;

“registered manager” means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a manager in respect of that activity, and “manage” should be construed accordingly;

“registered person” means, in respect of a regulated activity, a person who is the service provider or registered manager in respect of that activity;

“school” has the same meaning as in the Education Act 1996(a);

“service provider” means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a service provider in respect of that activity;

“service user” means a person who receives services provided in the carrying on of a regulated activity;

“treatment”, except in paragraph 6 of Schedule 1, includes—

- (a) a diagnostic or screening procedure carried out for medical purposes;
- (b) the ongoing assessment of a service user’s mental or physical state;
- (c) nursing, personal and palliative care; and
- (d) the giving of vaccinations and immunisations;

“vulnerable adult” has the same meaning as in section 59 of the Safeguarding Vulnerable Groups Act 2006(b).

PART 2 REGULATED ACTIVITIES

Prescribed activities

3.—(1) Subject to paragraphs (3) to (8), for the purposes of section 8(1) of the Act, the activities specified in Schedule 1 are prescribed as regulated activities.

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- (a) 1996 c.56; see section 4 for the meaning of “school”. Section 4 has been amended by the Education Act 1997 (c. 44), sections 51, 57(1) and (4) and Schedule 7, paragraphs 10(a) and (b) and Schedule 8, by the Education Act 2002 (c. 32), section 215(2) and Schedule 22, Part 3, and by the Childcare Act 2006 (c. 21), section 95(1), (2) and (3).
 - (b) 2006 c. 47. Section 59 was amended by S.I. 2008/912, Schedule 1, paragraph 21 and by the Education and Skills Act 2008 (c. 25), section 147(8).

(2) An activity which is ancillary to, or is carried on wholly or mainly in relation to, a regulated activity shall be treated as part of that activity.

(3) Subject to paragraph (4), until 1st October 2010, an activity is only a regulated activity if it is carried on by an English NHS body^(a).

(4) Where services involving, or connected with, the provision of social care are provided by an English NHS body which is registered as an establishment or agency under Part 2 of the Care Standards Act 2000^(b) in relation to the provision of those services then, to the extent that those services are capable of being a regulated activity for the purposes of these Regulations, they are only a regulated activity with effect from 1st October 2010.

(5) An activity is only a regulated activity if it is carried on in England.

(6) In Schedule 1, in paragraph 10(1), the words “by an English NHS provider” shall cease to have effect on 1st April 2011.

(7) Subject to paragraph (8), the activities specified in Schedule 2 are not regulated activities.

(8) In Schedule 2—

(a) paragraphs 3, 6 and 7 and, in paragraph 4, the words “and except where paragraph 3 applies”, shall cease to have effect on 1st April 2012; and

(b) paragraphs 9 and 11 shall cease to have effect on 1st April 2011.

PART 3

REQUIREMENTS RELATING TO PERSONS CARRYING ON OR MANAGING A REGULATED ACTIVITY

Requirements where the service provider is an individual or partnership

4.—(1) This regulation applies where a service provider (P) is an individual or a partnership.

(2) P must not carry on a regulated activity unless P is fit to do so.

(3) P is not fit to carry on a regulated activity unless P is—

(a) an individual who carries on the regulated activity, otherwise than in partnership with others, and satisfies the requirements set out in paragraph (4); or

(b) a partnership and each of the partners satisfies the requirements set out in paragraph (4);

(4) The requirements referred to are that P or, where applicable, each of the partners is—

(a) of good character;

(b) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and

(c) able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.

Requirement where the service provider is a body other than a partnership

5.—(1) This regulation applies where the service provider is a body other than a partnership.

(2) The body must give notice to the Commission of the name, address and position in the body of an individual (in these Regulations referred to as “the nominated individual”) who is employed as a director, manager or secretary of the body and who is responsible for supervising the management of the carrying on of the regulated activity by the body.

(3) The registered person must take all reasonable steps to ensure that the nominated individual is—

(a) See section 97(1) of the Act for the definition of “English NHS body”.

(b) 2000 c. 14.

- (a) of good character;
- (b) physically and mentally fit to supervise the management of the carrying on of the regulated activity and has the necessary qualifications, skills and experience to do so; and
- (c) able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

Requirements relating to registered managers

6.—(1) A person (M) shall not manage the carrying on of a regulated activity as a registered manager unless M is fit to do so.

(2) M is not fit to be a registered manager in respect of a regulated activity unless M is—

- (a) of good character;
- (b) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and
- (c) able to supply to the Commission, or arrange for the availability of, the information relating to themselves specified in Schedule 3.

Registered person: training

7.—(1) If the service provider is—

- (a) an individual, the individual must undertake;
- (b) a partnership, it must ensure that one of the partners undertakes; or
- (c) a body other than a partnership, it must ensure that the nominated individual undertakes,

from time to time such training as is reasonably practicable and appropriate to ensure that there are the necessary experience and skills available for carrying on the regulated activity.

(2) The registered manager must undertake from time to time such training as is appropriate to ensure that the manager has the experience and skills necessary for managing the carrying on of the regulated activity.

PART 4

QUALITY AND SAFETY OF SERVICE PROVISION IN RELATION TO REGULATED ACTIVITY

General

8. A registered person must, in so far as they are applicable, comply with the requirements specified in regulations 9 to 24 in relation to any regulated activity in respect of which they are registered.

Care and welfare of service users

9.—(1) The registered person must take proper steps to ensure that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe, by means of—

- (a) the carrying out of an assessment of the needs of the service user; and
- (b) the planning and delivery of care and, where appropriate, treatment in such a way as to—
 - (i) meet the service user's individual needs,
 - (ii) ensure the welfare and safety of the service user,
 - (iii) reflect, where appropriate, published research evidence and guidance issued by the appropriate professional and expert bodies as to good practice in relation to such care and treatment, and

- (iv) avoid unlawful discrimination including, where applicable, by providing for the making of reasonable adjustments in service provision to meet the service user's individual needs.

(2) The registered person must have procedures in place for dealing with emergencies which are reasonably expected to arise from time to time and which would, if they arose, affect, or be likely to affect, the provision of services, in order to mitigate the risks arising from such emergencies to service users.

Assessing and monitoring the quality of service provision

10.—(1) The registered person must protect service users, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to—

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirements set out in this Part of these Regulations; and
- (b) identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.

(2) For the purposes of paragraph (1), the registered person must—

- (a) where appropriate, obtain relevant professional advice;
- (b) have regard to—
 - (i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by service users, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 19,
 - (ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the regulated activity,
 - (iii) the information contained in the records referred to in regulation 20,
 - (iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a)),
 - (v) reports prepared by the Commission from time to time relating to the registered person's compliance with the provisions of these Regulations, and
 - (vi) periodic reviews and special reviews and investigations carried out by the Commission in relation to the provision of health or social care, where such reviews or investigations are relevant to the regulated activity carried on by the service provider;
- (c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—
 - (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a service user, and
 - (ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;
- (d) establish mechanisms for ensuring that—
 - (i) decisions in relation to the provision of care and treatment for service users are taken at the appropriate level and by the appropriate person (P), and
 - (ii) P is subject to an appropriate obligation to answer for a decision made by P, in relation to the provision of care and treatment for a service user, to the person responsible for supervising or managing P in relation to that decision; and
- (e) regularly seek the views (including the descriptions of their experiences of care and treatment) of service users, persons acting on their behalf and persons who are employed for the purposes of the carrying on of the regulated activity, to enable the registered person

to come to an informed view in relation to the standard of care and treatment provided to service users.

(3) The registered person must send to the Commission, when requested to do so, a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with, together with any plans that the registered person has for improving the standard of the services provided to service users with a view to ensuring their health and welfare.

Safeguarding service users from abuse

11.—(1) The registered person must make suitable arrangements to ensure that service users are safeguarded against the risk of abuse by means of—

- (a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
- (b) responding appropriately to any allegation of abuse.

(2) Where any form of control or restraint is used in the carrying on of the regulated activity, the registered person must have suitable arrangements in place to protect service users against the risk of such control or restraint being—

- (a) unlawful; or
- (b) otherwise excessive.

(3) For the purposes of paragraph (1), “abuse”, in relation to a service user, means—

- (a) sexual abuse;
- (b) physical or psychological ill-treatment;
- (c) theft, misuse or misappropriation of money or property; or
- (d) neglect and acts of omission which cause harm or place at risk of harm.

Cleanliness and infection control

12.—(1) The registered person must, so far as reasonably practicable, ensure that—

- (a) service users;
- (b) persons employed for the purpose of the carrying on of the regulated activity; and
- (c) others who may be at risk of exposure to a health care associated infection arising from the carrying on of the regulated activity,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

(2) The means referred to in paragraph (1) are—

- (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;
- (b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and
- (c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—
 - (i) premises occupied for the purpose of carrying on the regulated activity,
 - (ii) equipment and reusable medical devices used for the purpose of carrying on the regulated activity, and
 - (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection.

Management of medicines

13. The registered person must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity.

Meeting nutritional needs

14.—(1) Where food and hydration are provided to service users as a component of the carrying on of the regulated activity, the registered person must ensure that service users are protected from the risks of inadequate nutrition and dehydration, by means of the provision of—

- (a) a choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs;
- (b) food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background; and
- (c) support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.

(2) For the purposes of this regulation, "food and hydration" includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.

Safety and suitability of premises

15.—(1) The registered person must ensure that service users and others having access to premises where a regulated activity is carried on are protected against the risks associated with unsafe or unsuitable premises, by means of—

- (a) suitable design and layout;
- (b) appropriate measures in relation to the security of the premises; and
- (c) adequate maintenance and, where applicable, the proper—
 - (i) operation of the premises, and
 - (ii) use of any surrounding grounds,

which are owned or occupied by the service provider in connection with the carrying on of the regulated activity.

(2) In paragraph (1), the term "premises where a regulated activity is carried on" does not include a service user's own home.

Safety, availability and suitability of equipment

16.—(1) The registered person must make suitable arrangements to protect service users and others who may be at risk from the use of unsafe equipment by ensuring that equipment provided for the purposes of the carrying on of a regulated activity is—

- (a) properly maintained and suitable for its purpose; and
- (b) used correctly.

(2) The registered person must ensure that equipment is available in sufficient quantities in order to ensure the safety of service users and meet their assessed needs.

(3) Where equipment is provided to support service users in their day to day living, the registered person must ensure that, as far as reasonably practicable, such equipment promotes the independence and comfort of service users.

(4) For the purposes of this regulation—

- (a) "equipment" includes a medical device; and

- (b) “medical device” has the same meaning as in the Medical Devices Regulations 2002^(a).

Respecting and involving service users

17.—(1) The registered person must, so far as reasonably practicable, make suitable arrangements to ensure—

- (a) the dignity, privacy and independence of service users; and
 - (b) that service users are enabled to make, or participate in making, decisions relating to their care or treatment.
- (2) For the purposes of paragraph (1), the registered person must—
- (a) treat service users with consideration and respect;
 - (b) provide service users with appropriate information and support in relation to their care or treatment;
 - (c) encourage service users, or those acting on their behalf, to—
 - (i) understand the care or treatment choices available to the service user, and discuss with an appropriate health care professional, or other appropriate person, the balance of risks and benefits involved in any particular course of care or treatment, and
 - (ii) express their views as to what is important to them in relation to the care or treatment;
 - (d) where necessary, assist service users, or those acting on their behalf, to express the views referred to in sub-paragraph (c)(ii) and, so far as appropriate and reasonably practicable, accommodate those views;
 - (e) where appropriate, provide opportunities for service users to manage their own care or treatment;
 - (f) where appropriate, involve service users in decisions relating to the way in which the regulated activity is carried on in so far as it relates to their care or treatment;
 - (g) provide appropriate opportunities, encouragement and support to service users in relation to promoting their autonomy, independence and community involvement; and
 - (h) take care to ensure that care and treatment is provided to service users with due regard to their age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

Consent to care and treatment

18. The registered person must have suitable arrangements in place for obtaining, and acting in accordance with, the consent of service users in relation to the care and treatment provided for them.

Complaints

19.—(1) For the purposes of assessing, and preventing or reducing the impact of, unsafe or inappropriate care or treatment, the registered person must have an effective system in place (referred to in this regulation as “the complaints system”) for identifying, receiving, handling and responding appropriately to complaints and comments made by service users, or persons acting on their behalf, in relation to the carrying on of the regulated activity.

- (2) In particular, the registered person must—
- (a) bring the complaints system to the attention of service users and persons acting on their behalf in a suitable manner and format;
 - (b) provide service users and those acting on their behalf with support to bring a complaint or make a comment, where such assistance is necessary;

(a) S.I. 2002/618; the relevant amending instrument is S.I. 2008/2936.

- (c) ensure that any complaint made is fully investigated and, so far as reasonably practicable, resolved to the satisfaction of the service user, or the person acting on the service user's behalf; and
 - (d) take appropriate steps to coordinate a response to a complaint where that complaint relates to care or treatment provided to a service user in circumstances where the provision of such care or treatment has been shared with, or transferred to, others.
- (3) The registered person must send to the Commission, when requested to do so, a summary of the—
- (a) complaints made pursuant to paragraph (1); and
 - (b) responses made by the registered person to such complaints.

Records

20.—(1) The registered person must ensure that service users are protected against the risks of unsafe or inappropriate care and treatment arising from a lack of proper information about them by means of the maintenance of—

- (a) an accurate record in respect of each service user which shall include appropriate information and documents in relation to the care and treatment provided to each service user; and
- (b) such other records as are appropriate in relation to—
 - (i) persons employed for the purposes of carrying on the regulated activity, and
 - (ii) the management of the regulated activity.

(2) The registered person must ensure that the records referred to in paragraph (1) (which may be in paper or electronic form) are—

- (a) kept securely and can be located promptly when required;
- (b) retained for an appropriate period of time; and
- (c) securely destroyed when it is appropriate to do so.

Requirements relating to workers

21. The registered person must—

- (a) operate effective recruitment procedures in order to ensure that no person is employed for the purposes of carrying on a regulated activity unless that person—
 - (i) is of good character,
 - (ii) has the qualifications, skills and experience which are necessary for the work to be performed, and
 - (iii) is physically and mentally fit for that work;
- (b) ensure that information specified in Schedule 3 is available in respect of a person employed for the purposes of carrying on a regulated activity, and such other information as is appropriate;
- (c) ensure that a person employed for the purposes of carrying on a regulated activity is registered with the relevant professional body where such registration is required by, or under, any enactment in relation to—
 - (i) the work that the person is to perform, or
 - (ii) the title that the person takes or uses; and
- (d) take appropriate steps in relation to a person who is no longer fit to work for the purposes of carrying on a regulated activity including—
 - (i) where the person is a health care professional, informing the body responsible for regulation of the health care profession in question, or

- (ii) where the person is a social care worker registered with the General Social Care Council, informing the Council^(a).

Staffing

22. In order to safeguard the health, safety and welfare of service users, the registered person must take appropriate steps to ensure that, at all times, there are sufficient numbers of suitably qualified, skilled and experienced persons employed for the purposes of carrying on the regulated activity.

Supporting workers

23.—(1) The registered person must have suitable arrangements in place in order to ensure that persons employed for the purposes of carrying on the regulated activity are appropriately supported in relation to their responsibilities, to enable them to deliver care and treatment to service users safely and to an appropriate standard, including by—

- (a) receiving appropriate training, professional development, supervision and appraisal; and
- (b) being enabled, from time to time, to obtain further qualifications appropriate to the work they perform.

(2) Where the regulated activity carried on involves the provision of health care, the registered person must (as part of a system of clinical governance and audit) ensure that healthcare professionals employed for the purposes of carrying on the regulated activity are enabled to provide evidence to their relevant professional body demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise.

(3) For the purposes of paragraph (2), “system of clinical governance and audit” means a framework through which the registered person endeavours continuously to—

- (a) evaluate and improve the quality of the services provided; and
- (b) safeguard high standards of care by creating an environment in which clinical excellence can flourish.

Cooperating with other providers

24.—(1) The registered person must make suitable arrangements to protect the health, welfare and safety of service users in circumstances where responsibility for the care and treatment of service users is shared with, or transferred to, others, by means of—

- (a) so far as reasonably practicable, working in cooperation with others to ensure that appropriate care planning takes place;
- (b) subject to paragraph (2), the sharing of appropriate information in relation to—
 - (i) the admission, discharge and transfer of service users, and
 - (ii) the co-ordination of emergency procedures; and
- (c) supporting service users, or persons acting on their behalf, to obtain appropriate health and social care support.

(2) Nothing in this regulation shall require or permit any disclosure or use of information which is prohibited by or under any enactment, or by court order.

^(a) The General Social Care Council is established under Part 5 of the Care Standards Act 2000 (c.14). See section 55 of that Act for the definition of “social care worker”, and S.I. 2004/561.

PART 5

COMPLIANCE AND OFFENCES

Compliance with regulations

25. Where there is more than one registered person in respect of a regulated activity, or in respect of that activity as carried on at or from particular premises, anything which is required under these Regulations to be done by the registered person shall, if done by one of the registered persons, not be required to be done by any of the other registered persons.

Guidance and Code

26.—(1) For the purposes of compliance with the requirements set out in these Regulations, the registered person must have regard to—

- (a) guidance issued by the Commission in relation to the requirements set out in Parts 3 and 4 (with the exception of regulation 12 in so far as it applies to health care associated infections); and
- (b) in relation to regulation 12, any Code of Practice issued by the Secretary of State in relation to the prevention or control of health care associated infections.

(2) For the purposes of paragraph (1)—

- (a) “guidance” means the guidance referred to in section 23 of the Act; and
- (b) “Code of Practice” means the code of practice referred to in section 21 of the Act.

Offences

27.—(1) A failure to comply with any of the provisions of regulations 9 to 24 shall be an offence.

(2) The Commission may not bring proceedings in respect of a failure by a registered person to comply with any of those provisions unless—

- (a) the alleged failure is one in respect of which the Commission has given a warning notice to the registered person under section 29 of the Act;
- (b) that warning notice specified a time within which the registered person must take action to secure compliance pursuant to section 29(2)(c)(ii) of the Act; and
- (c) the registered person did not secure compliance within the specified time.

(3) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine not exceeding £50,000.

(4) In any proceedings for an offence under this regulation, it is a defence for the registered person to prove that they took all reasonable steps or exercised all due diligence to ensure that the provision in question was complied with.

PART 6

PENALTY NOTICES

28.—(1) The offences under the provisions listed in the first column of Schedule 4 are prescribed as fixed penalty offences for the purposes of section 86 of the Act.

(2) The monetary amount of the penalty for each fixed penalty offence is prescribed in the third column of Schedule 4.

(3) The time by which the penalty specified in a penalty notice is to be paid is the end of the period of 28 days beginning with the date of receipt of the notice.

(4) Subject to paragraph (5), the methods by which a penalty may be paid are by cash, cheque, credit or debit card, postal order or electronic transfer of funds to the Commission's bank account.

(5) A penalty may only be paid by credit or debit card from the date on which the Commission has in place arrangements to accept such payments.

(6) Where a person is given a penalty notice, proceedings for the offence to which the notice relates may not be instituted before the end of the period of 28 days beginning with the date of receipt of the notice.

(7) Section 93 of the Act applies to a penalty notice as it applies to a notice required to be given under Part 1 of the Act.

(8) Where a penalty notice is given by being sent by an electronic communication, in accordance with section 94 of the Act, the notice is, unless the contrary is proved, to be taken to have been received on the next working day after the day on which it is sent.

(9) A penalty notice must give such particulars of the circumstances alleged to constitute the offence as seem to the Commission to be reasonably required to provide the person to whom the notice is given with information about it.

(10) A penalty notice must state—

- (a) the name and address of the person to whom the notice is given;
- (b) the amount of the penalty;
- (c) the period during which proceedings will not be taken for the offence;
- (d) that payment within that period will discharge any liability for the offence;
- (e) the consequences of the penalty not being paid before the expiration of the period for paying it;
- (f) the person to whom and the address at which the penalty may be paid and to which any correspondence about the penalty may be sent; and
- (g) the means by which payment of the penalty may be made.

(11) The Commission may withdraw a penalty notice by giving written notice of the withdrawal to the person to whom the notice was given if—

- (a) the Commission determines that it ought not to have been given or it ought not to have been given to the person to whom it was addressed; or
- (b) it appears to the Commission that the notice contains material errors.

(12) A penalty notice may be withdrawn in accordance with paragraph (11) whether or not the period for payment referred to in paragraph (3) has expired, and whether or not the penalty has been paid.

(13) Where a penalty notice has been withdrawn in accordance with paragraph (11), the Commission must—

- (a) repay any amount paid by way of penalty in pursuance of that notice to the person who paid it, within 14 days beginning with the day on which written notice of the withdrawal was given; and
- (b) remove from publication any information about the payment of the penalty which has been published in accordance with regulations made under section 89 of the Act, within 7 days beginning with the day on which written notice of the withdrawal was given.

(14) Except as provided in paragraph (15), no proceedings may be instituted or continued against the person to whom a penalty notice was given for the offence to which the penalty notice relates where that notice has been withdrawn in accordance with paragraph (11).

(15) Where a penalty notice has been withdrawn pursuant to paragraph (11)(b), proceedings may be instituted or continued for the offence in connection with which that penalty notice was issued if a further penalty notice in respect of the offence has been given and the penalty has not been paid before the expiration of the period for payment referred to in paragraph (3).

(16) In this regulation—

“electronic communication” has the same meaning as in the Electronic Communications Act 2000^(a);

“working day” means any day other than—

- (a) a Saturday or Sunday;
- (b) Christmas Day or Good Friday; or
- (c) a day which is a bank holiday in England and Wales under the Banking and Financial Dealings Act 1971^(b);

“debit card” means a card the use of which by its holder to make a payment results in a current account of the holder at a bank, or at any other institution providing banking services, being debited with the payment;

“credit card” means a card which is a credit-token within the meaning of section 14 of the Consumer Credit Act 1974^(c).

PART 7 REVOCATION

Revocation

29. The Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009^(d) are revoked.

Signed by authority of the Secretary of State for Health

15th March 2010

Mike O'Brien
Minister of State,
Department of Health

SCHEDULE 1 Regulated Activities

Regulation 3

Personal care

1.—(1) Subject to sub-paragraphs (2) and (3), the provision of personal care for persons who, by reason of old age, illness or disability are unable to provide it for themselves, and which is provided in a place where those persons are living at the time the care is provided.

(2) This paragraph does not apply where paragraph 2 (accommodation for persons who require nursing or personal care) or paragraph 4 (accommodation and nursing or personal care in the further education sector) applies.

(3) The following types of provision are excepted from sub-paragraph (1)—

(a) 2000 c.7; see section 15 as amended by the Communications Act 2003 (c.21), Schedule 17, paragraph 158.
(b) 1971 c. 80.
(c) 1974 c. 39.
(d) S.I. 2009/660.

- (a) the supply of carers to a service provider by an undertaking acting as an employment agency or employment business for the purposes of that provider carrying on a regulated activity;
 - (b) the introduction of carers to an individual (other than a service provider) by a person (including an employment agency or an employment business) having no ongoing role in the direction or control of the service provided to that individual;
 - (c) the services of a carer employed by an individual, without the involvement of an undertaking acting as an employment agency or employment business, and working wholly under the direction and control of that individual in order to meet that individual's own care requirements; and
 - (d) the provision of personal care by a person managing a prison or other similar custodial establishment (other than a hospital within the meaning of Part 2 of the 1983 Act).
- (4) In sub-paragraph (3), "carer" means an individual who provides personal care to a person referred to in sub-paragraph (1).

Accommodation for persons who require nursing or personal care

- 2.—(1) The provision of residential accommodation, together with nursing or personal care.
- (2) Sub-paragraph (1) does not apply to the provision of accommodation—
- (a) to an individual by an adult placement carer under the terms of a carer agreement;
 - (b) in a school; or
 - (c) in an institution within the further education sector.

Accommodation for persons who require treatment for substance misuse

3. The provision of residential accommodation for a person, together with treatment for drug or alcohol misuse, where acceptance by the person of such treatment is a condition of the provision of the accommodation.

Accommodation and nursing or personal care in the further education sector

- 4.—(1) Subject to sub-paragraph (2), the provision of residential accommodation together with nursing or personal care for persons in an institution within the further education sector.
- (2) Sub-paragraph (1) only applies where the number of persons to whom nursing or personal care and accommodation are provided is more than one tenth of the number of students to whom both education and accommodation are provided.

Treatment of disease, disorder or injury

- 5.—(1) Subject to sub-paragraph (2), the provision of treatment for a disease, disorder or injury by or under the supervision of—
- (a) a health care professional, or a multi-disciplinary team which includes a health care professional; or
 - (b) a social worker, or a multi-disciplinary team which includes a social worker, where the treatment is for a mental disorder.
- (2) The activities set out in sub-paragraph (3) are excepted from sub-paragraph (1).
- (3) The activities referred to sub-paragraph (2) are—
- (a) assessment or medical treatment for persons detained under the 1983 Act;
 - (b) the provision of treatment by means of surgical procedures;
 - (c) diagnostic and screening procedures;
 - (d) services in slimming clinics;

- (e) the practice of alternative and complementary medicine, with the exception of the practice of osteopathy or chiropractic;
 - (f) the provision of treatment in a sports ground or gymnasium (including associated premises) where it is provided for the sole benefit of persons taking part in, or attending, sporting activities and events;
 - (g) the provision of treatment (not being first aid for the purposes of paragraph 14 of Schedule 2) under temporary arrangements to deliver health care to those taking part in, or attending, sporting or cultural events;
 - (h) the provision of hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber which is gradually pressurised with compressed air, where the primary use of that chamber is—
 - (i) pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997(a) or regulation 8 or 12 of the Work in Compressed Air Regulations 1996(b), or
 - (ii) otherwise for the treatment of workers in connection with the work which they perform; and
 - (i) the carrying on of any of the activities authorised by a licence granted by the Human Fertilisation and Embryology Authority under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990(c).
- (4) In this paragraph—
- (a) “health care professional” means a person who is—
 - (i) a medical practitioner,
 - (ii) a dental practitioner,
 - (iii) a dental hygienist,
 - (iv) a dental therapist,
 - (v) a dental nurse,
 - (vi) a dental technician,
 - (vii) an orthodontic therapist,
 - (viii) a nurse,
 - (ix) a midwife,
 - (x) a biomedical scientist,
 - (xi) a clinical scientist,
 - (xii) an operating department practitioner,
 - (xiii) a paramedic, or
 - (xiv) a radiographer;
 - (b) “biomedical scientist”, “clinical scientist”, “operating department practitioner”, “paramedic” and “radiographer” mean persons registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order(d);
 - (c) “dental practitioner” means a dentist registered as such with the General Dental Council pursuant to section 14 of the Dentists Act 1984(e);

(a) S.I. 1997/2776.

(b) S.I. 1996/1656.

(c) 1990 c. 37. Paragraph 1 of Schedule 2 was amended by the Human Fertilisation and Embryology Act 2008 (c. 22), Schedule 2, paragraph 2 and Schedule 8, Part I and by S.I. 2007/1522.

(d) “Relevant professions” are set out in Schedule 3, paragraph 1 of the 2001 Order. See S.I. 2004/2033, articles 3(4)(c) and 10(5)(b)(ii) and S.I. 2007/3101, Part 21, for relevant amendments.

(e) Section 14 of the Dentists Act 1984 (c.24) (“the 1984 Act”) was substituted by the Dentists Act 1984 (Amendment) Order 2005 (S.I. 2005/2011) (“the 2005 Order”), article 2(6) and amended by S.I. 2007/3101, regulation 111.

- (d) “dental hygienist”, “dental therapist”, “dental nurse”, “dental technician” and “orthodontic therapist” mean persons registered as such with the General Dental Council in the dental care professionals register^(a);
- (e) “mental disorder” means any disorder or disability of the mind, including dependence on alcohol or drugs;
- (f) “midwife” means a registered midwife;
- (g) “social worker” means a person who is registered as such with the General Social Care Council pursuant to section 56(1)(a) of the Care Standards Act 2000^(b).

Assessment or medical treatment for persons detained under the 1983 Act

6.—(1) The assessment of, or medical treatment (other than surgical procedures) for, a mental disorder affecting a person in a hospital where that person is—

- (a) detained in that hospital pursuant to the provisions of the 1983 Act (with the exception of section 135 or 136^(c));
- (b) recalled to that hospital under section 17E of that Act^(d); or
- (c) detained in that hospital pursuant to an order or direction made under another enactment, where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

(2) In this paragraph—

- (a) “hospital” means a hospital within the meaning of Part 2 of that Act^(e);
- (b) “medical treatment” has the same meaning as in section 145 of that Act^(f); and
- (c) “mental disorder” has the same meaning as in section 1 of that Act^(g).

Surgical procedures

7.—(1) Subject to sub-paragraphs (2) to (5), surgical procedures (including all pre-operative and post-operative care associated with such procedures) carried on by a health care professional for—

- (a) the purpose of treating disease, disorder or injury;
- (b) cosmetic purposes, where the procedure involves the use of instruments or equipment which are inserted into the body; or
- (c) the purpose of religious observance.

(2) Subject to sub-paragraph (3), the following procedures are excepted from sub-paragraph (1)—

- (a) nail surgery and nail bed procedures carried out by a health care professional on any area of the foot; and
- (b) surgical procedures involving the curettage, cautery or cryocautery of warts, verrucae or other skin lesions carried out by—
 - (i) a medical practitioner, or
 - (ii) another health care professional on any area of the foot.

(a) The dental care professionals register was established by section 36B of the 1984 Act as inserted by article 29 of the 2005 Order and amended by S.I. 2001/3101, regulation 122.

(b) 2000 c.14. See also S.I. 2007/3101, regulations 230 and 232(a) for relevant amendments.

(c) Section 135 was amended by the Mental Health (Scotland) Act 1984 (c.36) Schedule 3, paragraph 56, the Police and Criminal Evidence Act 1984 (c.60) Schedule 6, Part 1 and Schedule 7, Part 1, the National Health Service and Community Care Act 1990 (c.19) Schedule 10, the Care Standards Act 2000 (c.14) Schedule 4, paragraph 9, the Mental Health Act 2007 (“the 2007 Act”) (c.12) section 44 and Schedule 2, paragraph 10(a) and S.I. 2005/2078, Schedule 1, paragraph 2(9). Section 136 was amended by the 2007 Act, section 44 and Schedule 2, paragraph 10(b).

(d) Section 17E was inserted by section 32 of the 2007 Act.

(e) See sections 34(2) and 145(1) of the 1983 Act; relevant amendments were made by the Care Standards Act 2000, Schedule 4, paragraph 9.

(f) Section 145 was amended by section 7 of the 2007 Act.

(g) Section 1 was amended by section 1(2) of the 2007 Act.

- (3) Sub-paragraph (2) only applies where the procedures are carried out—
- (a) without anaesthesia; or
 - (b) using local anaesthesia.
- (4) The following cosmetic procedures are excepted from sub-paragraph (1)(b)—
- (a) the piercing of any part of the human body;
 - (b) tattooing;
 - (c) the subcutaneous injection of a substance or substances for the purpose of enhancing a person's appearance; and
 - (d) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.

Diagnostic and screening procedures

- 8.—(1) Subject to sub-paragraph (3), diagnostic and screening procedures involving—
- (a) the use of X-rays and other methods in order to examine the body by the use of radiation, ultrasound or magnetic resonance imaging;
 - (b) the use of instruments or equipment which are inserted into the body to—
 - (i) view its internal parts, or
 - (ii) gather physiological data;
 - (c) the removal of tissues, cells or fluids from the body for the purposes of discovering the presence, cause or extent of disease, disorder or injury;
 - (d) the use of equipment in order to examine cells, tissues and other bodily fluids for the purposes of obtaining information on the causes and extent of a disease, disorder or injury; and
 - (e) the use of equipment to measure or monitor physiological data in relation to the—
 - (i) audio-vestibular system,
 - (ii) vision system,
 - (iii) neurological system,
 - (iv) cardiovascular system,
 - (v) respiratory system,
 - (vi) gastro-intestinal system, or
 - (vii) urinary system,for the purposes of obtaining information on the causes and extent of a disease, disorder or injury, or the response to a therapeutic intervention, where such information is needed for the purposes of the planning and delivery of care or treatment.
- (2) Subject to sub-paragraph (3), the analysis and reporting of the results of the procedures referred to in sub-paragraph (1).
- (3) The procedures specified in sub-paragraph (4), and the analysis and reporting of the results of those procedures, are excepted from sub-paragraphs (1) and (2).
- (4) The procedures referred to in sub-paragraph (3) are—
- (a) the taking of blood samples where—
 - (i) the procedure is carried out by means of a pin prick, and
 - (ii) it is not necessary to send such samples for analysis to a place which is established for the purposes of carrying out tests or research in relation to samples of bodily cells, tissues or fluids;
 - (b) the taking and analysis of samples of bodily tissues, cells or fluids in order to ascertain—
 - (i) the existence of a genetically inherited disease or disorder, or
 - (ii) the influence of an individual's genetic variation on drug response,

where such procedures are part of neither the planning and delivery of care or treatment nor a national screening programme, other than for cancer;

- (c) the carrying out of procedures as part of a national cancer screening programme by a body established solely for the purpose of such a programme;
 - (d) fitness screening procedures carried out in a gymnasium in order to ascertain that a person is sufficiently healthy to use fitness equipment or take part in fitness routines safely;
 - (e) the taking of X-rays by chiropractors;
 - (f) the use of ultrasound equipment by physiotherapists; and
 - (g) the use of an auroscope.
- (5) For the purposes of this paragraph—
- (a) “chiropractor” means a person registered with the General Chiropractic Council pursuant to section 3, 4, 5 or 5A of the Chiropractors Act 1994^(a); and
 - (b) “physiotherapist” means a person registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order.

Management of supply of blood and blood derived products etc.

9. The management of—

- (a) the supply of blood, blood components and blood derived products intended for transfusion;
- (b) the supply of tissues and tissue derived products intended for transplant, grafting or use in a surgical procedure; and
- (c) the matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion.

Transport services, triage and medical advice provided remotely

10.—(1) Transport services provided by an English NHS provider^(b) by means of a vehicle which is designed for the primary purpose of carrying a person who requires treatment.

(2) Medical advice in cases where immediate action or attention is needed, or triage provided, over the telephone or by electronic mail by a body established for that purpose.

(3) For the purposes of this paragraph—

- (a) “triage” means the assignment of degrees of urgency to diseases, disorders or injuries in order to decide the order and place of treatment of service users; and
- (b) “vehicle” includes an air or water ambulance.

Maternity and midwifery services

11.—(1) Subject to sub-paragraph (2), maternity and midwifery services carried on by, or under the supervision of, a health care professional.

(2) The following services are excepted from sub-paragraph (1)—

- (a) midwifery services, where the provision of those services is carried on by an individual—
 - (i) acting on their own behalf,
 - (ii) otherwise than in pursuance of the 2006 Act, and
 - (iii) who provides such services only to service users in their own homes;

^(a) 1994 c. 17. Section 5A was inserted by S.I. 2007/3101, regulation 219.

^(b) See section 97(1) of the Act for the definition of “English NHS provider”. See regulation 3(6) which provides that the words “by an English NHS provider” cease to have effect on 1st April 2011.

- (b) the provision of advice, information and support in relation to pregnancy, childbirth or the acquisition of parenting skills, where provided by a body whose primary purpose or function is not the provision of health care (other than that advice, information and support);
- (c) services provided under arrangements relating to the care of pregnant women and women who are breast feeding made pursuant to section 254 of, and Schedule 20 to, the 2006 Act (local social services authorities).

Termination of pregnancies

12. The termination of pregnancies.

Services in slimming clinics

13. Services provided in a slimming clinic consisting of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of weight reduction.

Nursing care

14.—(1) Subject to sub-paragraph (2), the provision of nursing care, including nursing care provided in a person's own home which is not—

- (a) provided as part of any other regulated activity; and
- (b) exempted from being a regulated activity under any other paragraph in this Schedule.

(2) The following types of provision are excepted from sub-paragraph (1)—

- (a) the supply of nurses to a service provider by an undertaking acting as an employment agency or employment business for the purposes of that provider carrying on a regulated activity;
- (b) the introduction of nurses to an individual (other than a service provider) by a person (including an employment agency or an employment business) having no ongoing role in the direction or control of the service provided to that individual; and
- (c) the services of a nurse employed by an individual, without the involvement of an undertaking acting as an employment agency or an employment business, and working wholly under the direction and control of that individual in order to meet that individual's own nursing requirements.

Family planning services

15. The insertion or removal of an intrauterine contraceptive device carried out by, or under the supervision of, a health care professional.

SCHEDULE 2

Regulations 3(7) and (8)

Regulated Activities: General exceptions

1.—(1) Any activity which is carried on—

- (a) in the course of a family or personal relationship; and
- (b) for no commercial consideration.

(2) A family relationship includes a relationship between two persons who—

- (a) live in the same household; and
- (b) treat each other as though they were members of the same family.

(3) A personal relationship is a relationship between or among friends.

(4) A friend of a person (A) includes a person who is a friend of a member of A's family.

2. Any activity which involves the carrying on of an establishment or agency within the meaning of the Care Standards Act 2000^(a) for which Her Majesty's Chief Inspector of Education, Children's Services and Skills is the registration authority under that Act.

3. The provision of all medical services (including medical services provided otherwise than under the 2006 Act) by a provider whose sole or main purpose is the provision of primary medical services—

(a) under arrangements made pursuant to the following sections of the 2006 Act—

(i) section 3 (Secretary of State's duty as to provision of certain services),

(ii) section 83(2)(b) (primary medical services),

(iii) section 92 (arrangements by Strategic Health Authorities for the provision of primary medical services); or

(b) under a contract entered into pursuant to section 84 of that Act (general medical services contracts: introductory)^(b).

4. Subject to paragraph 5, and except where paragraph 3 applies, the provision of treatment in a surgery or consulting room otherwise than under arrangements made pursuant to the 2006 Act by—

(a) an individual medical practitioner who also provides services (whether there or elsewhere) under arrangements made pursuant to the 2006 Act; or

(b) a group of medical practitioners all of whom also provide services (whether there or elsewhere) under arrangements made pursuant to the 2006 Act.

5. Paragraph 4 does not apply in relation to—

(a) treatment carried out under anaesthesia or intravenously administered sedation;

(b) dental treatment carried out under general anaesthesia;

(c) obstetric services and, in connection with childbirth, medical services;

(d) the termination of pregnancies;

(e) cosmetic surgery, with the exception of the procedures referred to in paragraph 7(4) of Schedule 1;

(f) haemodialysis or peritoneal dialysis;

(g) endoscopy; or

(h) the provision of hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber which is gradually pressurised with compressed air, where such therapy is carried out by or under the supervision or direction of a medical practitioner.

6. The provision by a general medical practitioner (other than one who is a provider for the purposes of paragraph 3) of—

(a) primary medical services under arrangements made pursuant to the sections of the 2006 Act referred to in paragraph 3(a) and (b); or

(b) any of the services listed in paragraph 5 in premises which are the premises used by that practitioner for the purpose of the provision of primary medical services under the 2006 Act^(c).

(a) 2000 c.14.

(b) This paragraph will cease to have effect on 1st April 2012: see regulation 3(8)(a).

(c) This paragraph will cease to have effect on 1st April 2012: see regulation 3(8)(a).

7. The provision of services (other than in a surgery, consulting room or hospital) involving treatment by medical practitioners working for the purposes of an undertaking which also provides such services in pursuance of the 2006 Act(**a**).

8. Medical services provided (otherwise than in a hospital) only under arrangements made on behalf of service users by—

- (a) their employer;
- (b) a government department; or
- (c) an insurance provider with whom the service users hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity.

9. Treatment provided in a vehicle which is operated by an ambulance provider which is not an English NHS body(**b**).

10. Forensic medical services provided under arrangements made with a police authority as defined in section 101 (interpretation) of the Police Act 1996(**c**).

11. Dental services—

- (a) provided as primary dental services in pursuance of Part 5 of the 2006 Act, except where those services are provided—
 - (i) by a Primary Care Trust under section 99(2) (primary dental services) of that Act, or
 - (ii) by an NHS trust or NHS foundation trust; or
- (b) of a kind which, if provided in pursuance of that Act, would be provided as primary dental services under Part 5, except where those services are provided in a hospital(**d**).

12. Primary ophthalmic services provided under Part 6 of the 2006 Act and services of a kind which, if provided in pursuance of that Act, would be provided as primary ophthalmic services under that Part.

13. Pharmaceutical services and local pharmaceutical services provided under Part 7 of the 2006 Act and services of a kind which, if provided in pursuance of that Act, would be provided as pharmaceutical services or local pharmaceutical services under that Part.

14. The provision of first aid by—

- (a) health care professionals where it is provided in unexpected or potentially dangerous situations requiring immediate action;
- (b) organisations established for that purpose; or
- (c) non-health care professionals trained to deliver such treatment.

15. Defence medical and dental services being—

- (a) health or dental care provided by the Armed Services;
- (b) education and training provided by the Armed Services to service and other personnel in connection with the provision of health or dental care, including the maintenance of the clinical skills of such personnel; and
- (c) any service or facility falling within sub-paragraph (a) or (b) provided on behalf of the Armed Services under any agreement or arrangement made with the Armed Services.

16. Treatment provided in a school to the pupils of that school by a nurse who is engaged and directed by the school.

(a) This paragraph will cease to have effect on 1st April 2012: see regulation 3(8)(a).

(b) This paragraph will cease to have effect on 1st April 2011: see regulation 3(8)(b).

(c) 1996 c.16. The definition of police authority in section 101 was amended by the Greater London Authority Act 1999 (c. 29), section 312(2).

(d) This paragraph will cease to have effect on 1st April 2011: see regulation 3(8)(b).

17. In this Schedule—

- (a) “insurance provider” means—
 - (i) a person regulated by the Financial Services Authority who sells insurance, or underwrites the risk of such insurance, or
 - (ii) the agent of such a person; and
- (b) “primary dental services” includes the provision of dental implants.

SCHEDULE 3

Regulations 4, 5, 6 and 21

Information Required In Respect Of Persons Seeking To Carry On, Manage Or Work For The Purposes Of Carrying On, A Regulated Activity

- 1.** Proof of identity including a recent photograph.
- 2.** Where the certificate is required for a purpose referred to in—
 - (a) section 113A(2)(b) of the Police Act 1997^(a), a criminal record certificate issued under section 113A of that Act together with, after the appointed day and where applicable, relevant information relating to children or vulnerable adults; or
 - (b) section 113B(2)(b) of the Police Act 1997, an enhanced criminal record certificate issued under section 113B of that Act together with, where applicable, suitability information relating to children or vulnerable adults.
- 3.** Satisfactory evidence of conduct in previous employment concerned with the provision of services relating to—
 - (a) health or social care; or
 - (b) children or vulnerable adults.
- 4.** Where a person (P) has been previously employed in a position whose duties involved work with children or vulnerable adults, satisfactory verification, so far as reasonably practicable, of the reason why P’s employment in that position ended.
- 5.** Satisfactory documentary evidence of any relevant qualification.
- 6.** A full employment history, together with a satisfactory written explanation of any gaps in employment.
- 7.** Satisfactory information about any physical or mental health conditions which are relevant to the person’s ability to carry on, manage or work for the purposes of, the regulated activity.
- 8.** For the purposes of this Schedule—
 - (a) “the appointed day” means the day on which section 30 of the Safeguarding Vulnerable Groups Act 2006^(b) comes into force;
 - (b) “relevant information relating to children or vulnerable adults” has the same meaning as in section 31(2) and (3) of that Act;
 - (c) “satisfactory” means satisfactory in the opinion of the Commission; and
 - (d) “suitability information relating to children or vulnerable adults” means the information specified in sections 113BA and 113BB respectively of the Police Act 1997^(c).

(a) 1997 c. 50. Sections 113A and 113B were inserted by the Serious Organised Crime and Police Act 2005 (c. 15), section 163(2), and amended by the Safeguarding Vulnerable Groups Act 2006 (c. 47), Schedule 9, Part 2, paragraphs 14(1), (2) and (3).
 (b) 2006 c.47.
 (c) Sections 113BA and 113BB were inserted into the Police Act 1997 by the Safeguarding Vulnerable Groups Act 2006, section 63(1), Schedule 9, Part 2, paragraph 14(1) and (4).

SCHEDULE 4

Regulation 28

Fixed Penalty Offences

<i>Provision creating offence</i>	<i>General nature of offence</i>	<i>Monetary amount of penalty</i>
Regulation 27 of these Regulations	Contravention of, or failure to comply with, requirements relating to quality and safety of service provision in relation to a regulated activity	£4,000 in the case of an offence committed by a service provider; £2,000 in the case of an offence committed by a registered manager
Section 10(1) of the Act	Carrying on a regulated activity without being registered	£4,000
Section 33 of the Act	Failure to comply with conditions	£4,000 in the case of an offence committed by a service provider; £2,000 in the case of an offence committed by a registered manager
Section 34(1) of the Act	Carrying on a regulated activity whilst registration is suspended	£4,000
Section 34(2), (3) or (4) of the Act	Managing a regulated activity whilst registration is cancelled or suspended	£2,000
Section 63(7) of the Act	Obstructing entry and inspection	£300
Section 64(4) of the Act	Failure to provide documents and information	£300
Section 65(4) of the Act	Failure to provide an explanation	£300

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which are to come into force on 1st April 2010, are made under the Health and Social Care Act 2008 (“the Act”) and prescribe the kinds of activities that will be regulated activities for the purposes of Part 1 of the Act, and the requirements that will apply in relation to the way in which those activities are carried on. Part 1 of the Act establishes the Care Quality Commission and provides for the registration of persons carrying on a prescribed regulated activity. It also provides powers to make regulations imposing requirements in relation to the carrying on of those regulated activities.

Part 1 (regulations 1 and 2) are general provisions dealing with citation, commencement and interpretation.

In Part 2, regulation 3 deals with the activities that will be regulated activities for the purposes of section 8(1) of the Act. The activities are set out in Schedule 1 to the Regulations together with certain activity specific exemptions. Regulation 3(3) provides that, until 1st October 2010, an activity will only be a regulated activity if it is carried on by an English NHS body. Regulation 3(4) provides that where social care services are provided by an English NHS body which continues to be registered in respect of those services under the Care Standards Act 2000 then, in so far as those services are capable of being a regulated activity for the purposes of these Regulations, they will not be so until 1st October 2010. An activity is only a regulated activity if it is carried on in England (regulation 3(5)). In addition, regulation 3(7) provides that the activities listed in Schedule 2 (general exceptions) are not to be regulated activities for the purposes of the Regulations. Regulation 3(6) and (8) contain provisions relating to the time limiting of certain specified wording and provisions in Schedules 1 and 2.

In Part 3, regulations 4 to 7, and Schedule 3, contain requirements relating to the persons registered in respect of the carrying on or management of a regulated activity (“registered persons”), and require certain information to be available in relation to those persons. Where a regulated activity is carried on by a body other than a partnership, that body must nominate an individual (“the nominated individual”) in respect of whom this information must be available (regulation 5(2)). Regulation 7 imposes general requirements as to the need for appropriate training in the case of a registered person.

Part 4 makes provision about the conduct of the regulated activity and, in particular, about the quality and safety of service provision including in relation to the care and welfare of service users (regulation 9), assessing and monitoring the quality of service provision (regulation 10), safeguarding vulnerable service users (regulation 11), cleanliness and infection control (regulation 12), the management of medicines (regulation 13), the meeting of nutritional needs (regulation 14), the safety and suitability of premises and equipment (regulations 15 and 16), respecting and involving service users (regulation 17) and the obtaining of consent to care and treatment (regulation 18). Provision is also made about complaints (regulation 19), record keeping (regulation 20), the fitness of workers, staffing and co-operation with other service providers (regulations 21 to 24).

Part 5 deals with who is responsible for complying with the regulations in circumstances where there is more than one registered person in respect of a regulated activity (regulation 25). Regulation 26 states that, for the purposes of compliance with the Regulations, a registered person must take account of guidance issued by the Commission under section 23 of the Act and the Code of Practice issued by the Secretary of State under section 21 of the Act in relation to the prevention or control of healthcare associated infections. Regulation 27 provides that a breach of regulations 9 to 24 is to be an offence, and also includes a due diligence defence relating to any proceedings under the Regulations. In addition, it provides that no prosecution may be brought unless the breach is one which the registered person has failed to remedy in response to a warning notice given under section 29 of the Act.

In Part 6, regulation 28 (and Schedule 4) prescribe fixed penalty offences for the purposes of section 86 of the Act and the amount of the penalty, and make provision about the time by which a penalty notice must be paid and the method by which the payment may be made, the period during which proceedings cannot be instituted for the offence to which the penalty notice relates, the content of the penalty notice and when a penalty notice can be withdrawn.

In Part 7, regulation 29 revokes the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009.

An impact assessment of the effect that this instrument will have on the costs and benefits to the service providers in question, together with an Equality Screening Assessment is available on the Department of Health website at

<http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/index.htm> and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.

STATUTORY INSTRUMENTS

2009 No. 3112

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

The Care Quality Commission (Registration) Regulations 2009

Made - - - - 26th November 2009

Laid before Parliament 30th November 2009

Coming into force 1st April 2010

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 10(2), 13(1), 16(a), 17(1), 20, 30(3), 39(1) and (4), 41(1), 42, 65(1) and (3), 89 and 161(3) and (4) of the Health and Social Care Act 2008(a).

In accordance with section 20(8) of the Act, the Secretary of State has consulted such persons as he considers appropriate.

PART 1

GENERAL

Citation and commencement

1. These Regulations may be cited as the Care Quality Commission (Registration) Regulations 2009 and shall come into force on 1st April 2010.

Interpretation

2. In these Regulations—

“the Act” means the Health and Social Care Act 2008;

“health service body” means an English NHS body(b), NHS Blood and Transplant(c) or the Health Protection Agency(d);

“registered manager” means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a manager in respect of that activity;

(a) 2008 c.14. “Prescribed” and “regulations” are defined in section 97(1) of the Act.

(b) “English NHS body” is defined in section 97(1) of the Act.

(c) NHS Blood and Transplant was established as a Special Health Authority in October 2005 (see: S.I. 2005/2529) and is a cross-border Special Health Authority as defined in section 97(1) of the Act.

(d) The Health Protection Agency was established by the Health Protection Agency Act 2004 (c. 17), section 1.

“registered person” means, in respect of a regulated activity, the person who is the service provider or a registered manager in respect of that activity;

“relevant address” means—

- (a) where the service provider is registered to carry on the regulated activity to which the enforcement action relates from one address, that address; or
- (b) where the service provider is registered to carry on the regulated activity from more than one address, any of those addresses to which the enforcement action is relevant;

“service provider” means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a service provider in respect of that activity;

“service user” means a person who receives services provided in the carrying on of a regulated activity.

PART 2 REGISTRATION

Register of regulated activities

3. The Commission must establish and maintain a register containing such information as appears to the Commission to be necessary to keep the public informed about the identity of registered persons and their carrying on of regulated activities.

Persons to be regarded as the person carrying on a regulated activity

4.—(1) For the purposes of Chapter 2 of Part 1 of the Act (registration in respect of the provision of health or social care), the following provisions apply.

(2) Where a regulated activity is carried on by a person (A) and one or more other persons who are—

- (a) individuals; and
- (b) employees of A for the purpose of carrying on the regulated activity,

A is to be regarded as the person who carries on the regulated activity.

(3) For the purposes of paragraph (2), a person is an employee of A where that person—

- (a) is employed by A under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract (including under a carer agreement); or
- (b) has been granted practising privileges by A.

(4) Where the provision of services under arrangements between a body of trustees established for the purpose of providing services to meet the health or social care needs of a named beneficiary and a provider of such services falls to be regarded as a regulated activity, it is the provider and not the body of trustees which shall be regarded as the person who carries on that regulated activity.

(5) In this regulation—

- (a) “carer agreement” has the same meaning as in the Adult Placement Schemes (England) Regulations 2004^(a); and
- (b) “practising privileges” means the grant, by a person managing a hospital (as defined in section 275 of the National Health Service Act 2006^(b)), to a registered medical practitioner^(c) of permission to practise as a medical practitioner in that hospital.

(a) S.I. 2004/2071 to which there are amendments not relevant to these Regulations.

(b) 2006 c.41.

(c) The definition of “registered medical practitioner” in Schedule 1 to the Interpretation Act 1978 (c.30) has been substituted by S.I. 2002/3135, Schedule 1, paragraph 10 with effect from 16th November 2009.

Registered manager condition

5.—(1) Subject to paragraph (2), for the purposes of section 13(1) of the Act, the registration of a service provider in respect of a regulated activity must be subject to a registered manager condition where the service provider is—

- (a) a body of persons corporate or unincorporate; or
- (b) an individual who—
 - (i) is not a fit person to manage the carrying on of the regulated activity, or
 - (ii) is not, or does not intend to be, in full-time day to day charge of the carrying on of the regulated activity.

(2) Paragraph (1)(a) does not apply where the service provider is a health service body.

(3) A service provider (P) is not a fit person to manage the carrying on of a regulated activity unless P—

- (a) is of good character;
- (b) is physically and mentally fit to manage the carrying on of the regulated activity;
- (c) has the necessary qualifications, skills and experience to do so; and
- (d) is able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 1.

Cancellation of registration

6.—(1) The grounds specified for the purposes of section 17(1)(e) of the Act as grounds on which the Commission may cancel the registration of a registered person in respect of a regulated activity are that the registered person—

- (a) has made a statement which is false or misleading in a material respect, or provided false information, in relation to any application for—
 - (i) registration, or
 - (ii) the variation or removal of a condition in relation to their registration;
- (b) has failed to pay any fees payable under provision under section 85 of the Act; or
- (c) if the registered person is a service provider, is not, and has not been for a continuous period of 12 months ending with the date of the decision to cancel registration, carrying on that regulated activity.

PART 3

PUBLICATION OF INFORMATION AND EXPLANATIONS

Publication of information relating to enforcement action

7.—(1) Except in the circumstances specified in paragraphs 5 to 7 of Part 1 of Schedule 2, the Commission must publish the information prescribed in that Part of that Schedule in the time prescribed in paragraph 8 of that Part.

(2) The Commission may publish the information prescribed in Part 2 of Schedule 2 subject, in the case of the information prescribed in paragraph 13, to the conditions specified in sub-paragraph (2) of that paragraph.

Exemptions from the requirement to notify bodies of certain matters

8. Section 39(1) of the Act does not apply to—

- (a) a notice to a person who applies for registration as a registered person given under—
 - (i) section 26(2) or (3) of the Act (notice of proposals), or

- (ii) section 28(1) or (3) of the Act (notice of decisions);
- (b) a notice of proposal given under section 26(4)(c) or (d) of the Act, or a notice of decision given under section 28(3) of the Act, which—
 - (i) relates to the variation or removal of any condition for the time being in force in relation to a registration or the imposition of an additional condition in relation to a registration, and
 - (ii) appears to the Commission not to have a material impact on the regulated activity being carried on;
- (c) a notice of proposal given under section 26(5) of the Act or a notice of decision given under section 28(3) of the Act to refuse an application by the registered person under section 19(1) of the Act; and
- (d) a warning notice given under section 29 of the Act which appears to the Commission not to have a material impact on the regulated activity being carried on.

Notification to Primary Care Trust, English local authority and Strategic Health Authority

9.—(1) The Primary Care Trust or English local authority that is required to be given—

- (a) notice of an application for an order for cancellation of the registration of a registered person under section 30 of the Act; or
- (b) a copy of a notice under section 39 of the Act,

is to be determined in accordance with paragraphs (2) to (8).

(2) Where the application under section 30 of the Act, or the notice of which a copy is required to be given under section 39 of the Act, is in respect of a regulated activity that involves, or is connected with, the provision of health care, the Commission must give notice or a copy of the notice to the relevant Primary Care Trust.

(3) Where the application under section 30 of the Act, or the notice of which a copy is required to be given under section 39 of the Act, is in respect of a regulated activity that involves, or is connected with, the provision of social care, the Commission must give notice or a copy of the notice to the relevant local authority.

(4) Subject to paragraph (6), the relevant Primary Care Trust is any Primary Care Trust in whose area the regulated activity is being carried on.

(5) Subject to paragraph (6), the relevant local authority is any local authority in whose area the regulated activity is being carried on.

(6) Where a registered service provider is carrying on a regulated activity from more than one set of premises, and a notice of which a copy is required to be given under section 39 of the Act is in respect of the carrying on of a regulated activity from particular premises—

- (a) the relevant Primary Care Trust is any Primary Care Trust in whose area those particular premises are situated; and
- (b) the relevant local authority is any local authority in whose area those particular premises are situated.

(7) Subject to paragraph (8), the Strategic Health Authority that must be given notice under section 30(3)(b) of the Act or a copy of a notice under section 39(1)(b) of the Act is any Strategic Health Authority in whose area the regulated activity to which the application or notice relates is being carried on.

(8) Where a registered service provider is carrying on a regulated activity from more than one set of premises and a copy of the notice required to be given to a Strategic Health Authority under section 39(1)(b) is in respect of the carrying on of a regulated activity from particular premises, the Strategic Health Authority that must be given a copy of the notice is any Strategic Health Authority in whose area those particular premises are situated.

Power to require an explanation

10.—(1) Where the Commission considers an explanation of a relevant matter^(a) necessary or expedient for the purposes of any of its regulatory functions, the persons specified in paragraph (3) must, if so requested, provide an explanation of that matter to the Commission or to persons authorised by it.

(2) Explanations required under paragraph (1) must be provided at such times and such places as may be specified by the Commission.

(3) The persons referred to in paragraph (1) are —

- (a) a person carrying on a regulated activity;
- (b) a chair, director or employee of a person carrying on a regulated activity;
- (c) an English NHS body;
- (d) a member of an English NHS body other than an NHS foundation trust;
- (e) a member of a committee or sub-committee of an English NHS body other than an NHS foundation trust;
- (f) a member of a committee or sub-committee of the board of directors of an NHS foundation trust;
- (g) an employee of an English NHS body other than one falling within sub-paragraph (b);
- (h) a local authority;
- (i) a member or officer of a local authority;
- (j) a member of a committee or sub-committee of a local authority or a member of a joint committee of two or more local authorities;
- (k) an elected mayor of a local authority within the meaning given in section 39 of the Local Government Act 2000^(b);
- (l) a person (other than a person prescribed in sub-paragraphs (b) to (k)) who is assisting in the carrying on of a regulated activity;
- (m) a person providing equipment or premises to a registered person;
- (n) a chair, director or employee of a person providing equipment or premises to a registered person; and
- (o) a person (other than a person prescribed in sub-paragraph (n)) who is assisting a person providing equipment or premises to a registered person.

PART 4

REGISTRATION REQUIREMENTS

General

11. A registered person must, insofar as they are applicable, comply with the requirements specified in regulations 12 to 20 in relation to any regulated activity in respect of which they are registered.

Statement of purpose

12.—(1) The registered person must give the Commission a statement of purpose containing the information listed in Schedule 3.

(a) See section 65(2) of the Act for the definition of “relevant matter”.

(b) 2000 c. 22; section 39 has been amended by section 66 of the Local Government and Public Involvement in Health Act 2007 (c. 28).

(2) The registered person must keep under review and, where appropriate, revise the statement of purpose.

(3) The registered person must provide written details of any revision to the statement of purpose to the Commission within 28 days of any such revision.

Financial position

13.—(1) Subject to paragraph (2), the service provider must take all reasonable steps to carry on the regulated activity in such a manner as to ensure the financial viability of the carrying on of that activity for the purposes of—

- (a) achieving the aims and objectives set out in the statement of purpose; and
- (b) meeting the registration requirements prescribed pursuant to section 20 of the Act.

(2) This regulation does not apply where the service provider is—

- (a) an English local authority; or
- (b) a health service body.

Notice of absence

14.—(1) Subject to paragraphs (7) and (8), where—

- (a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or
- (b) the registered manager,

proposes to be absent from carrying on or managing the regulated activity for a continuous period of 28 days or more, the registered person must give notice in writing to the Commission of the proposed absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) must be given no later than 28 days before the proposed absence commences or within such shorter period as may be agreed with the Commission and must contain the following information in relation to the proposed absence—

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for the management of the carrying on of the regulated activity during the period of absence;
- (d) the name, address and qualifications of the person who will be responsible for the management of the carrying on of the regulated activity during that absence;
- (e) in the case of the absence of the registered manager, the arrangements that have been, or are proposed to be, made for appointing another person to manage the carrying on of the regulated activity during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence referred to in paragraph (1) arises as the result of an emergency, the registered person must give notice of the absence to the Commission within 5 working days of its occurrence specifying the matters set out in paragraph (2)(a) to (e).

(4) Where—

- (a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or
- (b) the registered manager,

has been absent for a continuous period of 28 days or more, and the Commission has not been given notice of the absence, the registered person shall forthwith give notice in writing to the Commission specifying the matters set out in paragraph (2)(a) to (e).

(5) The registered person must notify the Commission of the return to duty of the service provider or (as the case may be) the registered manager not later than 7 working days after the date of that return.

(6) In this regulation “working day” means any day other than a Saturday, a Sunday, Christmas Day, Good Friday or a day which is a bank holiday in England and Wales within the meaning of the Banking and Financial Dealings Act 1971^(a).

(7) Subject to paragraph (8), this regulation does not apply where the service provider is a health service body.

(8) Where the service provider is a health service body and is subject to a registered manager condition pursuant to regulation 5 or section 12(3) or (5) of the Act, this regulation shall have effect in relation any absence, proposed absence or return to duty of that registered manager.

Notice of changes

15.—(1) Subject to paragraph (2), the registered person must give notice in writing to the Commission, as soon as it is reasonably practicable to do so, if any of the following events takes place or is proposed to take place—

- (a) a person other than the registered person carries on or manages the regulated activity;
- (b) a registered person ceases to carry on or manage the regulated activity;
- (c) the name of a registered person (where that person is an individual) changes;
- (d) where the service provider is a partnership, any change in the membership of the partnership;
- (e) where the service provider is a body other than a partnership—
 - (i) a change in the name or address of the body,
 - (ii) a change of director, secretary or other similar officer of the body, or
 - (iii) a change of nominated individual;
- (f) where the service provider is—
 - (i) an individual, the appointment of a trustee in bankruptcy in relation to that individual, or
 - (ii) a company or partnership, the appointment of a receiver, manager, liquidator or provisional liquidator in relation to that company or partnership.

(2) Paragraph (1)(e)(ii) does not apply where the service provider is a health service body.

(3) In this regulation, “nominated individual” means the individual who is employed as a director, manager or secretary of the body and whose name has been notified to the Commission as being the person who is responsible for supervising the management of the carrying on of the regulated activity by that body.

Notification of death of service user

16.—(1) Except where paragraph (2) applies, the registered person must notify the Commission without delay of the death of a service user—

- (a) whilst services were being provided in the carrying on of a regulated activity; or
- (b) as a consequence of the carrying on of a regulated activity.

(2) Subject to paragraph (4), where the service provider is a health service body, the registered person must notify the Commission of the death of a service user where the death—

- (a) occurred—
 - (i) whilst services were being provided in the carrying on of a regulated activity, or
 - (ii) as a consequence of the carrying on of a regulated activity; and

(a) 1971 c.80.

- (b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care or treatment.

(3) Notification of the death of a service user must include a description of the circumstances of the death.

(4) Paragraph (2) does not apply if, and to the extent that, the registered person has reported the death to the National Patient Safety Agency^(a).

(5) This regulation does not apply where regulation 17 applies.

Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983

17.—(1) The registered person must notify the Commission without delay of the death or unauthorised absence of a service user who is liable to be detained by the registered person—

- (a) under the Mental Health Act 1983^(b) (“the 1983 Act”); or
- (b) pursuant to an order or direction made under another enactment (which applies in relation to England), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

(2) Notification of the death of a service user must include a description of the circumstances of the death.

(3) In this regulation—

- (a) references to persons “liable to be detained” include a community patient who has been recalled to hospital in accordance with section 17E of the 1983 Act^(c), but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42^(d), 73^(e) or 74^(f) of the 1983 Act;
- (b) “community patient” has the same meaning as in section 17A of the 1983 Act^(g);
- (c) “hospital” means a hospital within the meaning of Part 2 of that Act^(h); and
- (d) “unauthorised absence” means an unauthorised absence from a hospital.

Notification of other incidents

18.—(1) Subject to paragraphs (3) and (4), the registered person must notify the Commission without delay of the incidents specified in paragraph (2) which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity.

(2) The incidents referred to in paragraph (1) are—

- (a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—
 - (i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,
 - (ii) changes to the structure of a service user's body,
 - (iii) the service user experiencing prolonged pain or prolonged psychological harm, or

^(a) The National Patient Safety Agency is a Special Health Authority established by the National Patient Safety Agency (Establishment and Constitution) Order 2001 (S.I. 2001/1743), to which there are amendments which are not relevant to these Regulations.

^(b) 1983 c.20.

^(c) Section 17E was inserted by the Mental Health Act 2007 (c.12) (“the 2007 Act”), section 32(2).

^(d) Section 42 was amended by the 2007 Act, sections 40(2) and 55 and Schedule 11, Part 8.

^(e) Section 73 was amended by the 2007 Act, section 4(9) and S.I. 2001/3712 and 2008/2833.

^(f) Section 74 was amended by the Crime (Sentences) Act 1997 (c. 43), Schedule 4, paragraphs 12(10) to (12), the Criminal Justice Act 2003 (c. 44), section 295 and S.I. 2008/2833.

^(g) Section 17A was inserted by section 32(2) of the 2007 Act.

^(h) See sections 34(2) and 145(1) of the 1983 Act; relevant amendments were made by the Care Standards Act 2000, Schedule 4, paragraph 9 and by the National Health Service (Consequential Provisions) Act 2006 (c.43), Schedule 1, paragraph 70(c).

- (iv) the shortening of the life expectancy of the service user;
 - (b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—
 - (i) the death of the service user, or
 - (ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);
 - (c) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation, including the result of such a request;
 - (d) any application made to a court in relation to depriving a service user of their liberty pursuant to section 16(2)(a) of the 2005 Act;
 - (e) any abuse or allegation of abuse in relation to a service user;
 - (f) any incident which is reported to, or investigated by, the police;
 - (g) any event which prevents, or appears to the service provider to be likely to threaten to prevent, the service provider's ability to continue to carry on the regulated activity safely, or in accordance with the registration requirements, including—
 - (i) an insufficient number of suitably qualified, skilled and experienced persons being employed for the purposes of carrying on the regulated activity,
 - (ii) an interruption in the supply to premises owned or used by the service provider for the purposes of carrying on the regulated activity of electricity, gas, water or sewerage where that interruption has lasted for longer than a continuous period of 24 hours,
 - (iii) physical damage to premises owned or used by the service provider for the purposes of carrying on the regulated activity which has, or is likely to have, a detrimental effect on the treatment or care provided to service users, and
 - (iv) the failure, or malfunctioning, of fire alarms or other safety devices in premises owned or used by the service provider for the purposes of carrying on the regulated activity where that failure or malfunctioning has lasted for longer than a continuous period of 24 hours.
- (3) Paragraph (2)(f) does not apply where the service provider is an English NHS body.
- (4) Where the service provider is a health service body, paragraph (1) does not apply if, and to the extent that, the registered person has reported the incident to the National Patient Safety Agency.
- (5) In this regulation—
- (a) "the 2005 Act" means the Mental Capacity Act 2005(a);
 - (b) "abuse", in relation to a service user, means—
 - (i) sexual abuse,
 - (ii) physical or psychological ill-treatment,
 - (iii) theft, misuse or misappropriation of money or property, or
 - (iv) neglect and acts of omission which cause harm or place at risk of harm;
 - (c) "health care professional" means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(b) applies;
 - (d) "registration requirements" means any requirements or conditions imposed on the registered person by or under Chapter 2 of Part 1 of the Act;
 - (e) "standard authorisation" has the meaning given under Part 4 of Schedule A1 to the 2005 Act;

(a) 2005 c. 9. Schedule A1 was inserted by Schedule 7 to the Mental Health Act 2007 (c. 12).

(b) 1999 c. 8. Section 60(2) was amended by the Health and Social Care Act 2008, Schedule 8, paragraph 1(3) and Schedule 15, Part 2 and by S.I. 2002/253 and 254.

- (f) “supervisory body” has the meaning given in paragraph 180 (in relation to a hospital in England) or paragraph 182 (in relation to a care home) of Schedule A1 to the 2005 Act;
- (g) for the purposes of paragraph (2)(a)—
 - (i) “prolonged pain” and “prolonged psychological harm” means pain or harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days, and
 - (ii) a sensory, motor or intellectual impairment is not temporary if such an impairment has lasted, or is likely to last, for a continuous period of at least 28 days.

Fees etc.

19.—(1) Where a service user will be responsible for paying the costs of their care or treatment (either in full or partially), the registered person must provide a statement to the service user, or to a person acting on the service user’s behalf—

- (a) specifying the terms and conditions in respect of the services to be provided to the service user, including as to the amount and method of payment of fees; and
- (b) including, where applicable, the form of contract for the provision of services by the service provider.

(2) The statement referred to in paragraph (1) must be—

- (a) in writing; and
- (b) as far as reasonably practicable, provided prior to the commencement of the services to which the statement relates.

Requirements relating to termination of pregnancies

20.—(1) This regulation applies to a registered person who—

- (a) carries on or manages the regulated activity consisting of the termination of pregnancies; and
- (b) is not an English NHS body.

(2) The registered person must ensure that, unless two certificates of opinion have been received in respect of the service user—

- (a) no termination of pregnancy is carried out; and
- (b) no fee is demanded or accepted from a service user.

(3) The registered person must ensure that a certificate of opinion in respect of a service user undergoing termination of a pregnancy is completed and included with the service user’s medical record.

(4) The registered person must ensure that no termination of pregnancy is undertaken after the 20th week of gestation, unless—

- (a) the service user is treated by persons who are suitably qualified, skilled and experienced in the late termination of pregnancy; and
- (b) appropriate procedures are in place to deal with any medical emergency which occurs during or as a result of the termination.

(5) The registered person must ensure that no termination of a pregnancy is undertaken after the 24th week of gestation.

(6) The registered person must ensure that a register of service users undergoing a termination of pregnancy is maintained, which is—

- (a) completed in respect of each service user at the time the termination is undertaken; and
- (b) retained for a period of not less than 3 years beginning on the date of the last entry.

(7) The registered person must ensure that a record is maintained of the total numbers of terminations of pregnancies undertaken.

(8) The registered person must ensure that the record referred to in paragraph (7) (which may be in paper or electronic form) is—

- (a) accurate;
- (b) kept securely and can be located promptly when required;
- (c) retained for an appropriate period of time; and
- (d) securely destroyed when it is appropriate to do so.

(9) The registered person must ensure that notice in writing is sent to the Chief Medical Officer of the Department of Health of each termination of pregnancy^(a).

(10) If the registered person—

- (a) receives information concerning the death of a service user who has undergone termination of a pregnancy during the period of 12 months ending on the date on which the information is received; and
- (b) has reason to believe that the service user's death may be associated with the termination,

the registered person must give notice in writing to the Commission of that information, within the period of 14 days beginning on the day on which the information is received.

(11) The registered person must prepare and implement appropriate procedures to ensure that foetal tissue is treated with respect.

(12) In this regulation, "certificate of opinion" means a certificate required by regulations made under section 2(1) of the Abortion Act 1967^(b).

PART 5

OTHER MISCELLANEOUS REQUIREMENTS

Death of service provider

21.—(1) Where the service provider is a partnership and a partner dies, the surviving partner shall without delay notify the Commission of the death in writing.

(2) Where the service provider is an individual and that individual dies, that individual's personal representative must notify the Commission in writing—

- (a) without delay of the death; and
- (b) within 28 days of the date of death of their intentions regarding the future carrying on of the regulated activity.

(3) The personal representative of the deceased service provider may carry on the regulated activity without being registered in respect of it—

- (a) for a period not exceeding 28 days; and
- (b) for any future period as may be determined in accordance with paragraph (4).

(4) The Commission may extend the period specified in paragraph (3)(a) by such further period, not exceeding one year, as the Commission shall determine, and shall notify any such determination to the personal representative in writing.

(5) The personal representative of the deceased service provider shall appoint a person to take full-time day to day charge of the carrying on of the regulated activity during any period in which, in accordance with paragraph (3), they carry on the regulated activity without being registered in respect of it.

(a) See section 4 of the Abortion Act 1967 (c.87) which requires such notice to be given by the medical practitioner carrying out the termination. For relevant amendments see: S.I. 2002/887.

(b) The Regulations made under section 2 are S.I. 1991/499. Relevant amending instrument is S.I. 2002/887.

Appointment of liquidators

22.—(1) Any person to whom paragraph (2) applies must—

- (a) notify the Commission of their appointment and the reasons for their appointment;
- (b) appoint a manager to manage the regulated activity in any cases where there is not a registered manager; and
- (c) before the end of the period of 28 days beginning with the date of their appointment, notify the Commission of their intentions regarding the future carrying on of the regulated activity.

(2) This paragraph applies to any person appointed as—

- (a) a receiver or manager of the property of the relevant company^(a);
- (b) the liquidator or provisional liquidator of a relevant company; or
- (c) the trustee in bankruptcy of a relevant individual^(b).

PART 6

COMPLIANCE, GUIDANCE AND OFFENCES

Compliance with regulations

23. Where there is more than one registered person in respect of a regulated activity, or in respect of that activity as carried on at or from particular premises, anything which is required under these Regulations to be done by the registered person shall, if done by one of the registered persons, not be required to be done by any of the other registered persons.

Guidance

24.—(1) For the purposes of compliance with the requirements set out in these Regulations, the registered person must have regard to guidance issued by the Commission in relation to the requirements set out in Part 4 of these Regulations.

(2) For the purposes of paragraph (1), “guidance” means the guidance referred to in section 23 of the Act.

Offences

25.—(1) A contravention of, or failure to comply with, any of the provisions of regulations 12 and 14 to 20 shall be an offence.

(2) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale.

Signed by authority of the Secretary of State for Health

Mike O'Brien
Minister of State,
Department of Health

26th November 2009

(a) See section 41(3) of the Act for the definitions of “company” and “relevant company”.

(b) See section 41(3) of the Act for the definition of “relevant individual”.

SCHEDULE 1

Regulation 5

INFORMATION REQUIRED IN RESPECT OF A SERVICE PROVIDER WHO PROPOSES TO MANAGE THE CARRYING ON OF A REGULATED ACTIVITY

1. Proof of identity including a recent photograph.
2. Where the certificate is required for a purpose referred to in—
 - (a) section 113A(2)(b) of the Police Act 1997^(a), a criminal record certificate issued under section 113A of that Act together with, after the appointed day and where applicable, relevant information relating to children or vulnerable adults; or
 - (b) section 113B(2)(b) of the Police Act 1997, an enhanced criminal record certificate issued under section 113B of that Act together with, where applicable, suitability information relating to children or vulnerable adults.
3. Satisfactory evidence of conduct in previous employment concerned with the provision of services relating to—
 - (a) health or social care; or
 - (b) children or vulnerable adults.
4. Where a person (P) has been previously employed in a position whose duties involved work with children or vulnerable adults, satisfactory verification, so far as reasonably practicable, of the reason why P's employment in that position ended.
5. Satisfactory documentary evidence of any relevant qualification.
6. A full employment history, together with a satisfactory written explanation of any gaps in employment.
7. Satisfactory information about any physical or mental health conditions which are relevant to the person's ability to manage the carrying on of the regulated activity.
8. For the purposes of this Schedule—
 - (a) "the appointed day" means the day on which section 30 of the Safeguarding Vulnerable Groups Act 2006^(b) comes into force;
 - (b) "relevant information relating to children or vulnerable adults" has the same meaning as in section 31(2) and (3) of that Act;
 - (c) "satisfactory" means satisfactory in the opinion of the Commission; and
 - (d) "suitability information relating to children or vulnerable adults" means the information specified in sections 113BA and 113BB respectively of the Police Act 1997^(c).

(a) 1997 c. 50. Sections 113A and 113B were inserted by the Serious Organised Crime and Police Act 2005 (c. 15), section 163(2), and amended by the Safeguarding Vulnerable Groups Act 2006 (c. 47), Schedule 9, Part 2, paragraphs 14(1), (2) and (3).

(b) 2006 c. 47.

(c) Sections 113BA and 113BB were inserted into the Police Act 1997 by the Safeguarding Vulnerable Groups Act 2006, section 63(1), Schedule 9, Part 2, paragraph 14(1) and (4).

SCHEDULE 2

Regulation 7

PUBLICATION OF INFORMATION RELATING TO ENFORCEMENT ACTION

PART 1

INFORMATION RELATING TO ENFORCEMENT ACTION WHICH MUST BE PUBLISHED

- 1.** In relation to the cancellation or suspension of a registered person's registration under section 17, 18, 30 or 31 of the Act, the prescribed information, subject to paragraph 5, is—
- (a) a description of the regulated activity to which the cancellation or suspension relates;
 - (b) the name of the service provider in respect of that regulated activity;
 - (c) where the cancellation or suspension relates to a registered manager, the name of the registered manager;
 - (d) an explanation of why the registration has been cancelled or suspended and, where applicable, the period of suspension; and
 - (e) the relevant address.
- 2.** In relation to the conviction of any person in respect of an offence under Part 1 of the Act, except an offence under section 76 (disclosure of confidential personal information: offence), the prescribed information, subject to paragraph 6, is—
- (a) a description of the offence;
 - (b) a description of the regulated activity that the person so convicted is carrying on, or involved in carrying on;
 - (c) the name of the service provider in respect of that regulated activity;
 - (d) where the person convicted is the registered manager, the name of the registered manager; and
 - (e) the relevant address.
- 3.—(1)** This paragraph applies to a decision under section 12(5) of the Act to vary or remove a condition for the time being in force in relation to a person's registration, or to impose an additional condition, which—
- (a) takes effect from the time when the notice is given in accordance with section 31 of the Act; or
 - (b) appears to the Commission to have a material impact on the regulated activity being carried on.
- (2)** The prescribed information, subject to paragraph 5, in cases to which this paragraph applies is—
- (a) a description of the regulated activity that the variation or removal of a condition, or the imposition of an additional condition, relates to;
 - (b) the name of the service provider in respect of that regulated activity;
 - (c) where the decision relates to a condition in respect of a registered manager, the name of the registered manager;
 - (d) a description of the condition being varied, removed or imposed and, where applicable, the variation or removal;
 - (e) an explanation of why the decision was taken; and
 - (f) the relevant address.

4. In relation to the payment by any person of a penalty in accordance with a penalty notice issued under section 86 of the Act other than in respect of an offence under section 63(7), 64(4) or 65(4) of that Act, the prescribed information, subject to paragraph 7, is—

- (a) a description of the fixed penalty offence;
- (b) a description of the regulated activity that the person given the penalty notice was carrying on or involved in carrying on;
- (c) the name of the service provider in respect of that regulated activity;
- (d) where the penalty notice is given to a registered manager, the name of the registered manager; and
- (e) the relevant address.

5. Paragraphs 1 and 3 do not apply, and the information prescribed in that paragraph must not be published, where an appeal is brought under section 32 of the Act and the First-tier Tribunal has directed that the Commission's decision is not, or is to cease, to have effect, or the order made by a justice of peace is to cease to have effect.

6. Paragraph 2 does not apply, and the information prescribed in that paragraph must not be published, where an appeal is brought against a conviction for an offence under Part 1 of the Act and the conviction is quashed.

7. Paragraph 4 does not apply, and the information prescribed in that paragraph must not be published, where a penalty notice is withdrawn in accordance with regulations made under section 87(1)(e) of the Act after the penalty has been paid but before publication of the information prescribed in paragraph 4.

8.—(1) The time prescribed for information required to be published under paragraphs 1 and 3 where no appeal is brought under section 32 of the Act is within the period starting immediately after the end of the period of 28 days referred to in section 32(2) of the Act and ending 4 months after service on the person of the notice of the Commission's decision or the date of the order under section 30 of the Act.

(2) The time prescribed for information required to be published under paragraphs 1 and 3 where an appeal is brought under section 32 of the Act is within 3 months of the determination or abandonment of the appeal.

(3) The time prescribed for information required to be published under paragraph 2 where no appeal is brought against a conviction is within the period starting immediately after the end of the period of 28 days after the date of the conviction and ending 4 months after the date of the conviction.

(4) The time prescribed for information required to be published under paragraph 2 where an appeal is brought against a conviction is within 3 months of the determination or abandonment of the appeal.

(5) The time prescribed for information to be published under paragraph 4 is within 3 months of the date of payment of the penalty.

PART 2

INFORMATION RELATING TO ENFORCEMENT ACTION WHICH MAY BE PUBLISHED

9. In relation to a conviction in respect of an offence under Part 1 of the Act, except an offence under section 76, the prescribed information is the penalty imposed.

10. In relation to decisions under section 12(5) of the Act which do not fall within paragraph 3(1), the prescribed information is the information listed in paragraph 3(2)(a) to (f).

11. Where a person who is not a registered person is convicted of an offence under Part 1 of the Act, except an offence under section 76, the prescribed information is the name of, and such other details as the Commission considers relevant about, the individual convicted of the offence.

12. In relation to the payment by any person of a penalty in accordance with a penalty notice issued under section 86 of the Act in respect of an offence under section 63(7), 64(4) or 65(4) of that Act, which is committed in connection with the carrying on of a regulated activity, the prescribed information is the information listed in paragraph 4(a) to (e).

13.—(1) In relation to a warning notice given under section 29 of the Act, the prescribed information is—

- (a) a description of the regulated activity to which the warning notice relates;
- (b) the name of the service provider in respect of that regulated activity;
- (c) where the warning notice is given to a registered manager, the name of the registered manager;
- (d) a description of the conduct which appears to the Commission to constitute a failure to comply with the relevant requirements and a description of the requirements concerned; and
- (e) the relevant address.

(2) Before publishing the information prescribed under sub-paragraph (1), the Commission must—

- (a) provide the person to whom the notice was given an opportunity to make representations to the Commission relating to the matters dealt with in the notice; and
- (b) take any such representations into account when determining whether to publish the prescribed information.

SCHEDULE 3

Regulation 12

INFORMATION TO BE INCLUDED IN THE STATEMENT OF PURPOSE

- 1.** The aims and objectives of the service provider in carrying on the regulated activity.
- 2.** The kinds of services provided for the purposes of the carrying on of the regulated activity and the range of service users' needs which those services are intended to meet.
- 3.** The full name of the service provider and of any registered manager, together with their business address, telephone number and, where available, electronic mail addresses.
- 4.** The legal status of the service provider.
- 5.** Details of the locations at which the services provided for the purposes of the regulated activity are carried on.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which are to come into force on 1st April 2010, are made under the Health and Social Care Act 2008 ("the Act") and apply in relation to regulated activities carried on in England. Part 1 of the Act establishes the Care Quality Commission ("the Commission") and provides for the registration of persons carrying on a regulated activity.

Part 1 of the Regulations contains provisions relating to citation, commencement and interpretation (regulations 1 and 2).

Part 2 of the Regulations contains provisions relating to registration. Regulation 3 requires the Commission to keep a register of persons registered with the Commission under Chapter 2 of Part 1 of the Act as a service provider or a manager in respect of a regulated activity and regulation 4 contains details of the persons to be regarded as carrying on the regulated activity for the purposes of Chapter 2 of Part 1 of the Act (registration in respect of the provision of health or social care). Regulation 5 (and Schedule 1) sets out the circumstances in which the registration of a service provider is to be subject to a registered manager condition. Regulation 6 specifies the grounds on which the Commission may cancel a service provider's registration pursuant to section 17(1)(e) of the Act.

Part 3 contains provisions relating to the publication of information and explanations. Regulation 7 (and Schedule 2) prescribe information relating to enforcement action that the Commission must publish and the time by which it must be published, and information that the Commission may publish. Regulation 8 prescribes cases in which copies of notices of proposals given under section 26 of the Act, notices of decisions given under section 28 of the Act and warning notices given under section 29 of the Act do not need to be given to persons listed in section 39 of the Act. Regulation 9 defines which Primary Care Trust, local authority and Strategic Health Authority is required to be notified by the Commission of an application for an order for cancellation of the registration of a service provider under section 30 of the Act or given a copy of a notice referred to in section 39(2) of the Act. Regulation 10 enables the Commission to require the persons prescribed to provide an explanation of a relevant matter to the Commission, or to persons authorised by it, in circumstances where the Commission considers the explanation necessary or expedient for the purposes of its regulatory functions. It also gives the Commission power to require the explanation to be given at such times and such places as it specifies.

Part 4 contains registration requirements. Regulation 11 provides that a registered person must comply with the requirements contained in regulations 12 to 20 in so far as they apply to an activity in respect of which they are registered. Regulation 12 provides that the registered person must give to the Commission a statement of purpose containing the information set out in Schedule 3 and regulation 13 contains provision as to the financial viability of a service provider (excluding English local authorities or a health service body). Regulations 14 and 15 require the giving of notices to the Commission in relation to the absence of a registered person and in relation to certain changes affecting the carrying on of the regulated activity. Regulations 16 and 17 prescribe the circumstances in which notification of the death of a service user must be given to the Commission (and regulation 17 also requires notification of the unauthorised absence of a service user who is liable to be detained under the Mental Health Act 1983) and regulation 18 prescribes the incidents, occurring whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity, which must be notified to the Commission. Regulation 19 deals with information to be given to service users in relation to fees for care or treatment. Regulation 20 contains requirements relating to a registered person who carries on the regulated activity of termination of pregnancies.

Part 5 contains other miscellaneous requirements. Regulation 21 deals with the notification to be given to the Commission where a service provider dies. Regulation 22 contains provisions which apply where a liquidator or similar person has been appointed in relation to the carrying on of a regulated activity.

Part 6 contains provisions relating to compliance, guidance and offences. Regulation 23 deals with who is responsible for complying with the Regulations in circumstances where there is more than one registered person in respect of a regulated activity. Regulation 24 states that, for the purposes of compliance with the Regulations, a registered person must take account of guidance issued by the Commission under section 23 of the Act. Regulation 25 provides that a breach of certain of the requirements in the Regulations is to be an offence punishable, on summary conviction, with a fine not exceeding level 4 on the standard scale.

An impact assessment of the effect that this instrument will have on the costs and benefits to the service provider in question, together with an Equality Screening Assessment was published alongside a draft Statutory Instrument entitled the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009 and is available on the Department of Health website at <http://dh.gov.uk/en/Publicationsandstatistics/Legislation/index.htm>.

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