

Registration under the Health and Social Care Act 2008

The scope of registration

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Introduction to the Scope of registration

You may need to register with CQC if you provide, or intend to provide, health or adult social care activities in England. This is a legal requirement under the Health and Social Care Act 2008.

You must apply to be registered even if you do not intend to provide those services on a regular or permanent basis.

This guidance will help you decide whether you need to register with us. It explains:

- what we mean by regulated activities
- who and what needs to be registered we call this the scope of registration
- which regulated activities you are most likely to need to register for.

It is an offence to carry on a regulated activity without being registered.

To make sure you have all the information to register correctly, you need to read this guidance and refer to the <u>Health and Social Care Act 2008 and associated</u> regulations and our guidance on meeting the regulations. Make sure you always refer to the latest version of the regulations. This is a guide to the regulations but is not a substitute for them.

You can also see our guidance on how to <u>register as a new provider</u> or how to <u>make</u> changes to your registration.

This guidance on the scope of registration replaces the previous version published in March 2015. We have added information to clarify some sections and reflect changes in the way health and social care is now delivered.

To decide whether and how you need to register with CQC you may find it useful to ask yourself the following questions:

- Will I be carrying on a regulated activity? If so, which will apply to me?
- Who will be responsible for directing and controlling the regulated activity? (called 'carrying on' the activity)
- Will any exceptions apply?
- Where will the regulated activity be carried on at or from? (called location(s))
- Is a registered manager required at any or all locations?
- If I am intending to provide services to children, do these activities need to be registered with CQC, Ofsted or both?

This guidance will help you answer some of these questions.

It is important to focus on the activities that will trigger the need for registration. This depends on what regulated activity you provide within your 'service type'. See Information on service types.

If you are already registered and want to change the type of activities or services you provide, refer to the regulations and use this guidance to determine whether you need to apply for any changes to your regulated activities.

If you support people with a learning disability and/or autistic people, also refer to our guidance Right support, right care, right culture.

Who has to register?

'Service providers' must register with CQC. A service provider can be:

- an individual
- a partnership
- an organisation (for example, companies, charities, NHS trusts and local authorities).

We register the regulated activity that will be carried on – not service types or professions. To decide whether you need to register, it is important to determine what regulated activity will be carried on, and who is responsible for it.

It is the legal entity carrying on the regulated activity that must register – not the location or care setting where it is carried out. See guidance about locations.

What is a regulated activity?

Section 8(1) of the <u>Health and Social Care Act 2008</u> describes a regulated activity as "an activity involving, or connected with, the provision of health or social care".

The activities listed in Schedule 1 of <u>The Health and Social Care Act 2008</u> (<u>Regulated Activities</u>) <u>Regulations 2014</u> are the regulated activities specified for the purposes of the Act.

If you carry on any of the regulated activities specified in Schedule 1 in England, you **must** register unless an exception or exemption applies.

There are separate arrangements for regulating health and social care in other UK countries. CQC does not normally regulate providers based outside England that offer care and treatment to patients in England. If you are registered in England and you also intend to provide a service to people living in Scotland, Wales or Northern Ireland, we strongly advise you to contact the respective regulatory authority for that country to check whether you also need to register with them.

If a health or care service provider from Wales, Scotland or Northern Ireland occasionally delivers services in England (for example, an ambulance service), we will take a proportionate and reasonable approach to whether they should also be registered with us.

Types of service provider or legal entity

There are many different types of service provider. A service provider is the legal entity who is carrying on the regulated activity. The following are some examples of the main types of service provider.

Individuals

If you will be carrying on the regulated activity by yourself (sometimes referred to as a 'sole trader') you need to register as an individual. Individuals register in their own name as a legal entity and are directly responsible for carrying on the regulated activity or activities.

Organisations

You need to register as an organisation if you intend to carry on regulated activity and are a:

- local authority
- NHS trust
- registered company or charity
- limited liability partnership (LLP)
- other corporate body.

It is the organisation itself that registers – not the people who control it. However, Regulation 5 of the <u>Health and Social Care Act 2008 (Regulated Activities)</u>

Regulations 2014 requires organisations to satisfy themselves that their directors (or those individuals who perform similar functions) are <u>fit and proper persons</u>.

Partnerships

Where an activity is carried on by a partnership, the partnership needs to be registered as the service provider. We do not register each partner individually, but we place a condition on the partnership registration that details the names of each partner.

If there are any changes to the membership of the registered partnership, the provider needs to apply to vary that condition. Providers that registered as a partnership before 4 February 2013 did not have this condition, but we will add the condition to their registration if they apply to add or remove a partner or make another change to their registration details.

Corporate groups

Where a health or care provider is a subsidiary of a bigger parent company and is the legal entity responsible for the service it will need to register in its own right, rather than the parent company. For example, if several provider companies all trade under the same brand, each company that carries on regulated activities must register individually. We will manage our relationship across the parent corporate brand and our published assessments will distinguish clearly between the registered provider and the brand.

Franchises

Franchise holders are usually separate legal entities to the parent company and must register in their own right. When we publish our assessments, we will distinguish clearly between the registered provider and the brand. We will liaise with the parent company as necessary.

Joint ventures

Where an activity is provided as a joint venture between two providers, the venture will often be a corporate entity in its own right and therefore must register. Where the joint nature of the venture is reflected in contracts or agreements, rather than in how it is organised, each party may need to register depending on the individual case.

Primary care at scale

A growing number of primary care services are now working more collaboratively. GP practices are working more 'at scale' as part of a federation or a larger primary care network with community health and other primary care teams and services. Collaborative working arrangements also include single provider 'super practices' covering multiple sites. Regardless of whether arrangements are formal or informal, it is important for providers to clearly identify the legal entity responsible for carrying on the regulated activities.

Section 75 agreements

Section 75 agreements enable NHS bodies and local authorities to:

- establish joint funding
- delegate functions
- integrate resources and management structures, such as integrated community mental health care.

These agreements do not usually constitute a new, separate legal partnership and each body that provides a regulated activity must be registered for it separately. Generally, the body that has the original statutory obligation or power to provide the service is the one that should register for it, as it retains accountability for the service.

Example: Where two community mental health teams are integrated under section 75 agreements, the party with the original statutory obligation to provide the regulated activity of Treatment of disease, disorder or injury would need to register for the entire service covered by the section 75 agreement. Where both parties to the agreement have the same statutory obligation, both are likely to need to register, but they will only be accountable for their areas of responsibility. If either of the parties to a section 75 agreement provide services outside of that arrangement, they would need to be considered in their own right.

Services registered with Ofsted

Ofsted is responsible for regulating establishments and agencies that provide children's social care services. Services regulated by Ofsted are described on the Ofsted pages of the Gov.uk website.

CQC cannot regulate the accommodation element of any establishment or agency registered with Ofsted in England. However, if health care is also being offered, the provider will need to register with CQC separately for the health care element.

The Government guidance on <u>Children's homes and health care: registration with Ofsted or CQC</u> explains which regulated activities offered by children's homes are likely to need to register with CQC.

Services that provide the regulated activity of Personal care to children outside of an establishment or agency that is registered by Ofsted need to register with CQC. For example, a domiciliary or homecare agency may provide personal care to a child in their own home.

The **same** regulated activities cannot be dual registered with both the Care Quality Commission and Ofsted. Where a provider **must** register with Ofsted, the parts of its service that Ofsted regulates will be exempt from registration with CQC. This means the provider does not need to register the same regulated activity with CQC. A provider can still be registered with both regulators, but it cannot be accountable for the same activity (called double accountability). For example, a provider may be registered with Ofsted for activity A and be registered with CQC for activity B. Sometimes, activities A and B may be closely related, or take place in the same location.

We cooperate with Ofsted under the terms of a <u>Memorandum of Understanding</u>. We work together to share expertise and coordinate activity. This allows each regulator to monitor the different areas while avoiding duplication and overlap. See <u>How we inspect children's services</u>.

Hosting arrangements

Hosting is where one provider makes facilities available to another provider to enable it to carry on a regulated activity. In some cases, this may also include support staff such as reception, catering, and housekeeping.

It is the provider that carries on the regulated activity that needs to register – not the host.

Example: An independent provider of a private dialysis unit (provider A) operates within the premises of an NHS hospital (provider B). Provider A will need to register in its own right as a provider if it carries on a regulated activity – not provider B (the host NHS trust).

In these situations, we advise hosts to set out the extent of their role in formal agreements with the service provider (for example, through a contract or service level agreement). If the responsibilities of each provider are unclear, hosts may sometimes end up being held responsible for activities taking place in premises that are under their control, if nobody else is responsible for them.

Renting arrangements

In the same way, if a provider rents out its facilities to another provider, that other provider will need to register in its own right if it provides a regulated activity.

Example: A registered hospital (provider A) rents out its operating theatres to another provider (provider B) during times when they are not being used. Provider B will still need to register if it is carrying on regulated activities independently of the host hospital, even though the host hospital is already registered.

Practising privileges

Practising privileges are a well-established system of checks and agreements to enable doctors to practise in hospitals without being directly employed by them. Doctors sometimes rent consulting rooms to conduct private outpatient appointments in independent hospitals and in private facilities within an NHS hospital. Where these doctors provide a consultation in a service that is managed by the hospital, and the doctors have agreed practising privileges, the consultation may be covered by the hospital's registration.

Practising privileges are different to normal renting and sub-contracting arrangements because they have a specific exemption in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. For this exemption to apply, all aspects of a consultation must be carried out under the hospital's management and policies. For example, the consultation must meet the hospital's requirements for clinical governance and audit, and follow its policies and systems for complaints and

for record-keeping (with the hospital owning the records). It means that the hospital retains responsibility for ensuring that all regulations and relevant requirements are met. The hospital can do this by granting practising privileges.

Doctors (or other healthcare professionals) can also sometimes practise in outpatient departments under their own arrangements, with the hospital only acting as landlord. Where this happens, and the doctor or other healthcare professional is carrying on regulated activities independently of the hospital, they must register as this does not amount to the exercise of practising privileges, unless they are exempt for other reasons (see General exceptions and exemptions from registration).

Landlords should clearly set out the extent of their role in agreements with the service provider (for example, through a contract, service level agreement or practising privileges). If the extent of responsibilities is left unclear, landlords may sometimes end up being held responsible for activities taking place in premises that are under their control, if nobody else is responsible for them.

Subcontracted services

If a subcontractor provides treatment or care services that include a regulated activity, they will usually need to register in their own right. This will always depend on the nature of the subcontracting arrangement. But if a subcontractor does not provide treatment or care directly, such as providing equipment or support services that do not include providing a regulated activity (for example, catering or cleaning) they will not need to register.

Example of a subcontracted activity that needs to be registered: In a hospital's imaging service, the x-ray and scanning department is equipped, staffed and operated by a subcontractor. The overall service is seamless and people who use it may be unaware that some parts are subcontracted. The subcontractor will need to register for the activity as well as the provider of services at the host hospital, even though they provide a service that is part of a pathway of care, entirely within the hospital.

Generally, a subcontractor with a contract to supply part of a wider and more comprehensive service should register for any regulated activity they carry on if they retain any responsibility for delivering the service (such as the operational policies and protocols, day-to-day operational or staff management, clinical governance or quality assurance).

The provider that sub-contracts the work makes a commercial decision on who is responsible for delivering the regulated activity or activities. Commercially, the legal accountability for the quality of care remains the responsibility of both the provider and the sub-contractor. However, for registration under the Health and Social Care Act 2008, CQC will hold accountable the legal entity that is directly responsible for carrying on the regulated activity.

Example of a sub-contracted activity that may not need to be registered: A subcontractor provides an imaging service, but the hospital provider retains responsibility for all aspects of delivering the service. In this case, the hospital provider or the main contractor who retains ongoing control of delivering the service will be held accountable for the sub-contracted regulated activity or activities.

Secondments and similar service level agreements

In some cases, a service provider uses staff from another organisation who are 'loaned' to it, through a secondment or similar agreement, for a certain proportion of their time.

Example: provider A carries on the regulated activities of Surgical procedures and Treatment of disease, disorder or injury. Provider A employs two specialist registered nurses to administer chemotherapy and provide support to patients. When one or both of the specialist registered nurses are on leave, provider A borrows specialist chemotherapy registered nursing staff from provider B. An agreement is in place to enable this to happen. The staff are still paid by provider B, but provider A is the provider who is carrying on the service.

This arrangement does not make the delivery of the regulated activity a joint service (which might require both provider A and B to register for it). Instead, the original employer of the nursing staff is acting as a staffing agency. For the period in which the nursing staff have been seconded to work for and be managed by provider A, they are part of provider A. In this situation, provider B does not need to register for the service provided by provider A. This is often the case with arrangements for community mental health services.

In some cases, an NHS trust (A) may second its staff to a separate service (B) that is funded and facilitated by a charity, while retaining responsibility for the clinical services provided. Sometimes B may reimburse A for the cost of the staff. In these cases, the requirement to register will depend on the detail in the contractual arrangements. This should identify which provider is actually responsible for the treatment being provided. An example of this might be an air ambulance service.

Whether we are considering a secondment, a hosting arrangement or any other way of organising a service, our general principle is to identify who is responsible for the safety and quality of care or treatment. We do this by finding out:

- who has clinical responsibility?
- who would need to handle complaints?
- whose quality assurance or clinical governance system covers the activity?

The line of accountability will usually tell us who is responsible for ensuring compliance with the regulations, and therefore who needs to register.

Do I need to register a manager?

A manager is a person who is in day-to-day charge of delivering a service provider's regulated activity, or a service provider's regulated activity in a particular location. The <u>Care Quality Commission (Registration) Regulations 2009</u> set out the circumstances in which a service must have a registered manager as a condition of its registration. These are:

- Any service provider that is an organisation whether corporate (for example, a company) or unincorporated (for example, a partnership or a charity) must have a registered manager for every regulated activity that it carries on, unless it is a health service body. Health service bodies such as English NHS trusts do not need to have a registered manager unless we impose a condition on their registration that requires one. Others including independent organisations that work under contract to the NHS must always have a registered manager.
- If the service provider is an individual, they do not need to have a registered
 manager unless they are not a fit person to manage the regulated activity, or they
 do not intend to be in day-to-day charge of how the regulated activity is provided.
 See what we mean by 'fitness'.

When we register NHS trusts that have a care home and provide the regulated activity of Accommodation for persons who require nursing or personal care, we will use our discretion and may impose a condition to have a registered manager. This is because we consider the role of a manager who is in day-to-day charge of these services to be fundamental to providing positive outcomes for people who use the service.

To assess whether an individual is a fit person to manage the regulated activity, we consider whether they are:

- of good character
- physically and mentally able to manage the activity (taking into account any reasonable adjustments or plans that may support them to undertake the role)
- able to demonstrate that they have the necessary qualifications, competence, skills and experience to manage how the regulated activity is carried on
- able to provide the following required information:
 - proof of identity
 - enhanced Disclosure and Barring Service (DBS) check with barred list information
 - employment history including evidence of conduct (such as references) and reason for leaving, where the work involved children or vulnerable adults
 - records of qualifications
 - evidence of health (such as a medical reference).

Registered managers can be registered for more than one regulated activity. They can also be responsible for more than one location if they can provide evidence that they are able to do this effectively.

Further information:

- Regulation 7: Requirements relating to registered managers
- How to register as a manager.

General exceptions and exemptions from registration

A number of general exceptions may apply to registration with CQC (read Schedule 2 of the <u>Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</u>). These include exceptions that:

- clarify which aspects of a service do not need to be registered separately
- apply to certain types of provider
- apply only in certain circumstances (see the guidance for each regulated activity).

Where a provider is exempt from the need to register for a specific regulated activity or if an exception under Schedule 2 applies, they should still check if they need to register for any other regulated activities.

Medical practitioners in independent practice

In Schedule 2, paragraph 3, an exception applies to the provision of treatment in a surgery or consulting room by a medical practitioner who is (or a group of medical practitioners who are):

 a service provider already registered for the regulated activity of Treatment of disease, disorder or injury

or

employed by such a service provider

and either

- on the medical performers list for a <u>designated body</u>
 or
- employed by a service provider that is a designated body

By medical practitioner, we mean a doctor registered with the General Medical Council.

This exception does not apply to medical practitioners who are carrying out the following procedures detailed in Schedule 2, paragraph 4:

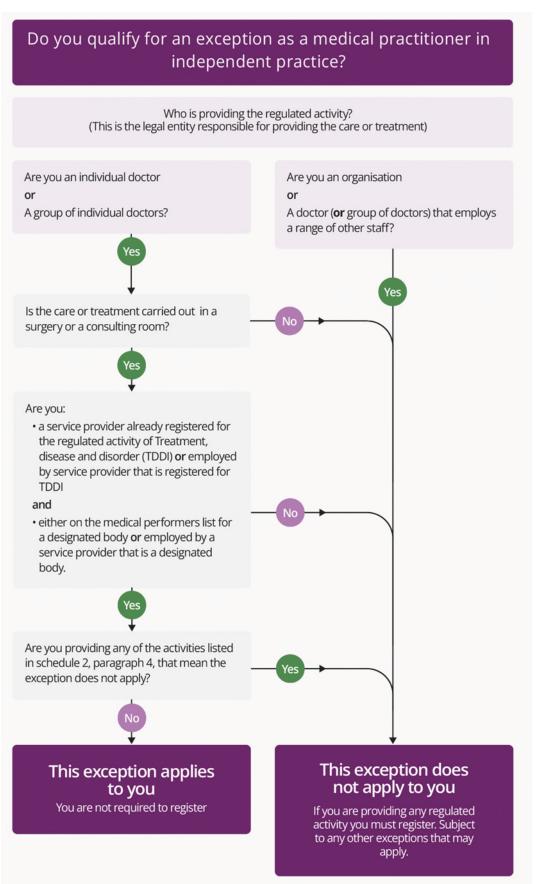
- a. treatment carried out under anaesthesia or intravenously administered sedation, apart from the following procedures detailed in Schedule 1, paragraph 6(2):
 - nail surgery and nail bed procedures on any area of the foot that are carried out using local anaesthesia or without anaesthesia

- curettage (scraping), cautery (burning) or cryocautery (freezing) of warts, verrucae or other skin lesions carried out using local anaesthesia or without anaesthesia
- b. medical services provided in connection with childbirth
- c. the termination of pregnancies
- d. cosmetic surgery, with the exception of:
 - the piercing of any part of the human body
 - tattooing
 - subcutaneous injections of a substance(s) to enhance appearance
 - removal of hair roots or small blemishes on the skin by applying heat using an electric current
- e. haemodialysis or peritoneal dialysis
- f. endoscopy, other than using a device that does not have a lumen or another channel designed to pass fluid or instruments through, or remove body tissue or fluid or any other item from, a person's body
- g. providing hyperbaric therapy, by administering oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber that is gradually pressurised with compressed air, where the therapy is carried out by or under the supervision or direction of a medical practitioner
- h. intravenous, intrathecal or epidural administration of medicines or diagnostic agents
- the therapeutic or diagnostic use of x-rays, radiation, protons or magnetic resonance imaging
- invasive cardiac physiology tests.

For the purpose of this guidance, granting of practising privileges by a designated body is considered the same as being employed by the designated body.

This exception does not apply to an organisation or a partnership that employs a range of staff as well as medical practitioners. It does not apply to treatment provided outside of a surgery or consulting room, or to treatment provided remotely over the telephone, by video consultation or by email.

This diagram illustrates this exception for medical practitioners working in private practice.



Individual budgets, self-funded nursing care or personal care and individual user trusts

Nursing care

A person can use their own finance or individual budget (provided by the local authority or health authority) and make their own arrangement for nursing care where a registered nurse works directly for them and under their control, without involving an agency or employer in managing or directing the care provided. In this case, the registered nurse **may** not need to register with CQC. However, this exception only applies to the regulated activity of Nursing care. If nursing activities involve treatment, then the regulated activity of Treatment of disease, disorder or injury is likely to apply instead. There is no exception from registration for the regulated activity of Treatment of disease, disorder or injury for nurses who are directly employed by an individual.

Personal care

A person, or <u>a related third party on their behalf</u>, can make their own arrangement for personal care where a care worker works directly for that person and under their control, without involving an agency or employer in managing or directing the care provided. In this case, the care worker does not need to register for the regulated activity of Personal care.

These exceptions for Personal care and Nursing care only apply where a person directly employs a care worker to provide their personal care or a nurse to provide them with nursing care. If the care worker or nurse stops working for the person in a directly employed capacity and instead sets up a limited company for business arrangements, they then work for their own company. The company then becomes responsible for providing personal or nursing care and has an ongoing role in how the service is provided. In this case, the company may be in scope for registration and need to register for the regulated activity of Personal care and/or Nursing care.

If directly employed individuals provide nursing or personal care in their own home overnight, they are providing the regulated activity of Accommodation for persons who require nursing or personal care, and they may be in scope for registration and need to register (unless the care is provided through a Shared Lives Scheme).

An individual user trust can be set up to make arrangements for services to meet the health or social care needs of a named person. The user trust is exempt from registration as it is the provider of the services and not the body of trustees that is carrying on the regulated activity. This is detailed in Regulation 4(4) of the Care Quality Commission (Registration) Regulations 2009.

Introductory or employment agencies

Employment agencies (sometimes known as introductory agencies) are exempt if:

- they only help people find registered nurses, nursing associates or care workers, and
- they do not have any role in managing or directing the nursing or personal care that a registered nurse, nursing associate or care worker provides.

See further details of what we mean by <u>having no ongoing role in providing a</u> personal care service.

Third party exceptions

The following are some examples of exceptions from registration for other services. They are grouped together because they represent services that may be organised through a third party, which may be the provider's 'customer'. This arrangement is different from most other health and care services, which are organised directly between the provider and the person who uses the service. It is not a complete list; see Schedule 2 for full details of exceptions.

- Medical or dental service occupational health schemes (that do not involve treatment requiring admission to hospital) organised through an employer, where these are for the benefit of the employee only.
- Medical or dental services organised by a government department that do not involve treatment requiring admission to hospital (for example, medical assessments to determine eligibility for social security benefits, or services arranged on behalf of people by the Maritime and Coastguard Agency).
- Assessment and treatment that is related to insurance and organised through insurers (for example, if an assessment is needed as part of assessing claims for injury through accident insurance, travel insurance or motor insurance). However, this exception does not include services organised through private medical insurance schemes.
- Defence medical and dental services organised through the armed services, including education and training for delivering health and dental care that is provided by, and delivered to, armed services personnel.
- Forensic medicine or dental services (for example, for people detained in police custody) that is organised solely through a local policing body as defined in section 101 of the Police Act 1996.

Other exceptions

The following are also activities excepted from registration:

- Any health or social care activity carried out by a carer for a member of their family or someone they are in a personal relationship with, where the care is provided during that family or personal relationship for no commercial consideration. This means a person does not pay another person when they provide or promise to provide a service. A family relationship can include people treating each other as if members of the same family, so long as they are living in the same household. A personal relationship means a relationship between or among friends, including family friends.
- Primary ophthalmic services (for example, high street optometrists) or ophthalmic services that are of the same kind as those provided by high street optometrists.
- Primary pharmacy services (for example, high street pharmacists) or pharmacy services that are of the same kind as those provided by high street pharmacy services.
- Treatment provided by a registered nurse to pupils in a school, where the nurse
 is engaged and directed by the school. In general, this will exempt school
 registered nurses in independent schools, but not in public sector or state
 schools, where the school nursing service will be included in the registration of
 the relevant provider.
- First aid provided in the following circumstances by:
 - organisations established to provide first aid
 - healthcare professionals in unexpected or potentially dangerous situations requiring immediate action
 - o non-healthcare professionals who are trained to deliver such treatment.
- Nurses' agencies acting as an employment agency that supplies staff to organisations carrying on regulated activities, but that do not provide any regulated activities themselves.
- Activity carried on for the purpose of testing for coronavirus (COVID-19)
 presence or antibodies, or for processing, analysing or reporting the results of
 those tests (see the <u>Health and Social Care Act 2008 (Regulated Activities)</u>
 <u>Regulations 2014</u>, Schedule 2 paragraph 12).

The regulated activities

The regulated activities are detailed in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

We describe each regulated activity and give some examples of services that are likely to carry on these activities. If the general exceptions and exemptions do not apply to you, you **must** register for each regulated activity that you provide, unless a specific exemption applies.

You need to be sure that the service you provide is covered by the regulated activities you register for. To do this, check all the activities, read the guidance and use the diagrams to help you decide if you need to register for that activity.

The <u>Quick reference guide</u> also shows which regulated activities you are likely to need to register for.

You may need to register for more than one regulated activity to cover the service(s) you provide. Some providers may need to register for several regulated activities.

How the regulated activities relate to each other

Each regulated activity requires a separate registration.

There is no hierarchy of regulated activities – they are all equally important and you must apply for all that relate to your service.

Sometimes, registration for one regulated activity will remove the need to register for another. For example, a provider will not need to apply for:

- Nursing care where it is part of another regulated activity (such as Treatment of disease, disorder or injury)
- Personal care where it is delivered as part of:
 - Accommodation for persons who require nursing or personal care
 - Accommodation for persons who require treatment for substance misuse
 - Treatment of disease, disorder or injury.

However, wherever nursing care or personal care is provided in its own right (not as part of another regulated activity), then a provider may need to register for it as a regulated activity, even if the provider is registered for other regulated activities.

Example: A provider is registered for Accommodation for persons who require nursing or personal care in respect of a residential care home, but they also provide care to people in their home (called a domiciliary or homecare service).

In this case, the provider must also register for the regulated activity of Personal care because the domiciliary or homecare service involves personal care that is separate to the care home service.

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Personal care

Description

Personal care is defined in Regulation 2 (Interpretation) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. See the <u>definition of personal care</u>.

The regulated activity of Personal care involves providing personal care for people who are unable to provide it for themselves because of old age, illness or disability. The personal care **must** be provided in the place where those people who need it are living at the time when the care is provided.

For example, this includes personal care provided through domiciliary or homecare services, and housing with care or supported living services. Sometimes, people receiving personal care live in accommodation where it is a requirement of occupation that they both need and receive a care service while living there. For the care service to be correctly registered for the regulated activity of Personal care, there must be a real separation between the provision of personal care and the accommodation agreements. See our <u>Guidance on supported living and extra care housing services</u>.

This regulated activity also includes <u>Shared Lives schemes</u> where the provider of the scheme is registered for personal care – not the owners of the individual homes (the accommodation). If you are carrying on the regulated activity of Treatment of disease, disorder or injury, you do not also need to register for Personal care if you deliver this as part of the treatment. However, if you provide personal care to people who are not also receiving treatment for a disease, disorder or injury, you will need to register for Personal care.

When this regulated activity does NOT apply

This regulated activity does not apply if your service does not provide the activities defined as personal care. See Regulation 2 and Schedule 1(1) of the <u>Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</u> for full details.

It is the nature of the care (activity) being provided that determines the need for registration and which regulated activity is applicable.

For example, you do not need to register if you **only** provide housing support or social support (such as help with shopping), but no tasks that are included in the <u>definition of personal care</u>. Similarly, you do not need to register for the activity if you **only** provide support to administer, prompt or supervise medicines but do not intend to provide any of the activities defined as personal care.

Examples of some specific exceptions

You are excepted from this regulated activity and do not need to register for Personal care if:

- You are a provider managing a prison or other similar custodial establishment (apart from a hospital within the meaning of Part 2 of the Mental Health Act 1983) and you provide personal care for people who are detained. A prison is considered to be where a person is living for the time that they are detained there. This means that if a domiciliary or homecare agency provides personal care in prisons or similar custodial settings, the provider of the domiciliary or homecare agency must register with us because the exemption only applies to the person managing the prison.
- You are a fostering agency that is inspected by Ofsted, and your services include providing personal care to children who are placed or being placed with foster carers.
- You are registered or registering to provide accommodation together with personal care for the people who use your service in a care home setting (the regulated activity of Accommodation for persons who require nursing or personal care). However, if you also intend to provide personal care services to people in places where they live (for example, in their own homes) as well as providing accommodation together with personal care, then you will also need to apply separately for the regulated activity of Personal care.
- Your role is an employment or introductory agency, and you supply care workers:
 - to another organisation who will then be responsible for directly providing the care, or
 - to a person who will then take whole responsibility for arranging to provide their own care under a personal budget or private arrangement.

See further information about people who introduce a care worker to an individual but then have <u>no ongoing role in the personal care that a carer provides after they are introduced.</u>

 You are a carer or personal assistant directly employed by a person or a related third party (without the involvement of an employment agency or employment business) and you work wholly under the direction and control of that person or related third party to meet the person's own personal care requirements. See what related third party means in our glossary of terms.

Shared lives schemes (previously known as adult placement schemes)

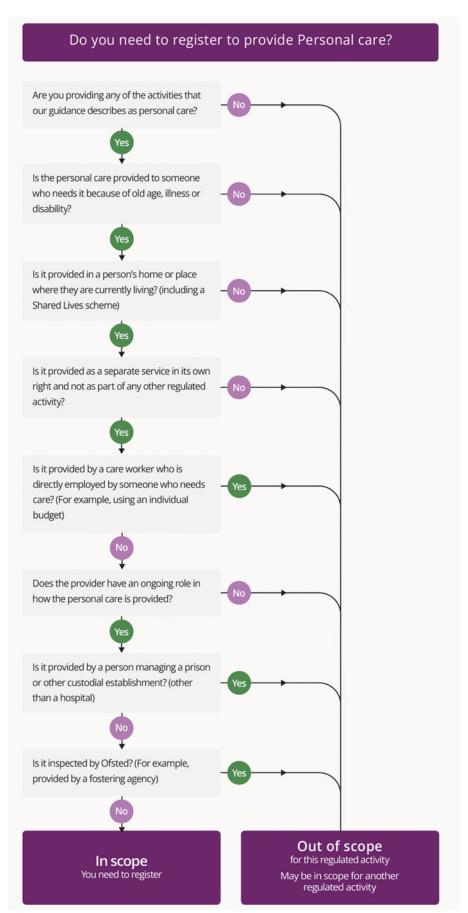
Shared lives schemes (referred to in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) should register **only** for the regulated activity of Personal care and **not** the regulated activity Accommodation for persons who require nursing or personal care. This is because:

The regulated activities

- the provider of the **scheme** is registered and not the owners or providers of the individual homes (the accommodation)
- the accommodation aspect of the service supplied by the shared lives carer is out
 of the scope of the regulations, and the homes where people live are not
 'regulated premises' that we can inspect.

Shared lives schemes should only register for Personal care where they provide placements for people with personal care needs. If they do not provide this type of placement, they will be out of scope for this regulated activity. See a description of shared lives schemes in our glossary of terms.

Check if you need to register for Personal care



Accommodation for persons who require nursing or personal care

Description

This regulated activity applies where residential accommodation is provided **together** with nursing care or personal care as a single package, for example nursing or personal care delivered in a care home setting.

A single package means the person using the service cannot choose to receive personal care from another provider while they are living in the accommodation. In the same way, to receive the accommodation they are required to receive their personal care from one specified provider. The accommodation and the care will usually be from the same provider, but they do not need to be, as long as any contractual arrangements make clear who is responsible for carrying on this regulated activity.

If accommodation and personal care are provided separately and people living in the accommodation can choose a different provider to meet their personal care needs, then it may be a supported living or extra care housing service. In this case the regulated activity of Personal care may apply.

You do not have to additionally register for the activities of Personal care or Nursing care if you provide the regulated activity of Accommodation for persons who require nursing or personal care. Where someone living in a care home needs nursing care, this may be provided by care staff where the tasks can be delegated appropriately by a <u>listed healthcare professional</u> who is employed by a provider registered to carry on the regulated activity of Treatment of disease, disorder or injury (for example, a district nursing service). See more information on <u>delegation</u> in Treatment of disease, disorder or injury.

You may need to apply for other regulated activities where these apply. For example, providers of care homes with nursing are likely to need to also register for Treatment of disease, disorder or injury if they employ registered nurses or other listed professionals who carry on this regulated activity. There may be exceptions to this principle, but only when registered nursing staff are not employed in their professional capacity and do not actually carry out the treatment for a disease, disorder or injury.

Further education sector

In some cases, this activity includes accommodation together with personal or nursing care provided in an establishment in the further education sector. For this activity to apply in the further education sector, more than 10% of the students receiving both accommodation and education at the establishment must also be receiving personal or nursing care. We will normally judge this by looking at the number of students over a 12-month period, rather than just on a single day.

An establishment in the further education sector means an establishment conducted by a further education corporation, or an establishment designated as such by an order of the Secretary of State for Education.

This activity does not include providing accommodation for people who require nursing or personal care in schools.

Shared lives

If you provide a shared lives service, you should register **only** for the regulated activity of Personal care and not for the regulated activity of Accommodation for persons who require nursing or personal care. See more information on <u>shared lives</u> schemes under the Personal care activity.

Check if you need to register for Accommodation for persons who require nursing or personal care



Accommodation for persons who require treatment for substance misuse

Description

This regulated activity consists of residential accommodation for people **together** with treatment for substance misuse.

Treatment

In this regulated activity, 'treatment' covers a range of recognised treatment interventions, such as managed withdrawal or detoxification, or a structured psychosocial treatment programme. It is not limited to treatment provided by a healthcare professional. These types of treatment will always trigger the need to register for this regulated activity if they are provided together with residential accommodation.

Accommodation

The activity covers residential accommodation – this is not the same as hospital accommodation where people receive detoxification treatment. For this activity to apply, a service provider must provide the accommodation 'together with' treatment to the same residents. This means that this activity does not apply to hospitals that provide detoxification treatments for substance misuse. The detoxification being provided in the hospital would be covered under the activity of Treatment of disease, disorder or injury.

The treatment for substance misuse does not necessarily need to be provided in the same place as the accommodation, it could be on a different site. For example, the treatment may be delivered in a community setting such as a day centre or community centre, with the people accommodated in separate facilities somewhere else. However, the accommodation and the treatment must be linked so that the accommodation is provided because someone requires and accepts treatment.

Related regulated activities

Personal care and Nursing care:

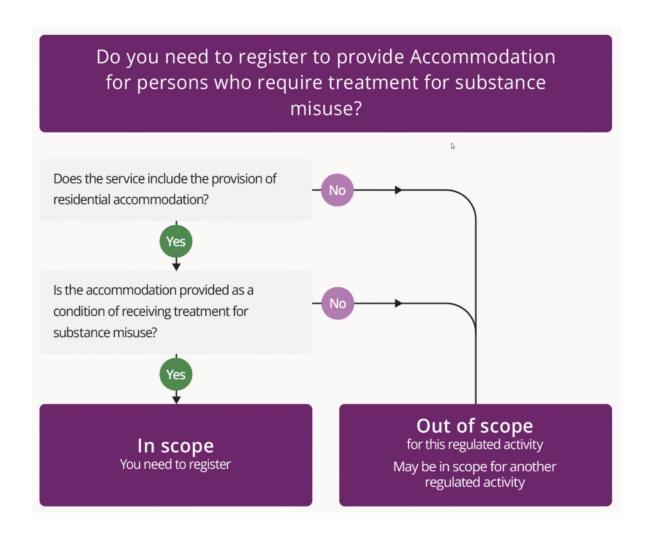
You do not have to additionally apply to register for the regulated activities of Personal care or Nursing care if you provide this activity. This is because they would be covered as part of the treatment you provide for the substance misuse. The only exception to this would be if you also provide personal or nursing care as a separate service (for example a domiciliary or homecare service).

Treatment of disease, disorder or injury:

In the same way, you do not also have to apply to register for Treatment of disease, disorder or injury. This is because the treatment for substance misuse is covered under the activity of Accommodation for persons who require treatment for substance misuse. You would only have to apply for Treatment of disease, disorder or injury if you provide other treatments that are separate from the treatment of substance misuse. For example, treating substance misuse includes detoxification, but you would also have to register for Treatment of disease, disorder or injury if:

- a doctor from the team treats a medical condition unrelated to the substance misuse, or is treating an eating disorder
- a registered nurse was managing a holistic care plan for a dual diagnosis patient and administering treatment for both mental illness and for substance misuse.

Check if you need to register for Accommodation for persons who require treatment for substance misuse



Treatment of disease, disorder or injury

Description

This activity covers a treatment that is:

- provided by or under the supervision of a defined list of <u>healthcare professionals</u>
 or by a multi-disciplinary team that includes a listed healthcare professional, or
- provided by or under the supervision of a social worker where the treatment is for a mental disorder, or by a multi-disciplinary team that includes a social worker where the treatment is for a mental disorder, and is
- for a disease, disorder or injury.

Treatment of a disease, disorder or injury covers a wide range of treatments. We don't provide a complete list here, but it includes examples such as:

- emergency treatment
- ongoing treatment for long-term conditions
- treatment for a physical or mental health condition or learning disability
- giving vaccinations or immunisations
- palliative care.

This regulated activity applies to the treatment of disease, disorder or injury in **any** setting, for example hospitals, clinics, hospices, ambulances, GP and dental surgeries, community services, and care homes.

What this regulated activity does NOT include:

- Interventions carried out purely for cosmetic purposes.
- Alternative and complementary medicine, with the exception of the practice of osteopathy or chiropractic.
- First aid where it is delivered by:
 - healthcare professionals in unexpected or potentially dangerous situations requiring immediate action
 - o non-healthcare professionals who are trained to deliver first aid
 - o organisations established for the purpose of providing first aid
- Treatment provided in a sports ground or gymnasium (including associated premises) where it is provided for the sole benefit of people taking part in, or attending, sporting activities and events.
- Treatment provided through temporary arrangements for sporting or cultural events (such as festivals, sporting or motor sport events).
- Hyperbaric oxygen therapy provided to workers in connection with their work or

when governed by the Diving at Work Regulations 1997 or Work in Compressed Air Regulations 1996.

 Activities authorised by a licence granted by the Human Fertilisation and Embryology Authority.

Read Schedule 1 (4)(3) of the <u>Health and Social Care Act 2008 (Regulated Activities)</u>
Regulations 2014 for the full list of excluded activities.

Sometimes, Treatment of disease, disorder or injury is provided as only one part of a service, for example in a large care home that has just a few intermediate care or specialist palliative care beds. If the activity is carried out by or under supervision of a listed healthcare professional employed by the provider, you will still need to register for it in addition to any other activities that you may need to register for your service.

If another body provides those services, our guidance on <u>hosted services</u> in the section on Who has to register? applies.

Other regulated activities covered by this regulated activity

If you are registered for Treatment of disease, disorder or injury, and when delivering it you provide:

- Personal care
- Nursing care

you do not need to apply for those additional regulated activities.

Additional regulated activities you may need to register for

You should also apply for other regulated activities if you are providing them. Examples might include, but are not limited to:

- Surgical procedures
- Diagnostic and screening procedures (where not provided as part of a treatment)
- Assessment or medical treatment for persons detained under the Mental Health Act 1983
- Services in slimming clinics.

Who must carry on the regulated activity for it to be in scope

You will need to register for this regulated activity if your service includes treatment that is carried out by:

- a listed healthcare professional, or if this professional supervises the treatment, or
- a social worker where the treatment is for a mental disorder, and is intended to treat disease, disorder or injury.

See the specific definition of a healthcare professional for this regulated activity only.

If a multi-disciplinary team includes one of these healthcare professionals (or a social worker in the case of mental health treatment) involved in their professional capacity, then the activity will be within scope and needs to be registered.

Where the situation is unclear, we will consider each case individually. For example:

- If the person providing treatment is not acting in the capacity of a listed healthcare professional, even if they hold a professional qualification. For example, a beautician who is also a registered nurse may be carrying out a cosmetic or aesthetic service. Similarly, a psychiatrist may also be qualified as a psychotherapist. Where they practise as a psychiatrist (a registered medical practitioner) it may be in the scope of this activity. Where they practise solely as a psychotherapist, it would not be in scope of this activity.
- Where it is not clear whether the service is treatment or is being carried out for another reason. For example, some interventions that are normally aesthetic, such as laser hair removal, may also be carried out in response to a clinical disorder.
- In community mental health care (including primary mental health care) some psychological therapies may be provided by healthcare professionals, social workers or by others with specific qualifications. In these cases, some service providers will need to register, whereas others will not. This depends on whether they use healthcare or social work professionals to deliver or supervise treatment.

Professionals who are NOT included in the scope of this regulated activity

The list of professionals in the regulations does not include:

- clinical psychologists
- occupational therapists
- physiotherapists
- pharmacists
- opticians
- dietitians
- nursing associates.

If you are one of these professionals and you run a standalone treatment service, you do not need to register for Treatment of disease, disorder or injury.

Social workers

Most (but not necessarily all) specialist mental health services provided by social workers who are working in their professional capacity as a social worker will be within the scope of this regulated activity, and the provider of that service will need to register. For example, where treatment includes ongoing assessment of a person's mental state or where the social worker is providing a psychological therapy. Other types of social work services will not be in the scope of this regulated activity.

Nursing associates

The role of nursing associate introduced in 2019 is not included in the list of healthcare professionals who can carry out activities covered by the regulated activity of Treatment of disease, disorder or injury. This means that a provider cannot register for this regulated activity based on the employment of nursing associates alone, though they may be employed to work as part of a nursing team with other listed healthcare professionals.

What we mean by treatment "under the supervision of" a listed healthcare professional or social worker

A person's treatment is 'under the supervision of a healthcare professional (as listed in paragraph 4(4) of Schedule 1 of the <u>Health and Social Care Act 2008 (Regulated Activities)</u> Regulations 2014) where the healthcare professional:

- is part of the team that directly provides health care to the person, or
- directly reviews the person's case and sets out a plan of care for them even if this plan is carried out by another person, or
- authorises a protocol of care, which is used by other care givers, that:
 - they are directly accountable for, and
 - they are required to continually monitor, and
 - can only be authorised by the healthcare professional by virtue of their professional registration, and
 - directly records the details of the people who receive care when the protocol is used.

Where a service solely produces <u>Patient Group Directions (PGDs)</u>, it is not carrying on a regulated activity. This is because there is no treatment 'by or under the supervision of' a healthcare professional from the service that produces the PGD, even though a <u>healthcare professional</u> may be involved in creating and/or authorising the PGD itself.

'Delegation' of healthcare tasks

Delegation is different to supervision. A healthcare professional employed by a provider registered for Treatment of disease, disorder or injury can delegate a procedure to a care worker or nursing associate who is employed by a second provider operating, for example, a care home without nursing or a domiciliary or homecare agency. The healthcare professional, for example a nurse employed by a community trust, must ensure that a task is appropriately delegated and assess that it is within the worker's competence.

The second provider cannot be considered to be carrying on this regulated activity and is not required to register for it, as they are not employing healthcare professionals to provide or supervise the activity. The first provider remains responsible for the treatment of a person using the second provider's service, including the outcome of any healthcare task they delegate to staff working for the second provider. However, a provider cannot be responsible for the day-to-day supervision of staff who are employed by another provider. It is therefore the second provider's responsibility to ensure that they do not allow their staff to accept delegated tasks unless the staff have enough support, supervision, education and training to competently undertake the aspects of care that are being delegated.

The professional standards that registered nurses, midwives and nursing associates must uphold are set out in The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates 2019 (Nursing and Midwifery Council). Registered nurses, midwives and nursing associates must act in line with the Code. This includes requirements about accountability for decisions to delegate tasks and duties, and for the outcome of the delegated tasks. The Royal College of Nursing also provides guidance on accountability and delegation.

Administering medicines

The activity of Treatment of disease, disorder or injury will apply:

- In a situation when a <u>listed healthcare professional</u> is required to either prescribe or administer medicines.
- When the <u>listed healthcare professional</u> is required to have knowledge or training to administer the medicines, or when a person would not normally be considered able to administer the medicine by themselves.
- When administering any intravenous (IV) product that includes any one or all of: mathematical calculation, reconstitution and use of equipment for the purpose and subsequent care of the patient and IV site.
- When administering chemotherapy in a person's home, a residential home, or in any other setting. This will require training in administration, IV pumps, checking blood results, examination and care of the IV site, and what to do if there is extravasation (unintentional leaking of vesicant medicines from the vein into the surrounding tissue causing blistering and tissue injury).

The activity will **not** apply:

- When a care worker or a healthcare professional administers medicines that have either been prescribed and dispensed for a person, or are a 'homely remedy' (including over-the-counter medicines, complementary therapies and herbal preparations), where:
 - the person using the service would normally be able to administer the medicines for themselves, including drawing up and injecting insulin and taking a controlled drug orally, but because of circumstances or personal choice, they have consented for the medicine to be administered to them, or
 - the person would normally be able to administer the medicines for themselves but because of circumstances, or where they are unable to make a decision about taking their medicines, it has been agreed to be in their best interest for the medicine to be administered to them.
- When a care worker prompts and/or supervises a person to take their prescribed medication.
- When a care worker or nursing associate cares for people receiving nutritional support through a PEG feed or provides care for pressure areas delegated by a district registered nurse (a listed healthcare professional) who works for another provider.

Professional roles and protected titles

The use of professional titles is protected by law. If a person uses a professional title, the assumption will be that the service is being carried out by someone acting in their capacity as a registered healthcare professional and directly using their professional qualification. This means that if the profession is one of those on the list in the regulations, registration will usually be required.

If we find that the service does not involve the professional qualification, and the service may be using the protected title inappropriately in the description of the service or solely for other purposes (such as marketing), we may refer the matter to the relevant professional regulator.

You must consider whether the person providing the service is using their professional qualification in the job they are employed to do. For example, where a care home without nursing has employed a registered nurse or other healthcare professional as a care worker. Where the employee's qualification is coincidental or only relevant as background knowledge, it will not trigger the need for registration.

However, in this case the health professional should not be using their professional registration status or presenting themselves as that health professional.

Examples:

A qualified psychoanalyst, who is also qualified as a psychiatrist but is not prescribing or using medical interventions, will not need to register for their psychoanalytic practice. They are acting in their capacity as a psychoanalyst (not in the list of healthcare professionals) and not as a doctor. They are not using the specific skills taught in medical training but are using the specific skills taught in psychoanalytic training. They are not using statutory authority or powers, which require a medical qualification (for example, prescribing). They are not presenting themselves as a psychiatrist, but as a psychoanalyst.

A drug and alcohol worker, who is also qualified as a social worker, will not need to register to provide a service where they are only working as a drugs worker. However, if they are working as a social worker then the service will need to register. We can tell whether they are working as a social worker if they are clearly using the specific skills taught as part of social work training, or they are presenting themselves as a social worker and using that protected title to describe their work.

Registering for specific services

Lasers and intense pulsed light (IPL)

Healthcare professionals and beauty therapists often use lasers and IPLs for nonsurgical procedures. For example, in cosmetic procedures such as hair removal, and for therapeutic procedures such as minor dermatological conditions.

These procedures can constitute appropriate treatment of recognised medical disorders and beauty therapists who are trained to use the laser or IPL can carry out the procedures safely and appropriately. Dermatologists sometimes refer or advise patients to visit a beauty therapist. This is because, even in a clinical service such as dermatology or plastic surgery, very few laser or IPL procedures require the skills of a healthcare professional.

Use of lasers and IPLs is not part of professional training in healthcare professions. Although a healthcare professional's knowledge of physiology and physical and mental conditions may add value to a service, it is usually useful as background knowledge rather than using their professional training.

If you provide laser and IPL services that are delivered by listed healthcare professionals, you will only need to register where:

the specific skills of a listed healthcare professional are used, for example where
the service is part of a package of clinical care and requires specialist
physiological and psychological knowledge such as use of a laser as part of
plastic surgery procedures (in this case the regulated activity of Surgical
procedures would apply), or

- the service is combined with other procedures that require a listed healthcare professional qualification, for example prescribing, or
- you describe the service as being carried out by someone acting in their capacity as a registered healthcare professional.

Intravenous (IV) products

Intravenous administration of vitamins and products that are prescription only medicine (including 0.9% saline) that are used to improve or enhance wellbeing constitutes treatment of a disease or disorder. We consider a 'disease' to include a pathophysiological response to internal or external factors, and a disorder to include a disruption to regular bodily structure and function.

If you provide intravenous administration services, you will need to register for the regulated activity if the procedures you offer:

- are delivered by, or under the supervision of, a listed healthcare professional, and
- include administering prescription-only products intravenously or products that require a prescription when delivered in intravenous form, and
- claim to alter a person's physiological state in response to a defined concern.

We do not consider this type of procedure to be alternative or complementary medicine.

Orthodontics – clear aligner treatment

Clear aligner treatment is an orthodontic treatment that corrects misaligned or crooked teeth using clear dental appliances. We consider the treatment planning and diagnosis associated with aligners to be a regulated activity, regardless of how the treatment is initiated. If you are a provider of clear aligner treatment, you are likely to need to register for the regulated activity of Treatment of disease, disorder or injury.

Treatment of obesity

The regulated activity of Services in slimming clinics only applies where a medical practitioner provides or supervises advice or treatment in a clinic, including prescribing medicines, for the purposes of weight reduction.

Treatment of disease, disorder or injury would apply where a medical practitioner provides treatment of obesity other than in a clinic (for example, through online services).

If you are another type of listed <u>healthcare professional</u> and you treat people for obesity, this is included in the regulated activity of Treatment of disease, disorder or injury. We interpret the term 'treatment of obesity' to include:

- using a medicine prescribed for this purpose
- supervising people's treatment for obesity with a medicine prescribed for this purpose
- treating people in a clinic or through an online web-based service.

<u>Contact us</u> if you are not sure whether the obesity treatment you deliver needs to be registered, or if you are registered for the correct regulated activities.

Earwax removal treatments

Earwax build-up is a natural physiological problem that can result in a health problem or can worsen the symptoms of an existing medical condition, leading a person to seek assistance from a professional. Whichever type of treatment is used, earwax removal is a regulated activity if:

- the person and a listed healthcare professional both agree that there is a problem that needs an intervention; and
- the treatment is carried out by a listed healthcare professional.

You will need to register for Treatment of disease, disorder or injury if this applies.

First aid

You do not need to register if you **only** provide first aid, as this is not regulated activity.

First aid is:

- the initial response to a sudden illness, condition or injury or exacerbation of an existing illness
- restricted to the aim of either alleviating it immediately through simple procedures and/or preventing it from worsening until professional medical help is available.

First aid may include simple non-invasive physiological monitoring techniques carried out as part of the overall first aid care and be provided by lay people or healthcare professionals.

If a healthcare professional administers first aid, they will not need to rely on their specific area of professional expertise but will only use skills and knowledge that will reasonably be expected of any person who has received training in first aid.

A first aid service may involve:

- Healthcare professionals, but only where they are acting in their capacity as a
 first aider alone. For example, they are not prescribing, following a patient group
 directive, using specialist drug administration techniques, or using other specialist
 skills that reflect their professional training rather than their first aid training.
- Simple procedures for assessment that:
 - o do not need to use a recognised professional diagnostic qualification (for example, as a radiographer or sonographer) and
 - are limited to only assessing the need for onward referral for treatment. This includes use of an electrocardiogram (ECG), automated non-invasive blood pressure measurement, pulse oximeter, use of a thermometer, sphygmomanometer or ophthalmoscope.

Urgent procedures that can be carried out by volunteers. For example, where
volunteers, including community first responders, are trained to carry out
cardiopulmonary resuscitation (CPR) and use an automatic external defibrillator (AED)
(sometimes called a community defibrillator or public access defibrillator (PAD)).

Care homes with nursing

If you are a provider of a care home with nursing, you are likely to need to register for this regulated activity. This is because you will probably employ registered nurses or other listed healthcare professionals who carry out these activities. There may be exceptions to this rule, but only when the registered nursing staff do not actually carry out or supervise the treatment for a disease, disorder or injury.

Care homes without nursing

Providers of care homes without nursing should **not** register for this regulated activity. This is because if you are carrying out these treatments in the care home, it will likely be by delegation from a healthcare professional working for another registered provider. This includes where you employ registered nursing associates, but they are carrying out treatment delegated by a listed healthcare professional such as a district registered nurse who is employed by another provider.

Treatment for substance misuse

The types of listed healthcare professionals that most commonly work in substance misuse services are:

- medical practitioners
- registered nurses
- social workers.

If any of these professionals are working in their registered capacity (under their protected professional titles) and providing treatment as part of a multi-disciplinary team, it means the whole team will be within the scope of registration as providers of this regulated activity. If you employ them you should register as your service is providing treatment for a disease, disorder or injury.

If your service provides substance misuse treatment but the team does **not** include a relevant listed healthcare professional working in their registered capacity, then you do not need to be registered for this regulated activity. For example, if you employ staff as drug and alcohol workers as part of a community based multi-disciplinary drug and alcohol team, but the team does not include a healthcare professional such as a medical practitioner, registered nurse or social worker, then you do not need to register for this activity.

If your service does not provide residential accommodation but people are receiving detoxification treatment delivered by a listed healthcare professional working in their professional capacity, then you should be registered for the regulated activity of Treatment of disease, disorder or injury.

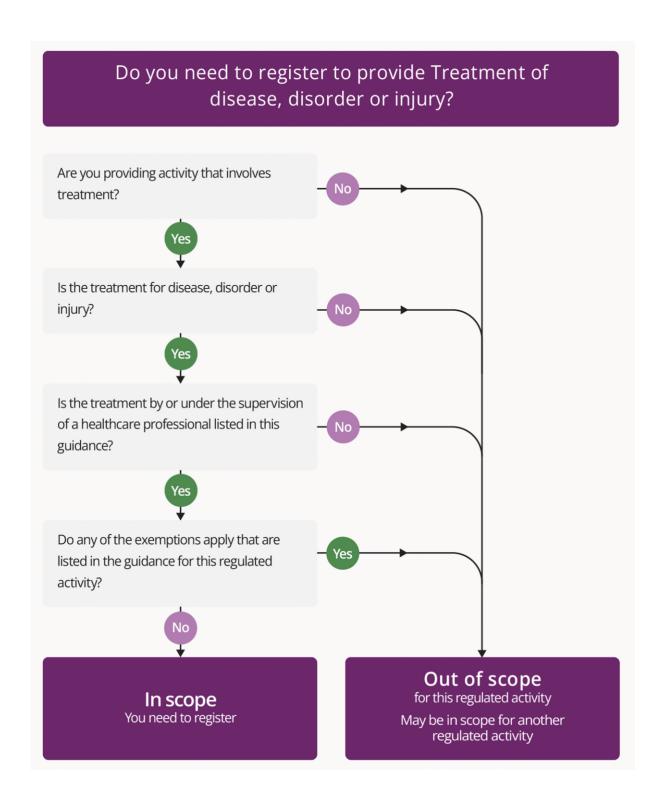
School nursing and health visiting

If you provide school nursing and health visiting services, you are likely to need to register for this regulated activity as you employ nurses or other listed healthcare professionals who deliver these activities. This can be the case even where the services delivered do not initially appear to include any treatment for a disease, disorder, or injury (for example, a baby weighing clinic). This is because treatment includes the ongoing assessment of a person's physical or mental state and giving vaccinations or immunisations. This does not apply where a nurse is directly engaged and directed by a school.

Research settings

Treatment of disease, disorder or injury may also be provided in research settings, sometimes as a secondary purpose. You should register for this regulated activity where the research forms part of a person's treatment for a disease, disorder or injury, and is carried out by or under supervision of a listed healthcare professional. Research organisations that carry out clinical trials on people who are not being treated will not be required to register for this activity.

Check if you need to register for Treatment of disease, disorder or injury



Assessment or medical treatment for people detained under the Mental Health Act 1983

Description

This regulated activity relates to the treatment of people who are detained in, or recalled to, hospital for assessment and/or medical treatment under the Mental Health Act 1983. This includes people whose initial detention was under another enactment, but which has taken effect as a Mental Health Act detention.

The activity only applies to the use of the Mental Health Act in **hospitals**, rather than in any other setting.

It includes the use of short-term, emergency holding powers under Section 5 of the Mental Health Act.

Importantly, this means it also applies to hospital services that are not specialist mental health inpatient services, such as acute hospitals, where the Mental Health Act could be used to detain patients for short periods under temporary arrangements.

The regulated activity does **not** apply to:

- locations that are not a hospital (including prison, community or residential treatment settings for substance misuse or community-based mental health services)
- detention under sections 135 or 136 of the Mental Health Act where people are removed to a designated place of safety (usually a hospital but which, under exceptional circumstances, can be a police cell)
- care homes, even if these have residents who are subject to a community treatment order or guardianship under the Mental Health Act or are on leave from detention in hospital under the Act.
- assessment or treatment by a medical practitioner appointed to provide a second opinion. This means that treatment for the purposes of Part 4 of the 1983 Act in giving a certificate under section 57, 58 or 58A of the Act is exempt from registration (we refer to this as treatment or assessment by a Second Opinion Appointed Doctor or SOAD).

Applying for other regulated activities

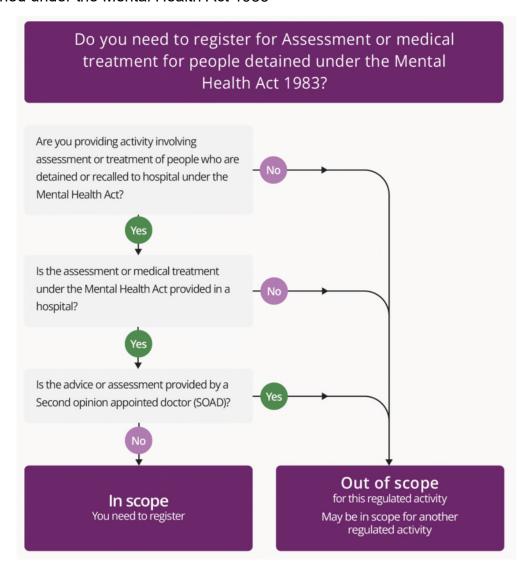
If you apply for this regulated activity and you also provide treatment for people who are not detained or not liable to be detained under the Mental Health Act, or informal hospital patients, you may also need to apply for the activity of Treatment of disease, disorder or injury.

You do not need to additionally apply to register for the activities of Personal care or Nursing care if you provide these activities in the delivery of this regulated activity. However, you may need to apply for other regulated activities if you are providing them in separate services.

Medical treatment in relation to mental health and this regulated activity Medical treatment, only for this regulated activity, is defined in the Mental Health Act 1983 as including:

 Nursing, psychological intervention and specialist mental health habilitation, rehabilitation and care offered to alleviate, or prevent a worsening of, a mental disorder or one or more of its symptoms or manifestations.

Check if you need to register for Assessment of medical treatment for people detained under the Mental Health Act 1983



Surgical procedures

Description

This regulated activity covers the following procedures when carried out by a healthcare professional:

- Surgical procedures for the purpose of:
 - treating disease, disorder or injury
 - cosmetic surgery
 - religious observance (for example, circumcision)
 - sterilisation or reverse sterilisation.

The activity does **not** cover the following surgical procedures if they are carried out using local anaesthesia or no anaesthesia:

- nail surgery and nail bed procedures on the foot carried out by any healthcare professional
- curettage (scraping), cautery (burning) or cryocautery (freezing) of warts, verrucae or other skin lesions, carried out by
 - a medical practitioner, or
 - another healthcare professional on any area of the foot.

Surgical egg retrieval

This regulated activity does **not** cover surgical egg retrieval carried out in connection with an activity listed in Schedule 2 of the Human Fertilisation and Embryology Act 1990 for which a licence has been granted under section 16 of that Act. This is because this procedure is carried out to assist a person to become pregnant, rather than to treat a disease, disorder of injury or reverse sterilisation.

Other procedures covered by Surgical procedures

If you provide surgical procedures, you will usually need to register for other regulated activities. For example, if you use imaging techniques during surgery you may need to register for the activity of Diagnostic and screening procedures.

Pre-operative and post-operative care

The regulated activity covers all pre-operative and post-operative care that is associated with the surgical procedures.

An example of pre-operative care might include assessment by an anaesthetist shortly in advance of the procedure (where this is to assess the patient's suitability directly related to the procedure). It would not include an initial consultation with a surgeon before the procedures had been decided.

For post-operative care, the activity must be related to the procedure to be within the scope of the regulated activity. This will normally mean that it is planned to be related to the procedure. For example:

- post-anaesthetic care (recovery)
- follow-up in an intensive care unit
- care on a ward following surgery

Post-operative care may include a planned follow-up consultation after surgery, but would not include any further additional treatment (apart from checking on the procedures) that is decided in that follow-up consultation.

It also includes other treatment that is directly related to the surgical procedures and carried out under the surgical team. For example, if an anaesthetist temporarily changes a patient's pre-existing prescription for medicines to avoid any conflict with anaesthetic drugs.

If the treatment goes beyond the surgical team, for example where the patient's cardiologist changes a prescription – not the anaesthetist – then that is considered to be treatment in its own right rather than associated with the surgical procedures.

The key principles are that the activity must be:

- directly related to the surgical procedures, so only from the point at which the surgical procedures are decided on.
- only the planned pathway of care, not subsequent treatment.
- only within the surgical team, not the activity of other healthcare teams that may be taking place at the same time.

Surgical procedures carried out for religious reasons

Surgical procedures for religious reasons, such as circumcision, are only included where they are carried out by a healthcare professional. Where a healthcare professional carries out surgery for religious purposes they will be acting in their capacity as a healthcare professional rather than in a religious or spiritual role. This is because the code of practice for a registered healthcare professional prohibits them from disregarding the need to have appropriate skills, experience, equipment and facilities for this procedure and they cannot 'opt out' of their core duties and responsibilities as a registered healthcare professional, even if they are acting in a spiritual or religious role.

Cosmetic surgery

The regulations do not define cosmetic surgery, but the procedures that are within the scope of the regulated activity include those described as being:

 carried out by a healthcare professional for cosmetic purposes, where the procedure involves the use of instruments or equipment that are inserted into the body.

As an example, we consider liposuction involving the insertion of instruments into the body to be included in this activity. This is regardless of whether the liposuction is carried out using general or local anaesthesia, or whether the procedure involves the administration of a laser through a cannula inserted into the body.

A procedure such as the external application of ultrasonic energy without any incision or insertion of instruments into the body is not considered a surgical procedure.

The regulated activity of Surgical procedures does **not** include the following procedures:

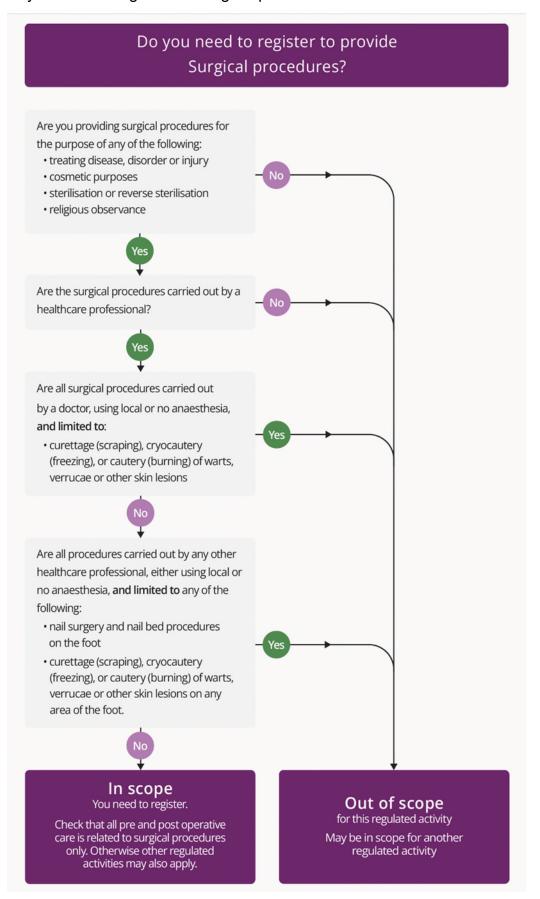
- piercing
- tattooing
- subcutaneous injections to enhance appearance
- removal of hair or minor skin blemishes by application of heat using an electric current.

Hospices

A hospice should not normally be registered for the regulated activity of Surgical procedures.

This is because it is unlikely that a hospice would carry out surgical procedures apart from pleural taps and abdominal paracentesis. We consider these as treatment under the regulated activity of Treatment of disease, disorder or injury for the purpose of registration.

Check if you need to register for Surgical procedures



Diagnostic and screening procedures

Description

This regulated activity includes a wide range of procedures related to diagnostics, screening and physiological measurement.

It includes all diagnostic and screening procedures to examine the body that involve the use of any form of:

- radiation (including X-ray)
- ultrasound
- magnetic resonance imaging.

This includes all main forms of diagnostic radiology, radiography and sonography.

But it does not include use of the same technology when it is used for therapeutic purposes, such as radiotherapy or some forms of interventional radiology as these need to be registered for the activity of Treatment of disease, disorder or injury.

The activity of Diagnostic and screening procedures also includes the analysis and reporting of the examinations that are carried out.

If you use the X-ray, ultrasound or magnetic resonance imaging and you also carry out the analysis and reporting, both will be included within a single registration. But if you use a remote contractor for diagnostic analysis, the provider carrying out the analysis and reporting will also need to register in its own right.

Antenatal or baby scans

This activity is not just limited to scans carried out to get a diagnosis – it includes all procedures involving examination of the body by ultrasound, including antenatal ultrasounds scans. For example, an ultrasound performed on a pregnant person for the sole purpose of baby memorabilia or a keepsake (that is, not as part of the maternity pathway) is within the scope of this regulated activity, regardless of whether the scan is being carried out by a qualified sonographer or another person.

Subcontracting arrangements

Where diagnostic images are reported remotely by a subcontracted provider who is outside England, the subcontractor cannot register as they are outside of CQC's remit. However, we will hold to account the registered provider who made the contract with the subcontractor for the way the service is delivered and to make sure there are appropriate arrangements to deliver the service, including arrangements for quality assurance.

What the regulated activity includes

- Most forms of endoscopy. This is included because the activity covers
 procedures if they involve the use of instruments or equipment that are inserted
 into the body to:
 - o view inside of the body, or
 - gather physiological data.
- Taking an intraoral scan. This is included because the activity involves the use
 of equipment inserted into the mouth to create a 3D visualisation of the teeth that
 can be used to:
 - make dental appliances and construct restorations and prostheses
 - help to diagnose orthodontic conditions and monitor the progress of treatment.
- Taking a sample or biopsy. This is included because the activity covers
 procedures if they involve removal of tissue, cells or fluids from the body, for the
 purpose of diagnosing disease, disorder or injury or monitoring its cause or
 extent. Therefore, anyone who 'removes' tissue, cells or fluids from the body for
 diagnostic reasons may need to register.
- **Examining a sample**. Anyone who uses equipment to examine tissue, cells or fluids from the body to obtain information on the cause and extent of a disease, disorder or injury may also need to register.
 - If you remove the sample and also carry out the examination, then you can include both in a single registration for the activity. But if you use a remote contractor for diagnostic analysis, such as a laboratory company, that provider will also need to register in its own right.
- Physiological measurement (the use of equipment to measure or monitor physiological data). This means obtaining information on the causes and extent of a disease, disorder or injury, or the response to a therapeutic intervention, where the information is needed to plan and deliver care or treatment. It relates to the following systems:
 - audio-vestibular
 - vision
 - neurological
 - cardiovascular
 - respiratory
 - gastro-intestinal
 - urinary.

Diagnostic services providing physiological measurement provide a wide range of specialist investigations and procedures that are often an essential part of care and treatment for patients. As well as assessing the function of major organ systems, physiological measurement includes measurement and tests that are part of normal clinical care when carrying on other regulated activities that a provider will already be registered for under the Health and Social Care Act 2008.

What the regulated activity does NOT include

You will **not** need to register for this regulated activity if you use:

- an auroscope
- a 12-lead electrocardiograph recording (ECG)

The following physiological tests are not included within the definition of physiological measurement, so you will not need to register if you carry out:

- pulse oximetry when used for 'spot' recording
- peak expiratory flow measured by a peak flow meter
- screening or non-diagnostic spirometry
- non-ambulatory blood pressure recording
- a hearing needs assessment or supply and fit a hearing aid if you are a hearing aid dispenser or are acting under the direction or supervision of a hearing aid dispenser, where:
 - o the person is aged 19 or over, or
 - the person is under 19 and the procedure is carried out in, or arranged by, a school or 16 to 19 Academy.

The following are also excepted from this activity (see the <u>Health and Social Care Act</u> <u>2008 (Regulated Activities) Regulations 2014</u>, Schedule 1(7)(4)):

- Procedures carried out for research or analysing and reporting such procedures. However, this exception only applies where those research procedures do not form part of a person's care or treatment. As an example, a university with an imaging department that carries out research would need to register with us if it carries out a radiological examination for research purposes that is part of a patient's care or treatment pathway.
- Taking X-rays by registered chiropractors or the use of ultrasound by registered physiotherapists.
- Carrying out procedures as part of some national cancer screening programmes.
- Fitness screening procedures in a gymnasium, related to the use of fitness equipment or fitness activities, (but treadmill tests for clinical purposes are not exempt).
- Blood tests carried out using a pin prick test or removing blood from a vein where the sample is not sent to a laboratory to be analysed.

- Taking urine samples where the sample is not sent to a laboratory to be analysed.
- Taking and analysing wound swabs.
- Sending samples of body fluids to a laboratory to be analysed, where a provider does not take the samples. For example, when a person produces a urine sample and gives it to a provider, and the provider then sends it away to be tested.
- Procedures carried out by a person in connection with any of the activities authorised by a licence granted by the Human Fertilisation and Embryology Authority.
- Taking or analysing samples of tissue, cells or fluids in order to determine the
 existence of a genetically inherited disease or disorder, or to determine the
 influence of a person's genetic variation on their response to a drug. But these
 tests are not exempt if carried out as part of:
 - o planning or delivering the person's treatment or care, or
 - o a national screening programme apart from a national cancer screening programme.

You can register for this regulated activity as well as any number of other activities. You do not have to be a healthcare professional to register for this activity.

We will consider certain low-risk procedures as part of a provider's overall registration with us. So, if you are registered with us for any other regulated activity, you will not have to register for the activity of Diagnostic and screening procedures just because you carry out the following procedures:

- taking blood or urine samples
- analysing urine or stools using a dip stick or other reagent
- taking a swab from any external part of the body or from the mouth, ear, nose or throat
- removing skin scrapings.

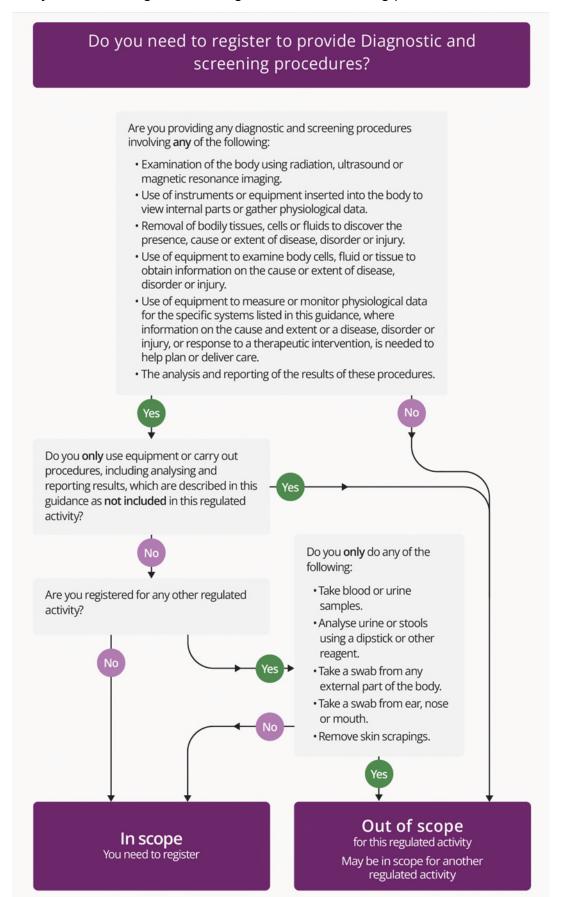
Organisations providing artificial intelligence software for clinical use

Some organisations that provide artificial intelligence (AI) software will need to register for this regulated activity. It is the use of this technology that may be a regulated activity, rather than the supply of the technology.

A healthcare provider that uses AI technology to deliver a regulated activity will be carrying on the regulated activity and will need to be registered with CQC. However, in some cases, the technology supplier may use its own technology to deliver a regulated activity, independently of any CQC-registered healthcare provider, and will need to register. This is becoming common in diagnostics and screening services, where a healthcare provider sends X-ray, CT or MRI images to an AI supplier that then uses its own AI to analyse the images and report the results. If the healthcare provider does not review the results of the analysis independently, then the AI supplier is likely to be carrying on the regulated activity and will need to register.

Suppliers of AI technology do not need to register with CQC where they only supply their technology to others.

Check if you need to register for Diagnostic and screening procedures



Management of supply of blood and blood-derived products

Description

This regulated activity covers the management of:

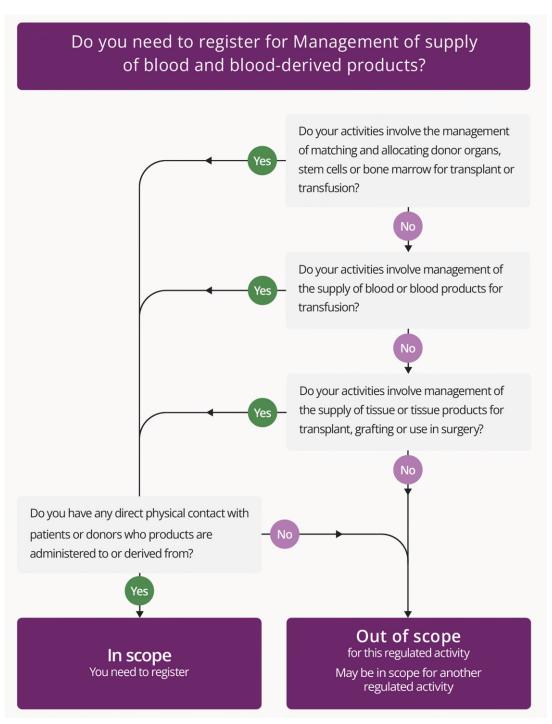
- The supply of blood, blood components and blood-derived products for transfusion. Some examples include:
 - where NHS Blood and Transplant manages the supply of blood
 - a provider managing the supply of blood to another provider
 - a service from a dedicated unit, such as a central or regional facility set up to provide this service to individual hospitals in a corporate group.
- The supply of tissues or tissue-derived products for transplant, grafting or use in surgery. For example, this will include supply of organs or tissue by NHS Blood and Transplant or any other provider of transplant organs.
- The matching and allocation of donor organs, stem cells or bone marrow for transplant or transfusion. For example, this will include the role of NHS Blood and Transplant or any other organisation that is involved in managing the supply of donor organs.

What this regulated activity does NOT include

- The management of supply of blood, blood components and blood-derived products for transfusion, and tissue or tissue-derived products for transplant, grafting or use in surgery where it does not involve direct physical contact with patients or donors.
- How the products are stored, accessed and used in a hospital. This activity is about how blood and tissue products are supplied. Having appropriate equipment and supplies, and storing them, will be part of other regulated activities such as Treatment of disease, disorder or injury or Surgical procedures, rather than an activity in its own right.
- Providing taxi services or other forms of transport that transports blood, organs or tissue products between providers.
- Autologous transplant, where tissue is taken from a person and stored in order to be implanted back into them later. For example, a dental provider removing and storing tissue or bone from a patient and re-implanting it into the same patient at a later date. It also does not include autologous blood transfusion.
- Situations in which a provider's role is only to remove an organ where the patient has chosen to be a donor. Removing an organ from a donor would be registerable under the regulated activity of Surgical procedures. In this case, a

- separate agency such as NHS Blood and Transplant will be responsible and would need to be registered for the onward supply of the organ to the transplantation service provider.
- In relation to donor organs, stem cells or bone marrow, the activity covers all of the supply procedures, from donation to matching and allocation, but does not cover the organ demand procedures, such as managing requests or waiting lists for transplantation.

Check if you need to register for Management of supply of blood and blood-derived products



Transport services, triage and medical advice provided remotely

Description

This regulated activity covers two main service types:

- transport (ambulance) services for the primary purpose of carrying a person who requires treatment
- remote medical advice services that give medical advice or triage by telephone or email in cases where immediate action or attention is needed, and are provided by a body established for this purpose.

Transport services

This regulated activity covers services that involve a vehicle designed for the primary purpose of transporting people who need treatment. The nature of the vehicles used determines the need to register.

The term 'designed for' applies to vehicles that are used to transport people who need treatment where this was the manufacturer's original design, as well as vehicles that have been made suitable for this purpose (for example, displaying livery to show what they are and/or being modified).

You need to register for this activity if your transport services are provided in vehicles that meet this definition. This applies whether ambulance transport is the only regulated activity you provide, or if you provide other services as well as transporting patients.

Air ambulances and water ambulances

These are also covered by this regulated activity. But you are exempt and do **not** need to register for this activity if:

- the aircraft you use is registered with the Civil Aviation Authority and you are not providing treatment to a patient
- the transport is not carried out in England or is carried out under travel insurance arrangements.

Read the <u>General exceptions from registration</u> and <u>Third party exemptions</u> for more information on the exception related to insurance.

What this regulated activity does NOT include

- Transport services provided in vehicles with a different primary purpose (such as taxis, volunteers using their private cars, or mortuary vehicles and Dial-A-Ride vehicles), even though they may be registered with the Driver and Vehicle Licensing Agency as ambulances.
- Search and rescue transport services. This is because the service is provided under arrangements made on people's behalf by a government department.

Although this regulated activity relates to transport, it does not cover other regulated activities that may be provided in or from a vehicle, such as Treatment of disease, disorder or injury or Diagnostic and screening procedures.

Our view is that this regulated activity will normally cover routine, planned patient transport that is related to treatment.

Sporting or other cultural events

This regulated activity will not apply if you only use a vehicle to transport a person within the boundaries of an event site or venue. As an example, if a person attending or participating in a sporting activity or event needs treatment and is carried in a vehicle from one part of the event ground to another, you do not have to register for that transport. However, if the same situation happens and the person is carried from the event ground to hospital, then you will need to register.

We will take a proportionate and reasonable approach if any emergency, unplanned treatment in this context includes some aspects of other regulated activities on an exceptional basis (such as Diagnostic and screening procedures, Surgical procedures or Maternity and midwifery services). We will also take a proportionate and reasonable approach if, in exceptional circumstances, a provider transports a patient outside an event ground and would not normally consider or plan to do this.

Other regulated activities you may need to register for

Some ambulance service providers may also need to register for the regulated activity of Treatment of disease, disorder or injury. For example, where they employ healthcare professionals and usually carry out treatment.

Where procedures are carried out, such as emergency tracheotomy, insertion of a chest drain or intubation, for registration purposes these would be considered as Treatment of disease, disorder or injury – not as the regulated activity of Surgical procedures.

Where procedures that require specialist surgical training and equipment are an expected part of the service, for example thoracotomy or amputation, we regard these as constituting the regulated activity of Surgical procedures. Therefore, if you expect to carry out such procedures and are equipped to do so you must register for that activity. However, if you carry out emergency procedures unexpectedly, we would take a proportionate view in considering whether this is regulated activity and needs to be registered.

When you register for this activity you will not have to additionally register for the regulated activity of Diagnostics and screening procedures if you only carry out the following diagnostic procedures along with transport:

- electrocardiogram (ECG)
- use of an automated external defibrillator (AED)
- pulse oximetry
- use of a sphygmomanometer
- analysis of urine or stool samples using a dip stick or other reagent
- taking blood, urine samples or swab specimens.

Medical advice provided remotely

This regulated activity applies where medical advice is:

- provided remotely, over the telephone or by email, and
- required in cases that need immediate attention or action, or <u>triage</u> (as opposed to a service where a person submits questions electronically to a provider who responds at a later time, or when a person seeks general health care or lifestyle advice), and
- provided by a body established for that purpose (as opposed to remote consultation and advice by a GP practice or the occasional provision of remote advice by a body such as a hospital or university on an informal basis).

This includes NHS 111 and any other organisation established to provide telephone or internet-based medical advice where immediate action or attention is needed, or that provides triage.

Ambulance control centres are also covered by this regulated activity where they provide triage using telephony services.

Maternity and midwifery services

Description

This regulated activity covers maternity and midwifery services where they are carried out by, or under the supervision of, a registered healthcare professional.

You do not have to register for this regulated activity if you **only** provide advice, support or information related to childbirth and parenting, and providing health care is not your main purpose.

An organisation that provides this advice and is not primarily a healthcare provider (such as the National Childbirth Trust) does not need to register, even if the advice is provided by a healthcare professional who it employs.

A hospital provider still needs to register for the activity if it provides advice, because its main purpose is to provide health care.

This regulated activity does not cover arrangements that local authority social services may make under the NHS Act 2006, for the care of pregnant women and women who are breastfeeding.

Midwifery services

Services provided by midwives are exempt and do not need to register for this activity as long as the midwife is:

- acting on their own behalf (self-employed rather than acting for a partnership or organisation), and
- providing non-NHS care (that is, not under contract for an NHS service), and
- providing services to their patients only in the patient's home and not as part of a hospital or clinic-based service.

This exemption only applies if **all** these circumstances are met.

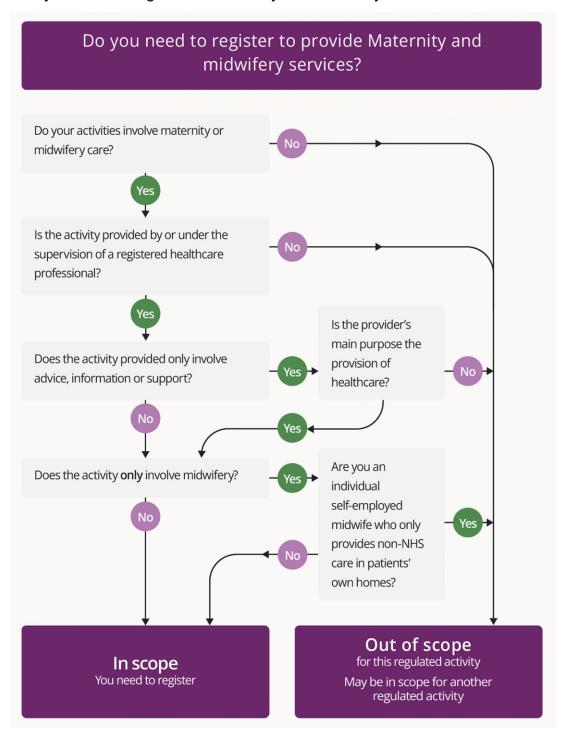
Midwives who provide independent maternity and midwifery services exclusively in people's own homes and who also carry out frenulotomy (tongue-tie treatment) procedures must register to carry on the regulated activity of Surgical procedures.

Antenatal care or postnatal care

Where antenatal or postnatal services are provided as part of primary medical care, the primary medical provider should register for Maternity and midwifery services. Where maternity services are provided as a community or outreach service, the provider will probably need to register for this regulated activity unless they only provide advice and are not primarily a healthcare provider.

The Health Care and Associated Professions (Indemnity Arrangements) Order 2014, is relevant to many healthcare professionals, including individual midwives that are exempt from registering for this activity.

Check if you need to register for Maternity and midwifery services.



Termination of pregnancies

Description

This activity includes the termination of pregnancy by surgical or medical methods, including feticide. It does not include advice on termination of pregnancy. The 'morning after pill' is not a form of termination of pregnancy when used as emergency contraception and has its effect before the earliest stages of implantation.

If you are not an NHS body, refer to Regulation 20 of the <u>Care Quality Commission</u> (<u>Registration</u>) <u>Regulations 2009</u>. These regulations place certain obligations on registered providers.

You may need to register for other regulated activities such as Treatment of disease, disorder or injury if, for example, you provide treatment for sexually transmitted infections alongside termination of pregnancy services.

Services in slimming clinics

Description

This regulated activity covers services provided in a slimming clinic that:

- consist of advice or treatment and include prescribing medicines for the purpose of weight reduction, and
- are provided by, or under the supervision of, a registered medical practitioner.

To be registered for this activity, the service must be carried out in a clinic that is a physical location rather than a remote website service.

You may still need to register for other regulated activities. For example, the regulated activity of Treatment of disease, disorder or injury may apply if you also provide treatment for a condition that is not an obesity or weight disorder.

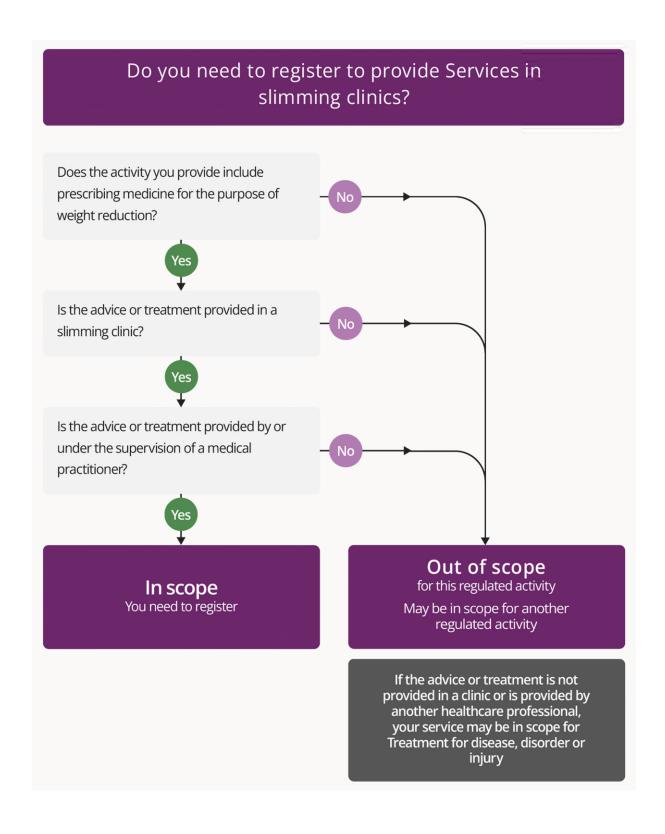
This activity does not apply if a slimming clinic does not prescribe medicines for the purpose of weight loss. For example, a slimming clinic that provides diet plans written or authorised by a medical practitioner will not need to register unless that service or clinic also prescribes medicine for weight loss.

Where a medical practitioner provides treatment of obesity other than in a clinic (for example, through an online service), the regulated activity Treatment of disease, disorder or injury will apply.

Other healthcare professionals who treat people for obesity

If you are another type of <u>healthcare professional</u> and you treat people for obesity this is included in the regulated activity of Treatment of disease, disorder or injury (see section on <u>Treatment of obesity</u>).

Check if you need to register for Services in slimming clinics



Nursing care

Description

This regulated activity covers nursing care where it is not part of another regulated activity.

Regulation 2(1) of the <u>Health and Social Care Act 2008 (Regulated Activities)</u>
Regulations 2014 describes nursing care as any service that is provided by a registered nurse and involves:

- providing care, or
- planning, supervising or delegating the provision of care.

If you provide nursing care as a necessary part of another regulated activity, for example Treatment of disease, disorder or injury, there is no need to register separately for Nursing care. This regulated activity normally covers services that **do not** constitute treatment.

Most treatment or care carried out by a registered nurse will involve another regulated activity. Often this will be Treatment of disease disorder or injury, but other regulated activities may also apply. For example, health visiting may include vaccination, which is included in the activity of Treatment of disease disorder or injury, or may include a test that is included in Diagnostics and screening procedures.

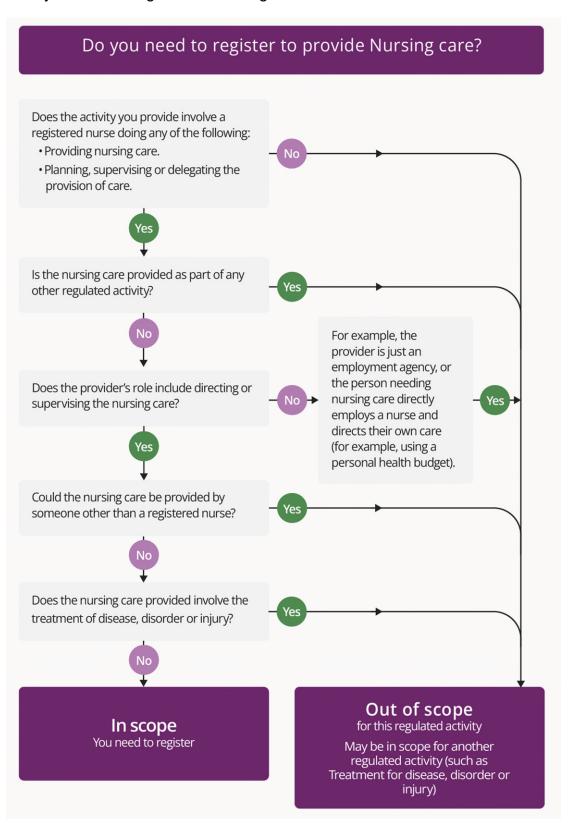
What this regulated activity does NOT include

The following types of services are excepted and do not need to register for this regulated activity:

- Nurses' agencies providing agency or locum registered nurses. The supply
 of registered nurses by an employment agency or employment business to
 another service provider is not a regulated activity. This exception only applies
 where the agency is not responsible for directing or supervising the role of the
 registered nurse in any way.
- Introductory services that connect people with registered nurses. These services provide contact details to enable a person to choose a registered nurse to employ. For example, this might be where a registered nurse is introduced to someone who directs their own care through private funding or a personal budget arrangement. For this exception to apply, the provider of the introductory service must have no ongoing role in the direction or control of the service that the person then receives. Where a person makes a private arrangement and secures a registered nurse for their own care, under their direction, the service provided is exempt even if it did not involve an introductory agency or employment agency. For example, this may include where a person uses a personal budget or a self-pay arrangement.

The above exceptions do **not** apply to other regulated activities that the registered nurse may be providing. For example, Treatment of disease, disorder or injury.

Check if you need to register for Nursing care



Family planning services

Description

This regulated activity involves services for inserting or removing all types of intrauterine contraceptive system or device by, or under the supervision of, a healthcare professional.

You may also need to register for other regulated activities such as Treatment of disease, disorder or injury if you provide treatment for sexually transmitted infections or menstrual disorders alongside the family planning services.

Glossary of terms

Armed services

Schedule 2 paragraph 10(2) of the 2014 Regulations defines the armed services as the naval, military and air forces of the Crown, including the reserve forces. (These are currently the British Army, the Royal Navy and the Royal Air Force.)

Designated body

A "designated body" means a body prescribed by Regulation 4 of the <u>Medical</u> Profession (Responsible Officers) Regulations 2010.

Healthcare professional (other than in relation to the regulated activity of Treatment of disease, disorder or injury)

A healthcare professional is a person registered with any of the following professional bodies, who is permitted by that body to provide or supervise the provision of the regulated activity:

- Health and Care Professions Council
- Nursing and Midwifery Council
- General Medical Council
- General Dental Council
- General Pharmaceutical Council
- General Osteopathic Council
- General Optical Council
- General Chiropractic Council
- Social Work England

The term healthcare professional also includes any professional who is included within a 'Section 60' order of the Health Act 1999. A medical practitioner is a doctor fully registered with the General Medical Council, who permits them to provide or supervise the provision of the regulated activity.

Listed healthcare professional in relation to the regulated activity of Treatment of disease, disorder or injury

For the purpose of this regulated activity only, a listed healthcare professional is defined under Schedule 1 paragraph 4(4) of the 2014 Regulations as a:

- medical practitioner
- dental practitioner
- dental hygienist
- dental therapist
- dental nurse
- dental technician
- orthodontic therapist
- nurse
- midwife
- biomedical scientist
- clinical scientist
- operating department practitioner
- paramedic
- radiographer

The relevant registration body permits these healthcare professionals to provide or supervise the activity being carried out under this regulated activity.

Local anaesthesia

Local anaesthesia is defined as any form of anaesthesia other than general or regional anaesthesia.

Nursing associate

The role of nursing associate was introduced in England from January 2019 to provide care and support for people using services, bridging the gap between health and care assistants and registered nurses, and enabling registered nurses to focus on more complex clinical duties. It is a stand-alone, professional role that is <u>regulated</u> by the Nursing and Midwifery Council.

Although intended to be part of the nursing team, nursing associates are not registered nurses and are not a listed healthcare professional for the purposes of carrying on the regulated activity of Treatment of disease, disorder or injury.

Patient Group Directions (PGDs)

Patient Group Directions (PGDs) allow specified health professionals to supply and/or administer medicines to specific groups of patients without a prescription or an instruction from a prescriber. PGDs are therefore not suitable for medicines that need frequent adjustments to dosage or continual monitoring. Healthcare professionals who act as signatories for authorising PGDs are responsible for ensuring the clinical and pharmaceutical content are accurate and supported by best available evidence. The healthcare professional supplying or administering the medicine is responsible for assessing the patient and making the decision to treat under the PGD.

Personal care

The definition of personal care covers:

- Physical assistance given to a person in connection with:
 - eating or drinking (including the administration of parenteral nutrition)
 - o toileting (including in relation to menstruation)
 - washing or bathing
 - dressing
 - oral care
 - the care of skin, hair and nails (except for nail care provided by a chiropodist or podiatrist)
- Prompting and supervising a person to do any of the types of personal care listed above, where that person is unable to make a decision for themselves about performing such an activity without being prompted and supervised.

Prompting and supervision

Prompting and supervision is where staff prompt and directly supervise a person when they are carrying out the actions defined as personal care and where they are unable to make a decision for themselves about performing such an activity without someone prompting them. Supervision will normally include direct observation of the action as it is carried out or checking on how it is being carried out. It will not normally include merely encouraging someone to perform the activity or checking at some point afterwards whether it has been done. This means that in any service where staff are prompting and supervising a person who is unable to make a decision for themselves as they perform those activities listed, the service will be classed as providing personal care.

Related third party

The definition of a related third party under Schedule 1, paragraph 1(4) of the <u>Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</u> in relation to the regulated activity of Personal care is:

- an individual with parental responsibility for a child who will receive personal care services.
- an individual who has power of attorney or other lawful authority to make arrangements on behalf of the person who will be receiving personal care services.
- a group of individuals described in (a) or (b) who make arrangements on behalf of one or more people who will be receiving personal care services.
- a trust established to provide services to meet the health or social care needs of a named individual.

Shared lives schemes

Shared lives schemes support adults with a learning disability, mental health problem or other needs that make it harder for them to live on their own. They are run by a local authority or other person either as a profit or non-profit scheme. The schemes recruit and train adult Shared lives carers, make arrangements to match a person with an approved Shared lives carer, and support and monitor placements. These types of scheme are referred to as Shared lives, Shared life schemes or Homeshare programmes. They were previously referred to as Adult Placement Schemes. See more details about Shared lives schemes.

Shared lives carers

Shared lives carers are people who provide accommodation and other support for an adult person in their own home (the placement). They may or may not provide the regulated activity of Personal care. It is the Shared lives scheme and not the individual carers who must be registered for the regulated activity of Personal care.

Triage

Triage is determining the urgency of diseases, disorders or injuries to decide the order of treatment for people and where to treat them.