

Registration under the Health and Social Care Act 2008

The scope of registration

March 2015

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

Our purpose

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

Our role

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

Our values

- Excellence – being a high performing organisation
- Caring – treating everyone with dignity and respect
- Integrity – doing the right thing
- Teamwork – learning from each other to be the best we can

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Introduction

This guidance is for people and organisations that provide, or intend to provide, health care or adult social care in England.

It will help you to decide whether you need to register with the Care Quality Commission (CQC) under the Health and Social Care Act 2008, and provides a guide to the scope of registration – who and what needs to be registered. However, you should not regard it as an interpretation of the law.

This is the sixth edition of our scope guidance and replaces earlier versions. The main changes to this version are:

- We have taken account of the amendments to the regulations that changed the regulated activity involving accommodation and nursing or personal care in the further education sector.
- We have added more detail to clarify some parts; in particular where we have learned from questions and queries sent to us by providers.

As a general point, we recommend that you read this alongside other guidance on applying to register, which you can find on our website:

www.cqc.org.uk/content/guidance-providers.

This guidance is about the scope of registration, and includes:

- A detailed explanation of what we mean by 'regulated activities' and which regulated activities you are most likely to need to register for.
- Guidance on who should register as a provider of regulated activities.
- Guidance on who should register as a manager.
- Frequently asked questions about registration from other providers.
- Information on where to find more details about the registration of health and social care.

Section 1 describes what is meant by a 'provider' and a 'manager' who, generally, need to consider making an application.

Sections 2 and 3 provide guidance on how Schedules 1 and 2 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 apply. We refer informally to these as the 'scope regulations', as they set the scope of the regulated activities that fall within this registration system.

Section 2 also sets out the general exemptions. If any of these apply, there is no need to register at present for these activities.

Section 3 sets out the regulated activities. If no exemptions apply, then a provider of any of these activities must register.

It is important to focus on the activities that will trigger the need for registration. This document is a guide to the regulations but not a substitute for them.

Click on the following links to see the regulations in full:

Health and Social Care Act 2008:

www.legislation.gov.uk/ukpga/2008/14/contents

Care Quality Commission (Registration) Regulations 2009:

www.legislation.gov.uk/uksi/2009/3112/contents/made

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

www.legislation.gov.uk/uksi/2014/2936/contents/made

Please note: The need for registration depends on what activity you provide within your 'service type'.

Section 1: Who has to register?

'Service providers' must register with CQC. A service provider can be an individual, a partnership or an organisation – examples of organisations are companies, charities, NHS trusts and local authorities (see page 5 for details).

It is the legal body that provides the regulated activity to people that has to register, not the location or care setting where it is carried out. You can find further guidance about locations on our website at www.cqc.org.uk/locations.

What are regulated activities?

Regulated activities are listed in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. They are:

- Personal care.
- Accommodation for person who require nursing or personal care.
- Accommodation for persons who require treatment for substance misuse.
- Treatment of disease, disorder or injury.
- Assessment or medical treatment for persons detained under the Mental Health Act 1983.
- Surgical procedures.
- Diagnostic and screening procedures.
- Management of supply of blood and blood-derived products.
- Transport services, triage and medical advice provided remotely.
- Maternity and midwifery services.
- Termination of pregnancies.
- Services in slimming clinics.
- Nursing care.
- Family planning services.

If you carry on any of these activities in England, you **must** register.

There are separate arrangements for regulating health and social care in other UK countries. Although we cooperate with the regulators, we do not regulate providers of health and social care in those countries.

If a provider from a neighbouring country occasionally delivers services in England (for example, an ambulance service), we will take a proportionate and reasonable approach to registration.

Types of service providers

There are many different ways of organising a service and we consider each case separately. The following are some examples.

Corporate groups

Where a provider is a subsidiary of a bigger company it will need to register in its own right if it is the legal entity responsible for the service, rather than the parent company. For example, if a number of provider companies all trade under the same brand, each company that carries on regulated activities must register individually. However, we will manage our relationship across the brand and ensure that when we publish our assessments of services, people will be able to recognise both the registered provider and the brand.

Franchises

Franchise holders are usually separate legal entities to the parent company and, as such, must register in their own right. When we publish our assessments, we will make sure that people can recognise both the provider and the brand, and we will liaise with the parent company as necessary.

Partnerships

Where an activity is provided by a partnership, all partners must be included in the registration. If an existing partner leaves or a new partner joins, generally this creates a new partnership, which is a new legal entity. Before 4 February 2013, a partnership had to cancel its registration and apply again for registration as a new provider every time one or more of its partners changed. However, we changed the way providers can add and remove partners from a registration. From 4 February 2013, new partnership registrations include a condition that details the names of the partners. The partnership can apply to make any subsequent changes to the membership of the registered partnership by submitting an application to vary that condition, rather than applying for a new registration. Providers registered as a partnership prior to 4 February 2013 who change one or more of their partners will still need to initially cancel their registration and apply under their new partnership, but their new registration will include the partnership condition. Please see the following link for more information about partnerships:
www.cqc.org.uk/content/making-changes-partnerships.

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 organisational form, each party, depending on the individual case, may need to register.

Section 75 agreements

Section 75 agreements enable NHS bodies and local authorities to establish joint funding, delegate functions, and integrate resources and management structures, such as integrated community mental health care. These do not usually constitute a new, separate legal partnership and each body that provides a regulated activity must be registered for it separately. In general, the body that has the original statutory obligation or power to provide the service is the one that should register for it, as they are the one that retains accountability for it.

For example, in community mental health teams integrated under section 75 agreements, the party with the original statutory obligation to provide 'treatment for 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 statutory obligations in that way, both are likely to need to register, but will only be accountable for their areas of responsibility. Any services provided by either of the parties to a section 75 agreement outside of that arrangement would need to be considered in their own right.

Services registered with Ofsted

Regulated activities cannot be dual registered with both the Care Quality Commission and Ofsted. Where a provider must register with Ofsted, the parts of their service that Ofsted regulates will be exempt from registration with CQC.

This does not mean that a provider cannot be registered with both regulators: it means that there cannot be double accountability for the same activity. For example, a provider may be registered with Ofsted for activity A and also be registered with CQC for activity B. Sometimes, activities A and B may be closely related, or take place in the same location. Our approach is that we will cooperate with Ofsted under the terms of a Memorandum of Understanding, with the aim of allowing each organisation to monitor our different areas while avoiding duplication and overlap. CQC and Ofsted work together to share expertise and coordinate activity, for example with joint inspection or single inspection that collects information for both regulators. You can find more information about this on our website: www.cqc.org.uk/public/reports-surveys-and-reviews/reports/joint-inspections.

Hosting arrangements

Where an activity is carried on by provider A but is hosted by provider B, then provider A will need to register, regardless of its host. For example, independent providers of health care or personal care in prisons must register, not the host prison. Similarly, the operator of a private dialysis unit in the grounds of an NHS hospital will need to register in its own right as a provider if it carries on a regulated activity – not the hospital.

However, 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 boundary of responsibilities is unclear, hosts may sometimes end up *de facto* being responsible for activities taking place in premises that are under their control, in the absence of anyone else being responsible for them.

Renting arrangements

In the same way, where provider A rents out its facilities to provider B, provider B will need to register in its own right if it provides a regulated activity. Where a registered hospital rents out its operating theatres to another provider (for example, during times that they would not otherwise be in use), that other provider 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.

In independent hospitals and private facilities within an NHS hospital, doctors sometimes rent consulting rooms to conduct private outpatient appointments. Where these doctors provide a consultation in a service managed by the hospital, and the doctors have agreed '**practising privileges**', it may be covered by the hospital's registration. Practising privileges are a well-established system of checks and agreements whereby doctors can practise in hospitals without being directly employed by them. They are different to normal renting and sub-contracting arrangements because they have a specific exemption in the Regulated Activities Regulations.

However, for this to apply, it means that all aspects of the consultation must be carried out under the hospital's management and policies. For example, being subject to the hospital's requirements for clinical governance and audit, and the hospital's policies and systems for complaints and for records (with the hospital owning the records). It means that the hospital takes responsibility for ensuring that essential levels of quality and safety are met. In practice, this may be done quite readily through granting 'practising privileges'.

Alternatively, doctors (or other health care professionals) sometimes practise in outpatient departments under their own arrangements, with the hospital only acting as landlord. In that case, where the doctor or other health care professional is carrying on regulated activities independently of the hospital, the doctor or other health care professional must register, as this does not amount to the exercise of practising privileges, unless they are exempt for other reasons (refer to 'exemptions' in [section 2](#)).

Landlords are advised to 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 boundary of responsibilities is left unclear, landlords may sometimes end up *de facto* being responsible for activities taking place in premises that are under their control, in the absence of anyone else being responsible for them.

Subcontracted services

Subcontractors that provide treatment or care services that include the provision of a regulated activity will usually need to register in their own right, although this will always depend on the nature of the subcontracting arrangement. Subcontractors for services other than the direct provision of treatment or care, such as providing equipment or support services that do not include provision of a regulated activity (for example, catering or cleaning) will not need to register.

An example of a subcontracted activity that will need to be registered is a hospital imaging service in which the x-ray and scanning department is equipped, staffed and operated by a subcontractor. The overall hospital service is typically seamless and people who use it may be unaware that parts are subcontracted. However, the subcontractor will need to register 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 sub-contractor with a contract to supply part of a wider and more comprehensive service will have to be registered for any regulated activity they perform if they retain any responsibility for the delivery of the service (such as the operational policies and protocols, day-to-day operational or staff management, clinical governance or quality assurance).

An example of a sub-contracted activity that may not need to be registered is where a sub-contractor provides an imaging service, but the hospital provider retains responsibility for all aspects of service delivery.

Secondments and similar service level agreements

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

For example, provider A carries out surgical procedures and treatment of a disease, disorder or injury. Provider A employs two specialist nursing staff to administer chemotherapy and provide support to patients. When one or both of the specialist nurses are on leave, provider A borrows specialist chemotherapy nursing staff from provider B. An agreement is in place to enable this to happen. The staff continue to be 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 A and B to register for it). Instead, the staff member's original employer is acting as a staffing agency. For the time that the member of staff has been seconded to work for service A and is managed by service A, they are part of service A. In that situation, Service B would not need to register for the service provided by service 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.

The general principle, whether we are considering a secondment, a hosting arrangement or any other of the possible ways of organising a service, is to identify **who is responsible for the safety and quality of care or treatment** as a person experiences it. For example, by considering who has clinical responsibility, who would need to handle complaints, whose quality assurance/clinical governance system covers the activity. That 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 the delivery of a service provider's regulated activity, or a service provider's regulated activity in a particular location. The Care Quality Commission (Registration) Regulations 2009 set out the circumstances in which a service must have a registered manager as a condition of registration:

- 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 require a registered manager unless we impose a condition to require one, but others – including independent organisations who work under contract to the NHS – always do.
- If the service provider is an individual, they do not need to have a manager unless they are not a fit person to manage the regulated activity, or do not intend to take on the role of a manager in day-to-day charge of how the regulated activity is provided.

However, when registering 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 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) and whether they are able to provide certain information. The following information must be available:

- 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).

Further information about how to register as a manager is available on our website: www.cqc.org.uk/content/guidance-providers.

Section 2: General exemptions from registration

There are a number of general exemptions that always apply to CQC registration.

Some exemptions add clarity to aspects of a service that do not require separate registration, while some apply to certain types of provider.

There are also some exemptions that apply only in certain circumstances, which are described in [Section 3](#). Where a provider is exempted from the need to register for a specific regulated activity, they still need to check their responsibility for other regulated activities.

Medical practitioners in independent practice

From October 2013, an exemption applies to a service provider who must be an individual medical practitioner who is (or a group of medical practitioners who are):

1. A service provider, or employed by a service provider, that is registered with CQC for carrying on the regulated activity of ‘treatment of disease, disorder or injury’;
and
either that service provider is a designated body,^{*}
or
all the individuals of the group are on the medical performers list of a designated body;^{*}
and
2. The provision of treatment must be carried out in a surgery or consulting room by the medical practitioner or group of medical practitioners;
and
3. the provision of treatment in the surgery or consulting room must not include any of the following:

^{*} In paragraph 1, a “designated body” means a body prescribed by Regulation 4 of the Medical Profession (Responsible Officers) Regulations 2010 www.legislation.gov.uk/ukxi/2010/2841/made.

- a. treatment carried out under anaesthesia or intravenously administered sedation, other than:
 - i. nail surgery and nail bed procedures on the foot and which are carried out using local anaesthesia
 - ii. surgical procedures involving curettage (scraping), cautery (burning) or cryocautery (freezing) of warts, verrucae or other skin lesions carried out using local anaesthesia
- b. medical services provided in connection with childbirth;
- c. the termination of pregnancies;
- d. cosmetic surgery, with the exception of the following:
 - i. the piercing of any part of the human body
 - ii. tattooing
 - iii. subcutaneous injections of a substance(s) to enhance appearance
 - iv. removal of hair roots or small skin blemishes by application of heat using an electric current;
- e. haemodialysis or peritoneal dialysis;
- f. endoscopy other than using a device which does not have a lumen or other channel for the purpose or design of passing fluid or instruments through, or removing body tissue or fluid or any other item from, a person's body;
- g. the provision of hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber which is gradually pressurised with compressed air, where such therapy is carried out by or under the supervision or direction of a medical practitioner;
- h. intravenous, intrathecal or epidural administration of medicines or diagnostic agents;
- i. the therapeutic or diagnostic use of x-rays, radiation, protons or magnetic resonance imaging;
- j. invasive cardiac physiology tests.

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

As set out in paragraph 2, this exemption only applies if the treatment is provided in a surgery or consulting room. This exemption does not apply to treatment carried out in any other place or to treatment provided remotely, over the telephone or by electronic mail.

This exemption does not apply to an organisation or partnership that employs a range of staff including medical practitioners. **It only applies to an individual medical practitioner, or a group of individual medical practitioners.**

This exemption means that an individual medical practitioner or group of medical practitioners, who are a provider registered with CQC for 'treatment of disease, disorder or injury', or all of whom are employed by a provider registered with us for 'treatment of disease, disorder or injury', may be exempt from registration. However, the exemption would only apply if they are a designated body, or the provider they are employed by is a designated body, or all of those medical practitioners are on the medical performers list of a designated body, and the criteria in paragraphs 2 & 3 are met.

Independent midwives

Independent midwives are exempt if they meet all of the following criteria:

- They provide services independently (not in the NHS).
- They work on their own (not as part of an organisation or partnership), and
- They only provide services on an individual basis to people in their own homes.

All three of these criteria must be met. This is described in more detail in the guidance in Section 3 on '[maternity and midwifery services](#)'.

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

Where a person, or a related third party on their behalf, makes their own arrangement for nursing care or personal care, and the nurse or carer works directly for them and under their control without an agency or employer involved in managing or directing the care provided, the nurse or carer does not need to register for that regulated activity. A related third party means:

- a) An individual with parental responsibility for a child to whom personal care services are to be provided.
- b) An individual with power of attorney or other lawful authority to make arrangements on behalf of the person to whom personal care services are to be provided.
- c) A group or individuals mentioned in a) and b) making arrangements on behalf of one or more persons to whom personal care services are to be provided.
- d) A trust established for the purpose of providing services to meet the health or social care needs of a named individual.

This means that individual user trusts, set up to make arrangements for nursing care or personal care on behalf of someone are exempt. The exemption about individual user trusts is also set out in a different set of regulations to the other issues covered in this guidance. See Regulation 4(4) of the Care Quality Commission (Registration) Regulations 2009.

Also exempt are organisations that only help people find nurses or carers, such as employment agencies (sometimes known as introductory agencies), but who do not have any role in managing or directing the nursing or personal care that a nurse or carer provides. We have set out separate guidance on our website to help explain what we mean by 'ongoing direction and control' of a service

www.cqc.org.uk/sites/default/files/documents/20120223_800199_v2_00_personal_care_and_ongoing_direction_external_version_for_publication.pdf

These exemptions are again described in [Section 3](#) of this guidance, under the activities of personal care and nursing care.

Third party exemptions

The following services are also exempt. We have grouped them together because they represent services that may be organised through a third party. The third party may be the provider's 'customer', which is unlike most other services that are organised directly between the provider and the person who uses the service. We have grouped them as a convenient way to understand them; in the regulations, they only appear as a list.

- 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.
- Defence medical and dental services organised through the armed services.
- Forensic medical services (for example, for people detained in police custody) organised solely through a local policing body and Chief of Police.
- 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 exemption does not include services organised through private medical insurance schemes.
- Medical 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).

Other exemptions

The following are also exempt:

- Any health or social care activity carried out by a carer for a member of their family or someone in a personal relationship, where the care is provided in the course of that family or personal relationship for no commercial consideration. 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.
- School nurses who are employed and managed by the school and who provide services to the school's pupils. (In general, this will exempt school nurses in independent schools, but not in public sector schools where the school nursing service will be included in the registration of the relevant provider.)
- First aid by first aid organisations or non-health care professionals who are trained in first aid or by health care professionals in unexpected or potentially dangerous situations requiring immediate action.
- Nurses' agencies that act as employment agencies supplying staff to organisations that carry on regulated activities, BUT do not provide any regulated activities themselves.
- Shared Lives schemes that do not arrange placements for people with personal care needs.

Section 3: Activities that are covered by registration

How to use this section of the guidance

If the general exemptions set out in section 2 do not apply to you, you must register for each of the regulated activities that you provide.

In this section we look at the regulated activities:

- What they are and what they include.
- What type of services would be most likely to apply for these activities.
- Any notes or questions that will help you to know what regulated activities to apply for.

For each regulated activity, we have provided a 'decision tree' diagram that will help you to decide if you need to register for that activity.

You should check all the activities to be sure that you are registering correctly, following the diagram for each activity.

You can also look at the 'Quick reference guide' on our website to see which regulated activities you are likely to need to register for, and then look at these in more detail (www.cqc.org.uk/content/service-types).

You may need to register for more than one regulated activity to cover the service(s) you provide. Some providers may find that they are registering for a number of regulated activities.

Remember: this is only a guide and you need to be sure that the service you provide is covered by the regulated activities you choose to register for.

It is an offence to carry out a regulated activity without being registered. This document on its own will not tell you all the information you need to register effectively.

How do regulated activities relate to each other?

Each activity requires a separate registration.

There is no hierarchy of regulated activities and providers must apply for all that relate to their service.

There are only two cases where registration for one regulated activity will remove the need to register for another:

- 'Nursing care' does not need to be registered where it is part of another regulated activity.
- 'Personal care' does not need to be registered where it is part of:
 - Accommodation for persons who require nursing or personal care.
 - Accommodation for persons who require treatment for substance misuse.

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 an activity, even if the provider is registered for other activities.

For example, where a provider is registered for 'accommodation for persons who require personal or nursing care' in respect of a care home, but also provides a domiciliary care service, the provider must also register for 'personal care' because the domiciliary care service involves personal care that is separate to the care home service.

The regulated activities are described in detail on the following pages.

Personal care

Description

The regulated activity of personal care consists of the provision of personal care for people who are unable to provide it for themselves, because of old age, illness or disability, and which is provided to them in **the place where those people are living at the time when the care is provided**. As an example, this includes personal care provided by a domiciliary care agency. It also includes Shared Lives schemes, in which cases the provider of the **scheme** is registered for personal care and not the owners or providers of the individual homes (accommodation).

A person managing a prison or other similar custodial establishment is exempt from having to register if **they** provide personal care for persons detained. However, for the purpose of the regulations, a prison will be considered where a person is living for the time that they are detained there. This means that if a domiciliary care agency provides personal care in prisons or similar custodial settings, the provider of the domiciliary care agency is required to register with CQC, because the exemption only applies to the person managing the prison.

A fostering agency that is inspected by OFSTED, whose services include the provision of personal care to children that are placed or being placed, is exempt from having to register with us for the activity of personal care.

You do not need to register for this activity if you are registered or registering to provide the people using your service with accommodation together with the personal care for example, 'accommodation for persons who require nursing or personal care' or 'accommodation and nursing or personal care in the further education sector'. You need to think about the service you provide and if you are registering to provide a service that is accommodation together with personal care but you also provide personal care services to people **in the place they live**, then you will also need to apply for 'personal care'.

CQC will normally impose conditions on a provider's registration that restrict a regulated activity to a given location. These conditions mean that if a provider runs a care home at location A as well as a domiciliary care service from location B, registering only for 'accommodation for persons who require nursing or personal care' at location A will not cover the provision of 'personal care' from location B. This needs to be registered as a separate regulated activity from this separate location (see guidance on locations at: www.cqc.org.uk/locations).

The regulated activities

You may need to apply for other regulated activities if they are being provided to people at the location that forms the accommodation (such as 'diagnostic and screening procedures'). It may form part of a list of activities that a provider is registered for.

You should not register if you provide carers (in the role of an employment or introductory agency):

- To another organisation who will then be responsible for direct provision of the care, or
- To an individual who will then wholly take responsibility for the provision of their own care under a personal budget or private arrangement.

You should not register if you are a carer employed by an individual or a related third party (without the involvement of an employment agency or employment business) and working wholly under the direction and control of that individual or related third party in order to meet the individual's own personal care requirements. A related third party means:

- An individual with parental responsibility (within the meaning of section 3 of the Children Act 1989) for a child to whom personal care services are to be provided.
- An individual with power of attorney or other lawful authority to make arrangements on behalf of the person to whom personal care services are to be provided.
- A group of individuals mentioned in either of the above 2 bulleted points making arrangements on behalf of one or more persons to whom personal care services are to be provided.
- A trust established for the purpose of providing services to meet the health or social care needs of a named individual.

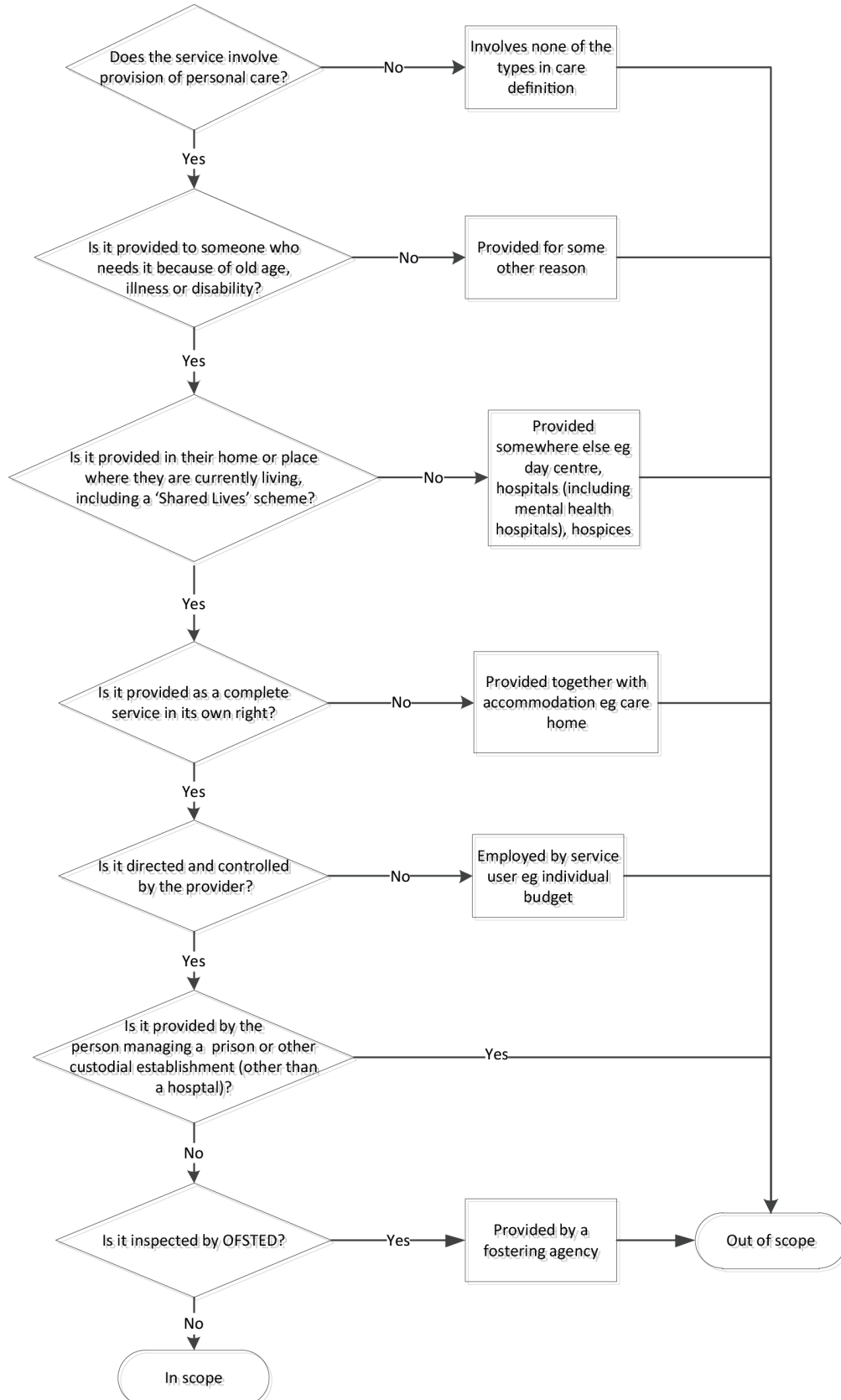
Shared Lives schemes (previously known as adult placement schemes)

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 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 service users live are not 'regulated premises' that we can inspect.

However, Shared Lives schemes should **only** be registered 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.

Decision tree: Personal care



Accommodation for persons who require nursing or personal care

Description

The regulated activity consists of providing residential accommodation together with personal care (for example, a care home) or nursing care (for example, a care home with nursing).

It is important to consider the relationship between the accommodation provider and the care provider – whether personal care or nursing care is provided 'together with' the accommodation or whether they are provided separately – so that we can be clear about where the boundaries of responsibility lie.

In some cases, this activity includes accommodation together with personal or nursing care provided in an institution 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 institution in question must also be receiving personal or nursing care. We will normally judge this by considering student numbers over 12 months, rather than just on a single day.

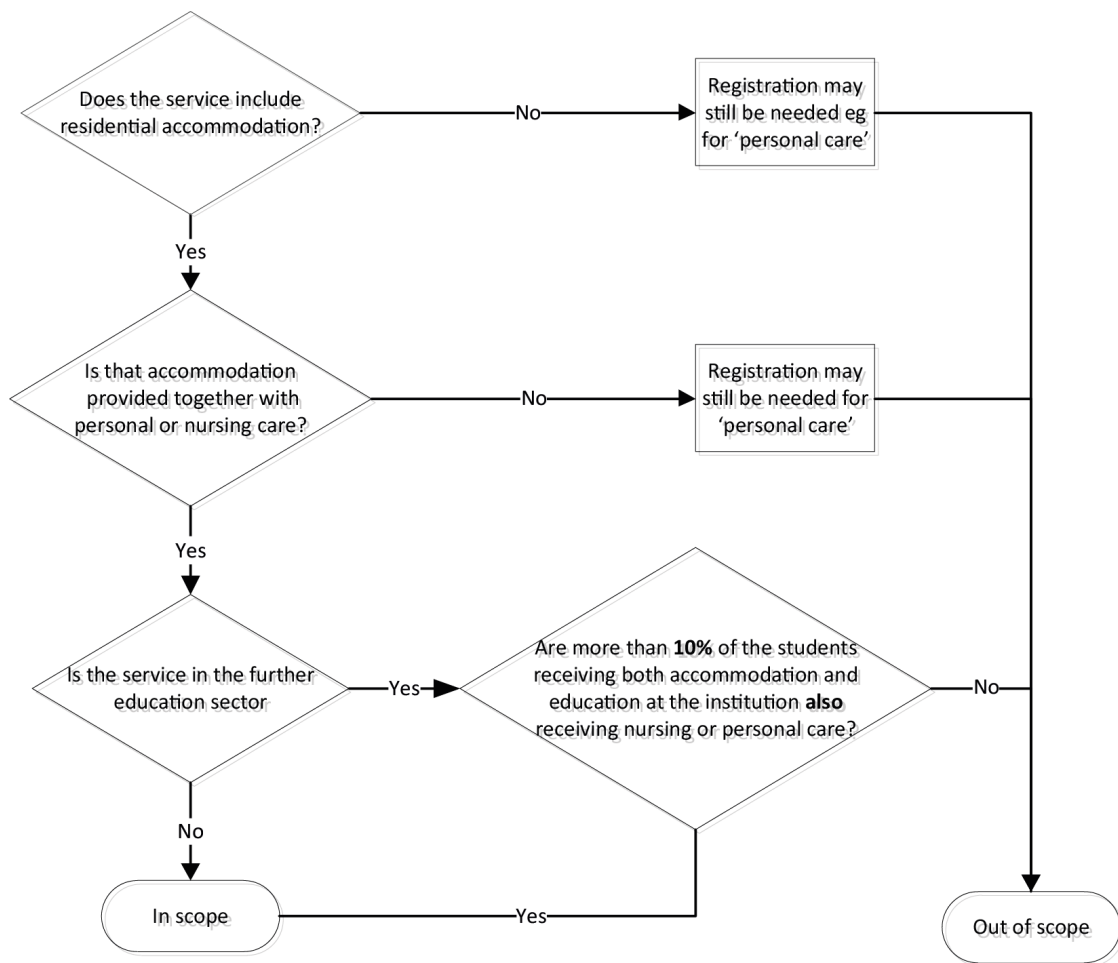
An institution within the further education sector means an institution conducted by a further education corporation, or an institution designated as such by an order of the Secretary of State for Children, Schools and Families.

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

This activity is explicitly exempt from the provision of accommodation together with personal or nursing care to an individual by a Shared Lives scheme under the terms of a carer agreement. Shared Lives schemes should register **only** for the regulated activity 'personal care' **if** personal care is being provided and **not** the regulated activity of 'accommodation for persons who require nursing or personal care'. See the section on [personal care](#) for more information.

You do not have to additionally register for the activities of personal care or nursing care if you provide 'Accommodation for persons who require nursing or personal care'. The only exception to this would be if, as a provider, you also provide domiciliary care as a separate service. However, a provider may need to apply for other regulated activities where these apply. For example, a care home that also has intermediate care or palliative care services provided by one of its own health care professionals, may need to think about also registering for 'treatment of disease, disorder or injury'.

Decision tree: 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.

This covers 'residential' accommodation, which is not the same as hospital accommodation, as in detoxification treatment. For this activity to be carried on, the accommodation has to be provided to the same residents 'together with' treatment. This means that this activity does not apply to hospitals that provide detoxification treatments for substance misuse. In such cases, the detoxification being provided in the hospital would be covered under the activity of 'Treatment of a disease, disorder or injury'.

This does not necessarily mean that the treatment must 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 (a day centre or community centre), whereas people may be accommodated in separate facilities geographically. However, the accommodation and the treatment must be linked so that the accommodation is provided because someone requires and accepts treatment.

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

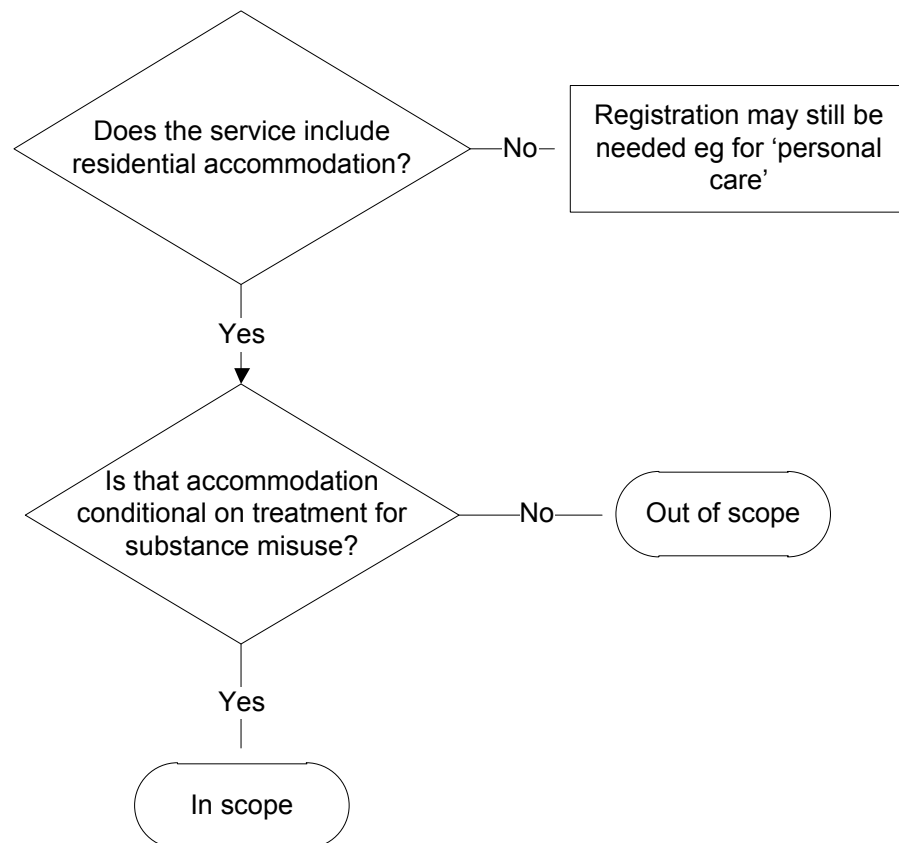
In respect of the regulated activity of 'treatment of disease, disorder or injury', the treatment for substance misuse is covered under the activity of 'accommodation for persons who require treatment for substance misuse'. The service would only have to apply for 'treatment of disease, disorder or injury' if other treatments were provided that are separate from the treatment of substance misuse. For example, this includes detoxification, but if a doctor from the substance misuse team treated a medical condition unrelated to the substance misuse, or was treating an eating disorder, or if a nurse was managing a holistic care plan for a dual diagnosis patient and administering treatment for both mental illness and for substance misuse, then the provider would also have to register for 'treatment of disease, disorder or injury'.

'Treatment' in this regulated activity would cover a range of recognised treatment interventions, such as managed withdrawal or detoxification or a structured

The regulated activities

psychosocial treatment programme. These types of treatment will always trigger the need for registration for this regulated activity if they are provided together with residential accommodation: this is not limited only to cases where they are provided by healthcare professionals.

Decision tree: Accommodation for persons who require treatment for substance misuse'



Treatment of disease, disorder or injury

Description

This activity covers a treatment service that is:

- a) provided by a health care professional (see list in [glossary](#)), or a social worker in the case of mental health treatment, or by a multi-disciplinary team that includes a listed health care professional, or social worker where the treatment is for a mental disorder, and is
- b) related to disease, disorder or injury.

It includes a wide range of treatment, such as, but not limited to, emergency treatment, ongoing treatment for long-term conditions, treatment for a physical or mental health condition or learning disability, giving vaccinations/immunisations, and palliative care.

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

What is included in this regulated activity?

- Any treatment that is for the treatment of a disease disorder or injury.

What is excluded from this regulated activity?

- Purely cosmetic interventions.
- Most alternative and complementary therapy.
- First aid where it is delivered by:
 - Health care professionals in unexpected or potentially dangerous situations requiring immediate action.
 - Non-health care professionals who are trained to deliver such treatment.
- Treatment provided in a sports ground or gymnasium (for people taking part in, or attending, sporting activities or events).
- Treatment provided through temporary arrangements for sporting or cultural events (such as festivals, championship sporting events or motor sport events).

The regulated activities

- Hyperbaric oxygen therapy provided to workers in connection with their work or when governed by the Diving at Work or Work in Compressed Air regulations.
- Activities authorised by a license granted by the Human Fertilisation and Embryology authority.

Sometimes, 'treatment of disease, disorder or injury' is provided as a minor component of a service – for example, a large care home that has just a few intermediate care or specialist palliative care beds. 'Treatment of disease, disorder or injury' if carried out by or under supervision of a listed health care professional will still require registration in its own right and in addition to any other activities that the provider may need to register for that service.

If those services are provided by another body (such as a primary care trust), please see the guidance on hosted services earlier in this document which will apply.

What other regulated activities do I need to register for?

You should apply for other regulated activities if you are providing them, for example:

- 'Surgical procedures'.
- 'Diagnostic or screening procedures'.
- 'Assessment or medical treatment for patients who are detained under the Mental Health Act'.
- 'Services in slimming clinics'.

Are any other regulated activities covered by this one?

Yes, if you are registered for this activity and its delivery includes:

- personal care
- nursing care

you would not need to additionally apply for those activities.

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

The principle is that a provider will require registration for this regulated activity if the service includes treatment carried out by or under the supervision of a listed health care professional, or a social worker where the treatment is for a mental disorder, and is intended to treat disease, disorder or injury. Health care professionals are defined, for the purpose of this activity only, in a list (see [glossary](#)).

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

However, there may be occasions when the person providing treatment is not acting in the capacity of a listed health care professional, even if holding a professional qualification (for example, a beautician undertaking a cosmetic/aesthetic service who is also qualified as a nurse).

Also, there may be times when it is not clear if 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).

It may also be unclear if a particular treatment is for a disorder (for example, obesity may in some cases be classified as a disorder, and a certain medical treatment recommended, while a person may also be seeking that same treatment for cosmetic or wellbeing reasons).

These scenarios will normally be rare, and will need consideration on a case-by-case basis. However, a significant area in which they may arise frequently is community mental health care (including primary mental health care). Some psychological therapies may be provided by health care professionals, social workers or by others with specific qualifications. In these cases, some services will require registration, whereas others will not, depending on the use of, or supervision by, health care or social work professionals.

What professionals would not be included in the scope of this regulated activity?

Certain defined professionals are not included on the list in the regulations. These include:

- Clinical psychologists
- Occupational therapists
- Physiotherapists
- Pharmacists.

Standalone treatment services run by these professionals are not required to register.

This means 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. For example, treatment includes the 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 captured by this regulated activity.

Health care professionals and social workers are only relevant to this regulated activity where they are involved in it in their capacity as a listed health care professional or social worker. For example, a psychiatrist may also be qualified as a psychotherapist. Where he or she practices as a psychiatrist – a registered medical practitioner – it may be captured by this activity. Where he or she practices solely as a psychotherapist, it would not be captured by this activity.

This principle will apply in the same way to many other services in addition to the examples given and these will need to be considered on a case-by-case basis.

What is treatment "under the supervision of" a listed health care professional or social worker?

The care of the person is under the supervision of a health care professional (HCP) (as listed in paragraph 4(4) of Schedule 1 of the [regulations](#)) where the HCP:

1. Is part of the team who directly provides care to the person, or
2. Directly reviews the individual person's case and sets out a plan of care for the person even if this plan is executed by another person, or
3. Authorises a protocol of care, used by other care givers, that:
 - a) they are directly accountable for, and
 - b) they are required to continually monitor, and
 - c) can only be authorised by them by virtue of their professional registration, and
 - d) when it is used, the individual details of the people who are provided care under its remit are directly recorded for the purposes of the protocol

Is delegation different to "under the supervision of"?

Yes, when a health care professional employed by one provider delegates a procedure to a care worker employed by a second provider, such as a care home without nursing or a domiciliary care agency, the second provider cannot be considered to be carrying on the regulated activity. The provider accepting the delegated task will not be required to register for this regulated activity.

This is because a health care professional employed by one provider will not be responsible for the supervision of staff of another provider. A provider (employing staff) cannot accept vicarious responsibility for non-employees.

The Nursing and Midwifery Council (NMC) has published *The Code: Standards of conduct, performance and ethics for nurses and midwives* (2008), which sets out the requirements for registered nurses and midwives to delegate effectively to other people, and to always act within their area of competence.

The NMC has also issued advice regarding delegation by nurses to other people such as carers. You can find this advice on the NMC website www.nmc-uk.org/Nurses-and-midwives/Advice-by-topic/A/Advice/Delegation/.

It is the employer's responsibility to ensure that they do not allow their staff to accept delegated tasks unless the staff have sufficient support, supervision, education and training to competently undertake the aspects of care that are being delegated.

Examples

Administering medication where the activity of 'treatment of disease, disorder or injury' will not apply:

In the case of administration of medication that has been prescribed and dispensed for the person or is a 'homely remedy' (including over-the-counter medicines, complementary therapies and herbal preparations) and is administered by a carer or a health care professional, the regulated activity will **NOT** apply:

- a) Where the person using the service would normally be able to administer the medication in question for themselves, but where, due to circumstances or personal choice, the person has consented for the medicine to be administered to them, or
- b) Where the person would ordinarily be able to administer the medication for themselves but due to circumstances, or where the person is unable to make a decision in relation to taking their medication, it has been agreed to be in the person's best interest for the medicine to be administered to them.

The following examples will also **NOT** constitute the activity of 'Treatment of disease, disorder or injury':

- A care worker or health care professional administers prescribed insulin that has been dispensed and the person cannot manage to draw up or inject the insulin themselves, where the person would normally be able to administer the insulin themselves.
- A care worker administers an oral prescribed controlled drug, where the person would normally be able to take their own prescribed drug.
- A care worker who prompts and/or supervises a person to take their prescribed medication.
- A care worker may care for people receiving nutritional support through a PEG feed or provide pressure area care delegated by a district nurse (a registered health care professional) who works for another provider.

The regulated activities

The following **WILL** constitute the activity of 'Treatment of disease, disorder or injury':

- A situation when a nurse or health care professional is required to either prescribe or administer medication.
- When the nurse or health care professional is required to have knowledge or training to undertake the administration of the medication, or when a person would not normally be considered to be able to administer the medicine by themselves.
- Administration of an intravenous (IV) antibiotic or other IV drug (requiring training in reconstitution, mathematical calculation, examination and care of the IV site and more).
- Administration of chemotherapy in a person's home or a residential home, or any other setting. This will require training in administration, IV pumps, blood result checks, examination and care of the IV site, and what to do if extravasation occurs.

The list of professional roles are protected titles, why is this important?

Use of professional titles is protected by law. Where a professional title is used, the assumption will be that the service is being carried out by someone acting in their capacity as a registered health care 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 the service does not involve the professional qualification, and the protected title might be being used inappropriately in the description of the service or solely for other purposes (such as marketing), the matter may be referred to the relevant professional regulator.

Anomalies have occurred where care homes without nursing have employed nurses or other health professionals as care workers. The key question to consider is whether the person providing the service is using their professional qualification in the job they are employed to do.

Where the person'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.

Example:

- A qualified psychoanalyst, who is also qualified as a psychiatrist but is not prescribing or using medical interventions, will not need to register for her psychoanalytic practice. She is acting in her capacity as a psychoanalyst (not in the list of health care professionals) and not as a doctor. She is not using the specific skills taught in medical training, but is using the specific skills taught in psychoanalytic training. She is not using statutory authority or powers, which require a medical qualification (e.g. prescribing).

She is not presenting herself as a psychiatrist, but as a psychoanalyst.

- A drugs worker, who is also qualified as a social worker, will not need to register if he is working as a drugs worker. However, if he is working as a social worker then the service will require registration. It is possible to ascertain if he is working as a social worker because he is clearly using the specific skills taught as part of social work training, or he is presenting himself as a social worker and using that protected title to describe his work.

Service specific guidance

Lasers and intense pulsed light (IPL)

Lasers and IPLs used for non-surgical procedures are often used for cosmetic procedures such as hair removal, and for therapeutic procedures, e.g. minor dermatological conditions. They are used by beauty therapists and health care professionals.

These procedures can constitute appropriate treatment of recognised medical disorders and can be safely and appropriately carried out by beauty therapists with training in the use of the laser or IPL. It is not uncommon for dermatologists to refer or advise patients to visit a beauty therapist because, even in a clinical service such as dermatology or plastic surgery, very few laser or IPL procedures require the skills of a health care professional.

Use of lasers and IPLs is not part of professional training in health care professions, and while a health care professional's knowledge of physiology and physical and mental conditions may well add value to a service, it is usually as background knowledge rather than as use of professional training.

Providers of laser and IPL services provided by listed health care professionals will only need to register where:

- The specific skills of a listed professional are used, e.g. 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 health care professional qualification, e.g. prescribing, or
- The service is described by the provider as carried out by someone acting in their capacity as a registered health care professional.

First aid

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 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 health care professionals.

In the case of health care professionals, they will not rely upon broader knowledge and skills developed through professional training but will use only skills and knowledge that are to be reasonably expected of a person having received recognised training in first aid.

Our view is that:

- A first aid service may involve health care professionals, but only where they are acting only in their capacity as a first aider. 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.
- A first aid service may involve simple procedures for assessment that do not require a recognised professional diagnostic qualification (eg as a radiographer or sonographer) and that are limited in their purpose to assessing the need for onward referral for treatment. This includes use of a 2- or 12-lead ECG, automated non-invasive blood pressure measurement, pulse oximeter, use of a thermometer, sphygmomanometer or ophthalmoscope.

Care homes with nursing

Care homes with nursing are likely to need to register for this regulated activity, as they will probably employ nurses or other listed professionals that carry out these activities. There may be exceptions to this rule, but only when the nursing staff do not actually carry out the treatment for a disease, disorder or injury.

Care homes without nursing

Care homes without nursing should not register for this regulated activity. This is because if they are carrying out these treatments, it will likely be by delegation from a health professional already registered under another provider.

Treatment for substance misuse

The types of professionals in the list that most commonly work in substance misuse services are medical practitioners, nurses and social workers. If any of these professionals are working in their **registered capacity** and providing treatment as part of a multi-disciplinary team, it means that the whole team will be within the scope of registration as providers of this regulated activity, and the organisation that employs them will have to be registered as providing treatment for a disease, disorder or injury.

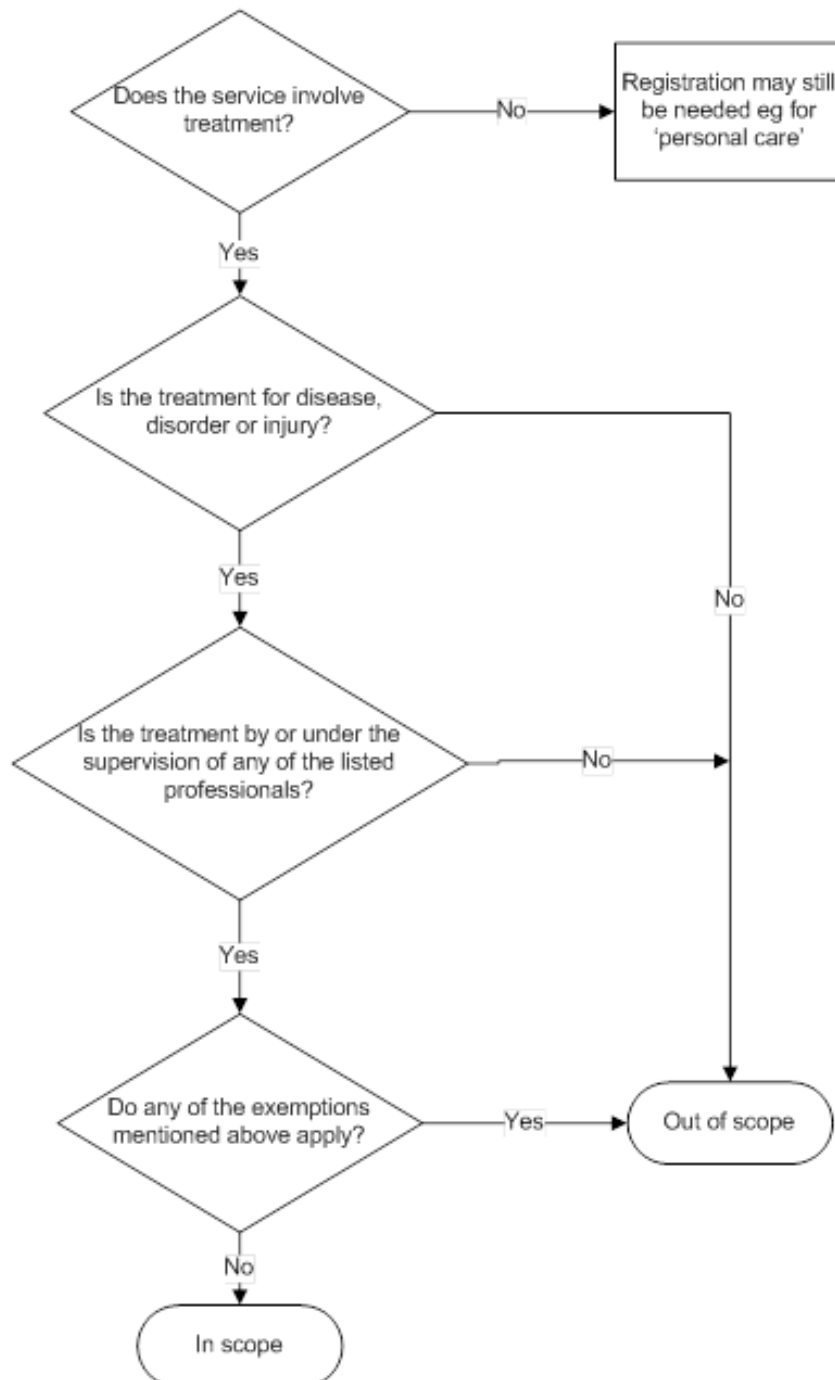
However, if the service does provide substance misuse treatment but the team does not include any of these professionals working in their registered capacity (under their protected professional titles), then the provider does not need to be registered for this regulated activity. For example, if the service provider employs 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 medical practitioner, nurse or social worker, then the provider **does not** need to register for this activity.

Where people are **not** being provided with residential accommodation and they are receiving treatment of detoxification, then the provider will have to be registered for the regulated activity of treatment for a disease, disorder or injury if prescribed professionals are involved in that activity.

Research settings

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

Decision tree: 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.

This regulated activity only applies to the use of the Mental Health Act in **hospitals**, rather than its use in any other setting, so it 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). It excludes detention under sections 135 or 136 of that Act where people are removed to a designated place of safety (usually a hospital but which, under exceptional circumstances, can be a police cell).

It includes the use of short term, emergency holding powers under Section 5 of the Mental Health Act. It therefore also applies to hospital services other than 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.

This regulated activity does not apply to 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. (This is commonly referred to as treatment or assessment by a SOAD.)

If you apply for this regulated activity and you also provide treatment for persons who are not detained or not liable to be detained, you may also need to apply for the activity of 'treatment of disease, disorder or injury'.

You would not need to additionally apply to register for the activities of personal care or nursing care if you provide these activities in the same service. However, you would need to apply for other regulated activities if you were providing them, for example, treatment for disease, disorder or injury in cases where treatment is provided for informal patients (those not detained in hospital under the Mental Health Act).

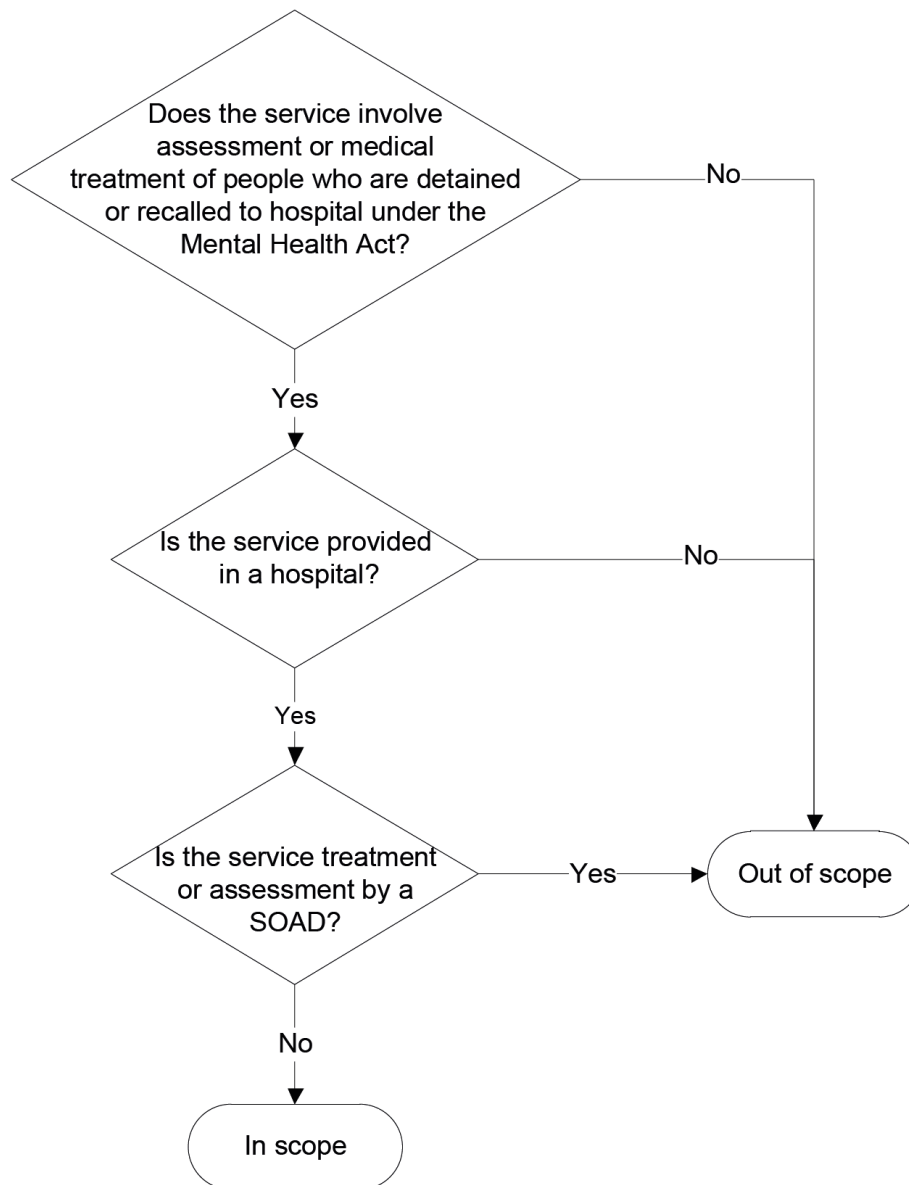
The regulated activities

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.

Decision tree: Assessment of medical treatment for people detained under the Mental Health Act 1983



Surgical procedures

Description

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

- Surgical procedures for the purpose of treating disease, disorder or injury; or cosmetic surgery; or for religious observance (eg circumcision)
- Surgery carried out for the purpose of sterilisation or reverse sterilisation.

However, minor surgical procedures are not captured if they are:

- Undertaken by a medical practitioner **and** the minor procedures are limited to:
 - curettage (scraping), cautery (burning) or cryocautery (freezing) of warts, verrucae or other skin lesions, and
 - are carried out using local anaesthesia (or no anaesthesia).

or

- Undertaken by any health care professional **and** the procedures are limited to:
 - nail surgery and nail bed procedures on the foot and which are carried out using local anaesthesia (or no anaesthesia)
 - curettage (scraping), cautery (burning) or cryocautery (freezing) of warts, verrucae or other skin lesions on any area of the foot and which are carried out using local anaesthesia (or no anaesthesia).

What does the regulated activity cover?

The regulated activity covers the surgical procedures referred to above. A provider of surgical procedures will usually need to register for other regulated activities. For example, the use of imaging techniques during surgery may require registration for 'diagnostic and screening'.

It covers all pre- and post-operative care associated with the surgical procedures. In relation to pre-operative care, this might include, for example, assessment by an anaesthetist shortly in advance of the procedure (where that assessment is an assessment of the patient's suitability directly related to the procedure) but would not include an initial consultation with a surgeon before the procedures had been decided.

In relation to post-operative care, the activity must be related to the procedure for it to be captured and this will normally mean that it is planned to be related to them. This may include, for example, post-anaesthetic care (recovery), follow-up in an intensive care unit, or rehabilitation where they are part of a planned pathway of care. The extent of pre- and post-operative care may include a planned subsequent follow-up consultation after surgery, but would not include any further treatment (that is additional, beyond checking on the procedures) that is decided in that follow-up consultation. It would include other treatment where that is directly related to the surgical procedures and carried out under the surgical team. For example, if a pre-existing prescription for medicines is temporarily changed by the anaesthetist in order to avoid any conflict with anaesthetic drugs. But if the treatment goes beyond the surgical team, for example, change of prescription not by the anaesthetist but by the patient's cardiologist, 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 upon.
- Only the planned pathway of care, not subsequent treatment.
- Only within the surgical team, not the activity of other health care teams that may be taking place at the same time.

Surgical procedures carried out for religious reasons, such as circumcision, are included where they are carried out by a health care professional. Where a health care professional carries out surgery for religious purposes they will be acting in their capacity as a health care professional rather than in a religious or spiritual role. This is because a registered health care professional's code of practice will prohibit 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 health care professional, even if they are acting in a spiritual or religious role.

Cosmetic surgery

Cosmetic surgery is not defined separately but the procedures that are captured by this regulated activity include those described as being for cosmetic purposes if they involve the insertion of instruments or other equipment into the body. For the avoidance of doubt, the activity does **not** include:

- Piercing
- Tattooing
- Subcutaneous injections to enhance appearance
- Removal of hair or minor skin blemishes by application of heat using an electric current.

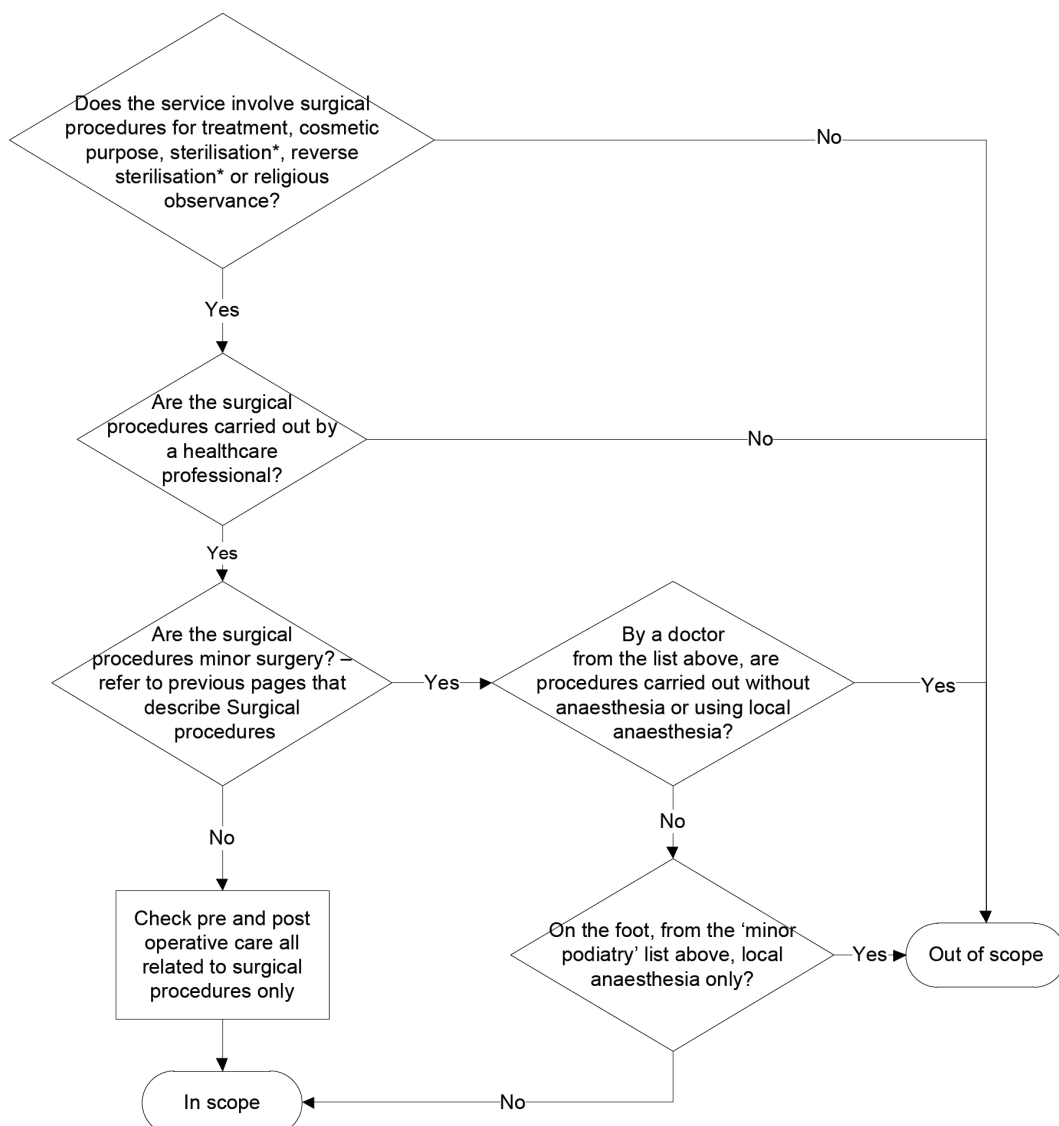
As an example, we consider liposuction involving the insertion of instruments into the body to be included in this activity. This is regardless of whether the liposuction is carried out using general or local anaesthesia, or whether the procedure involves the administration of a laser through a cannula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

Hospices

A hospice should not ordinarily be registered for the regulated activity of 'surgical procedures'.

This is because it is unlikely that a hospice would carry out surgical procedures other than pleural taps and abdominal paracentesis. These will instead be considered as treatment under the regulated activity of 'treatment for disease, disorder or injury' for the purpose of registration.

Decision tree: Surgical procedures



Diagnostic and screening procedures

Description

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

All diagnostic procedures involving the use of any form of radiation (including x-ray), ultrasound or magnetic resonance imaging to examine the body are included. This will include all main forms of diagnostic radiology, radiography and sonography (including antenatal ultrasound scans), but it will not include use of the same technology for therapeutic purposes such as radiotherapy or some forms of interventional radiology (those will require registration for the activity of 'treatment of disease, disorder or injury'). The activity also includes the analysis and reporting of the examinations that are carried out.

If the provider using the x-ray, ultrasound or magnetic resonance imaging is the same provider who is carrying out the analysis and reporting, then this may be included within a single registration; if a remote contractor is used for diagnostic analysis, the analysis and reporting will require registration in its own right.

Where diagnostic images are reported remotely by a subcontracted provider who is outside England, the subcontractor will not be registerable as they fall 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 that there are appropriate arrangements for the service to be delivered, including arrangements for quality assurance.

The activity includes many, if not all, forms of endoscopy because it captures procedures if they involve the use of:

- Instruments or equipment, which are inserted into the body to:
 - view inside of the body, or
 - gather physiological data.

The activity includes instances of taking a sample or biopsy because it captures 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 must register.

The activity also includes 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. If the provider removing the sample is the same provider who is carrying out the examination then this may be included within a single registration; if a remote contractor is used for diagnostic analysis, such as a laboratory company, the analysis will also require registration in its own right.

There are a number of exclusions that apply to this activity, which are set out further on in this section.

This regulated activity also includes physiological measurement; that is the use of equipment to measure or monitor physiological data in relation to the following systems:

- audio-vestibular
- vision
- neurological
- cardiovascular
- respiratory
- gastro-intestinal system, or
- urinary system

for the purposes of obtaining information on the causes and extent of a disease, disorder or injury, or the response to a therapeutic intervention, where such information is needed for the purposes of the planning and delivery of care or treatment.

Physiological measurement diagnostic services provide a wide range of specialist investigations and procedures that are often an essential part of care and treatment for patients. Physiological measurement includes not only assessment of the function of major organ systems, but also measurement and tests that are part of normal clinical care when carrying out other regulated activities that a provider will already be registered for under the Health and Social Care Act 2008 (HSCA).

Exclusions

The following physiological tests are **not** included within the definition of physiological measurement and so will not lead to registration for this regulated activity:

- 12 lead electrocardiograph recording (ECG).
- 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.

The regulated activities

- Use of an auroscope.
- Carrying out a hearing needs assessment or supply and fitting of a hearing aid carried out by a hearing aid dispenser or a person acting under the direction or supervision of a hearing aid dispenser, where:
 - a) The person is aged 19 or over, or
 - b) The person is under 19 and the procedure is carried out in, or arranged by, a school or 16-19 Academy.

The following procedures are also excluded from this activity:

- Procedures carried out for research, or analysing and reporting such procedures. However, this exemption only applies where those research procedures do not form part of a person's care or treatment. As an example, a university that has an imaging department would only be required to register with us if they carry out a radiological examination as part of the care of a patient. This is because such procedures would be part of a person's treatment pathway. They would not be required to register with us if they restricted their examinations to research exposures on subjects or for teaching purposes using 'phantoms'.
- The national cancer screening programmes are excluded. However, other national screening programmes are not excluded and must register if they are providing any aspect of the regulated activity.
- The taking of x-rays by registered chiropractors or the use of ultrasound by registered physiotherapists.
- Fitness screening procedures in a gymnasium, related to the use of fitness equipment or fitness activities, (treadmill tests for clinical purposes, however, are not exempt).
- Blood tests carried out by means of a pin prick test, or removing blood from a vein where the sample is **not** sent to a laboratory for analysis.
- Taking urine samples where the sample is not sent to a laboratory to be analysed.
- The sending of samples of body fluids to a place to be analysed, where the samples are not collected or taken by the provider. For example, when a person produces a urine sample and the provider 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.
- The taking or analysing of 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 an individual's genetic variation on a drug response.

The regulated activities

However, such tests are **not exempt** if carried out as part of:

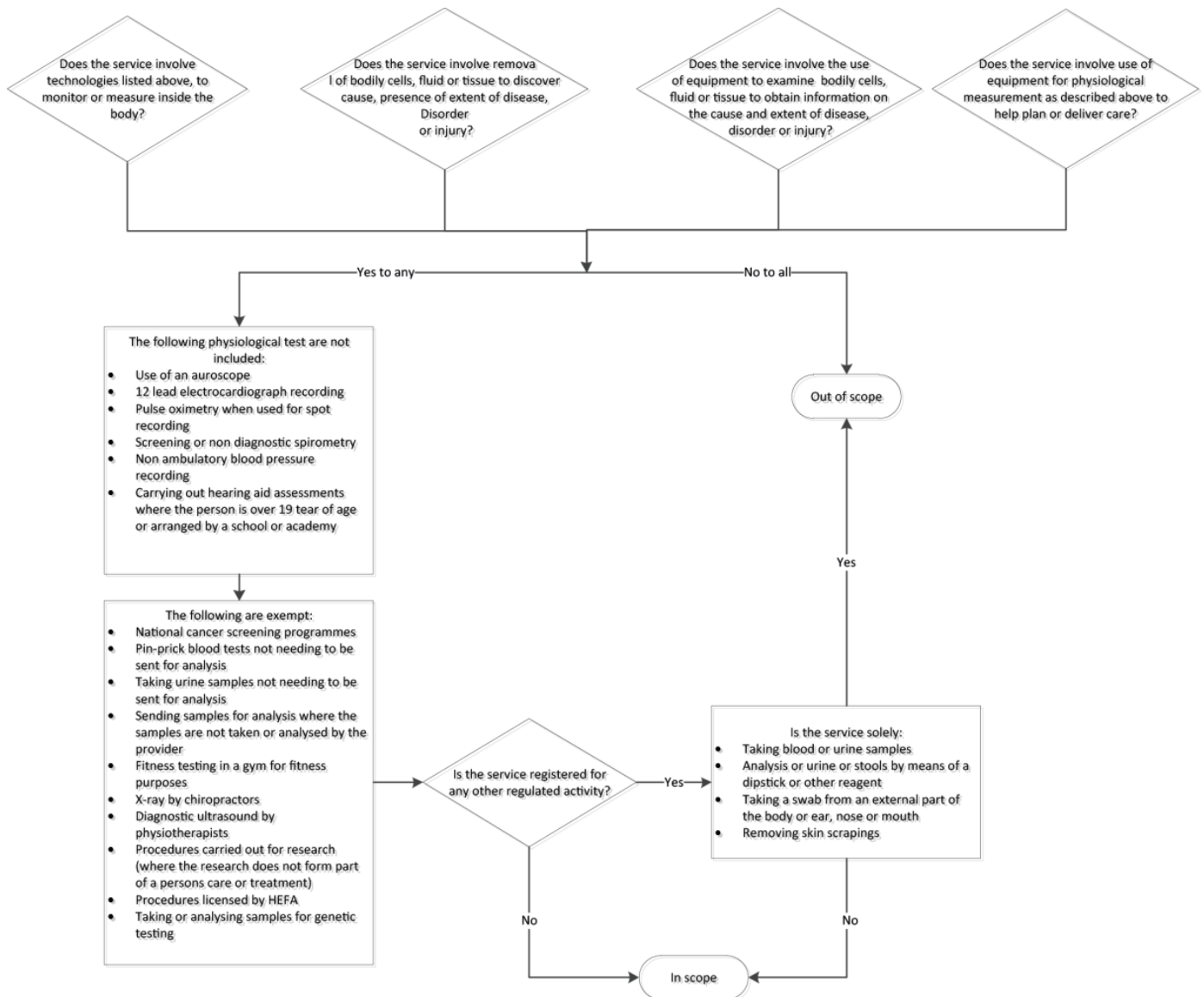
- a) the planning or delivery of the individual's treatment or care, or
- b) a national screening programme other than a national cancer screening programme.

A provider may be registered for this regulated activity in addition to any number of other activities. This activity is not restricted to services provided by health care professionals.

There are certain low risk procedures that we will consider as part of a provider's overall registration with us; in other words **providers registered with us** will not have to register for this activity solely because they carry out the following procedures:

- Taking blood or urine samples.
- The analysis of urine or stools by means of a dip stick or other reagent.
- The taking of a swab from any external part of the body or from the mouth, ear, nose or throat.
- Removing skin scrapings.

Decision tree: Diagnostic and screening procedures



Management of supply of blood and blood-derived products

Description

This regulated activity covers the management of:

- a) The supply of blood, blood components and blood-derived products for transfusion. For example, this will include the management of supply of blood by NHS Blood and Transplant; a provider managing the supply of blood to another provider; or a service from a dedicated unit, such as a central or regional facility set up for the purpose of providing this service to individual hospitals in a corporate group.
- b) The supply of tissue 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.
- c) 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.

This activity does not apply to the management of supply of products described in paragraphs a) and b) where that management does not involve direct physical contact with patients or donors from whom products are administered or derived.

In relation to blood and tissue products, this activity concerns the management of the supply. That does not include storage of, access to, and use of these products within a hospital. Having appropriate equipment and supplies, and storing them, will be part of other activities such as 'treatment of disease, disorder or injury' or 'surgical procedures', rather than an activity in its own right.

This activity does not capture a taxi service or other form of transport provision that transports blood, organs or tissue products between providers.

It does not capture autologous transplant, in which tissue is taken from an individual and stored in order to be implanted back into him/her 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.

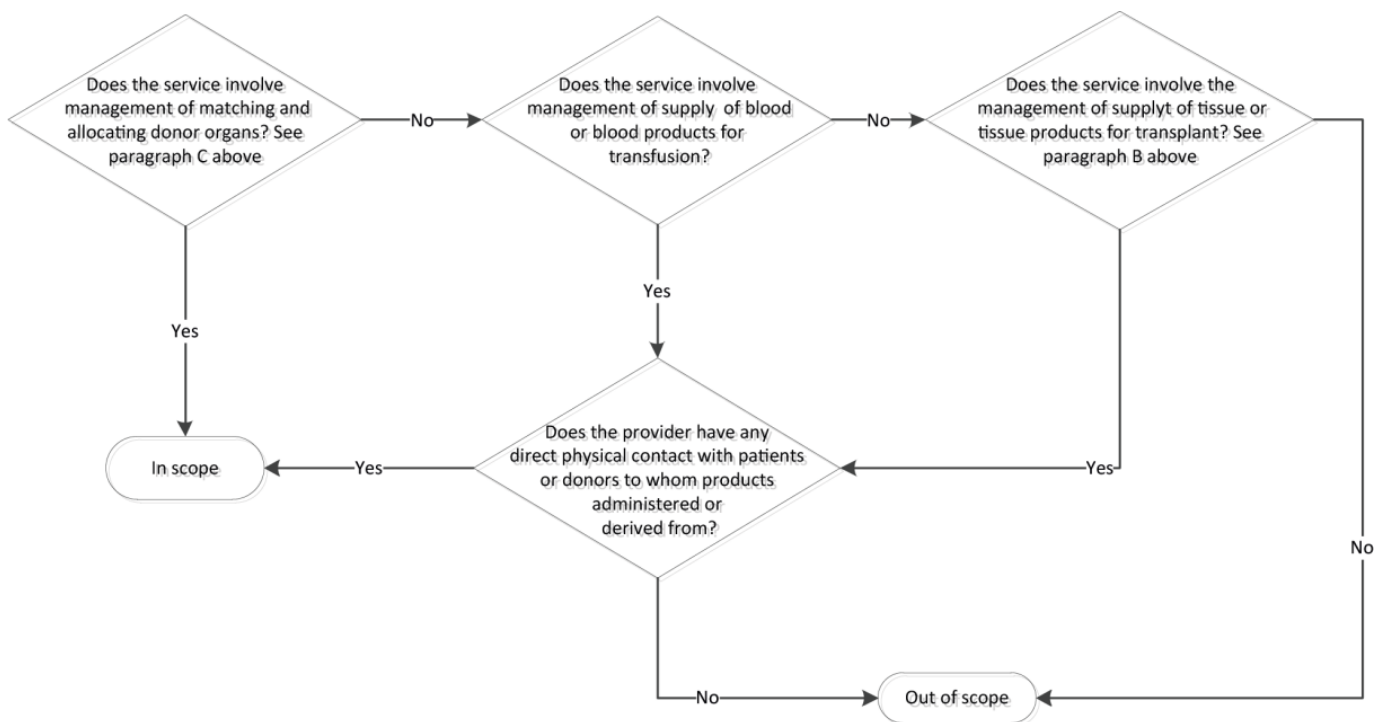
The regulated activities

It does not capture situations in which a provider's role is only to remove an organ where the patient has chosen to be a donor (for example, 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.

It does not cover the organ demand procedures, such as managing requests or waiting lists for transplantation.

Decision tree: 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, and
- Remote medical advice.

Transport services

Services are captured by this regulated activity where they involve a vehicle that was designed for the primary purpose of transporting people who require treatment. Transport services provided in vehicles that have a different primary purpose (such as taxis, volunteers using their private cars, or mortuary vehicles and Dial-A-Ride vehicles) are not captured in this regulated activity, even though they may be registered with the Driver and Vehicle Licensing Agency as ambulances. Search and rescue transport services are also currently exempt because the service is provided under arrangements made on people's behalf by a government department.

Because it is the nature of the vehicles used that determines the need to register, transport services provided in ambulances operated by hospital providers will require registration, as well as transport services provided by ambulance only providers. The term 'designed for' will apply to vehicles used to transport people who require treatment not only where this was the manufacturer's original design, but where a vehicle has been made suitable for this purpose (e.g. modification, livery, etc). Air ambulances and water ambulances are also included in this regulated activity. However, providers of air ambulances services are exempt from the activity where the aircraft used is registered with the Civil Aviation Authority and that same provider is not carrying out treatment to a patient. Air ambulance providers are also exempt if the transport is not carried out in England or if it is carried out under travel insurance arrangements. Refer back to [section 2](#) of this document and in particular '[third party exemptions](#)' for further detail.

This regulated activity relates to transport, but will not cover other 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 related to treatment.

The transport activity will not apply where a provider only uses a vehicle to transport a person within the confines of an event site. As an example, if a person attending or participating in a sporting event requires treatment, and as such, is carried in a vehicle from one part of the event ground to another, then registration for that transport is exempt. However, if the same situation arose and the person was carried from the event ground to hospital, then registration will be required.

We will take a proportionate and reasonable approach if 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 ordinarily would not consider or plan to do this.

Some ambulance providers may also need to register for the regulated activity of 'treatment of disease, disorder or injury'. For example, where they employ health care professionals and ordinarily carry out treatment.

Where procedures are carried out, such as emergency tracheotomy, insertion of a chest drain or intubation, for the purpose of registration these would be considered as treatment for 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 providers that are equipped, and expect to carry out such procedures must register for that activity. However, if a provider carries out emergency procedures unexpectedly, we would be proportionate and would not regard this as committing an offence where they are not separately registered for 'surgical procedures'.

Providers registering for this activity will not have to additionally register for the regulated activity of 'diagnostics and screening procedures' if they only carry out the following diagnostic procedures along with transport:

- 12-lead ECG.
- Use of an AED.
- Pulse Oximetry.
- Use of a Sphygmomanometer.
- The analysis of urine or stool samples by means of dip stick or other reagent.
- Taking blood, urine samples or swab specimens.

Remote advice

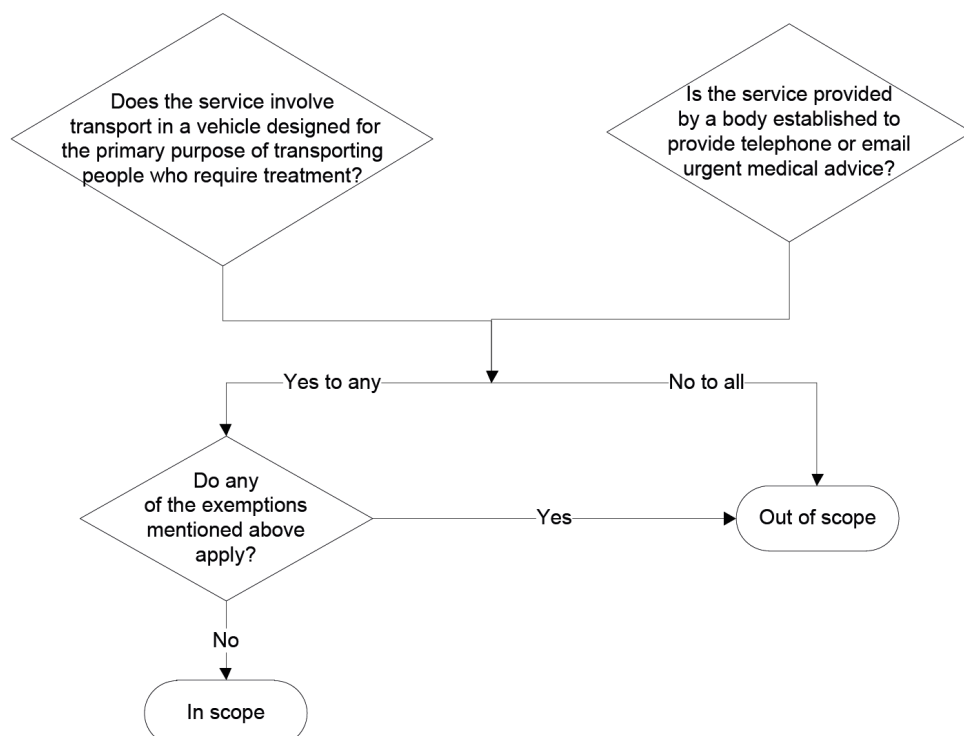
Remote advice is a regulated activity when:

- The advice is medical, **and**
- It is responsive, i.e. for immediate attention or action (as opposed to, for example, a service in which a person electronically submits questions to a provider who provides responses at some later time, or when a person seeks general health care or lifestyle advice), **or**
- It constitutes triage (see [glossary](#)), **and**
- It is provided over the telephone or by electronic mail, **and**
- It is provided by a body established for that purpose (as opposed to, for example, the occasional provision of advice by a body such as a hospital or university on an informal basis).

The second consideration above means that:

- NHS Direct and any other organisation established for the purpose of providing telephone or internet-based medical advice where immediate action or attention is needed or triage provided will be covered.
- Ambulance control centres will be covered where they provide triage by means of telephony services.

Decision tree: Transport services, triage and medical advice provided remotely



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 health care professional.

Organisations that provide advice, support or information related to childbirth and parenting are not included in this regulated activity, so long as the provision of health care (other than that advice, information and support) is not their main purpose.

This means that a hospital provider would not become exempt if providing advice, because its main purpose is health care. But an organisation that is not primarily a health care provider and that provides this advice (such as the National Childbirth Trust) would not have to register, even if the advice is provided by a health care professional employed by such an organisation.

Exemptions

Services by midwives are exempt in the following specific circumstances:

- The midwife must be acting on their own behalf (i.e. self-employed rather than acting for a partnership or organisation), **and**
- Providing non-NHS care (e.g. not under contract for an NHS service), **and**
- Providing services to their patients **only** in the patients' homes (e.g. not as part of a hospital or clinic based service).

This exemption would not apply unless **all** of the circumstances set out above are met.

For the avoidance of doubt, this activity does not cover arrangements that local social services authorities may make under the NHS Act 2006, for the care of pregnant women and women who are breastfeeding.

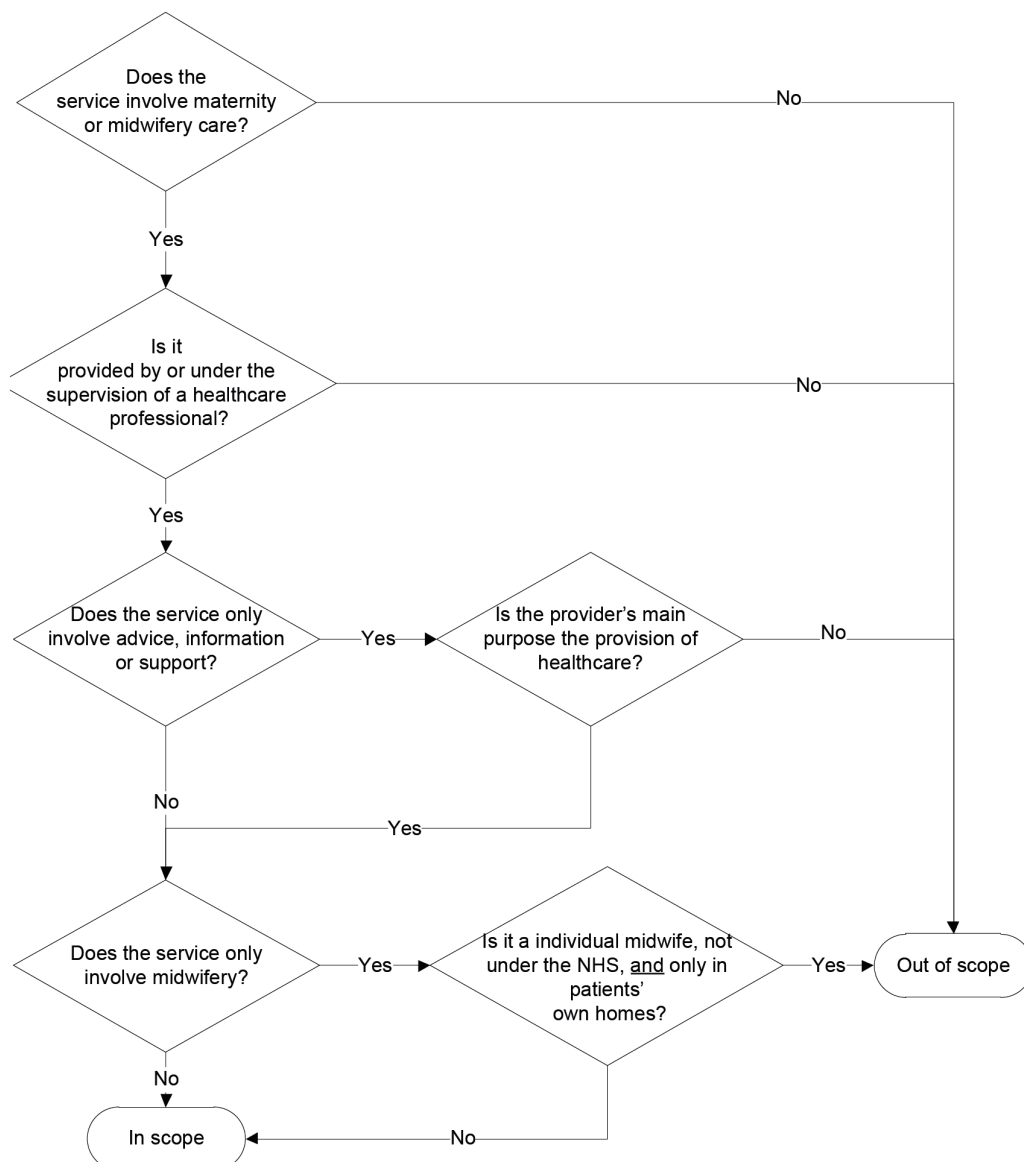
Antenatal care or postnatal care

Where antenatal or postnatal services are provided as part of primary medical care, the primary medical provider should register for this activity. Where maternity services are provided as a community or outreach service, the provider is likely to need to register.

The current exemptions that apply to independent midwives providing services in a woman's own home were expected to be changed by the Department of Health at some point in the future. However, at the time of publishing this guidance, the exemption remained in place. It may be helpful to note that [The Health Care and Associated Professions \(Indemnity Arrangements\) Order 2014](#) came into force in July 2014. This Order is relevant to many health care professionals, including individual midwives that meet the exemption set out above.

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_133119

Decision tree: Maternity care and midwifery



Termination of pregnancies

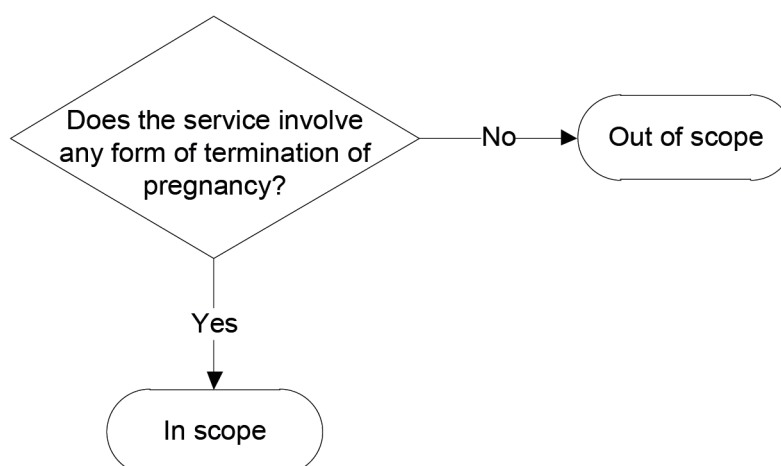
Description

The termination of pregnancy, by surgical or medical methods, including feticide is included in this activity. Advice on termination of pregnancy is not included. 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.

Where the service provider is not an NHS body, the provider should refer to Regulation 20 of the Care Quality Commission (Registration) Regulations 2009, SI no. 3112, available at www.legislation.gov.uk/uksi/2009/3112/contents/made. These regulations place certain obligations on registered providers.

Providers may need to register for other regulated activities such as 'treatment of disease, disorder or injury' if, for example, they are providing treatment for sexually transmitted infections alongside termination of pregnancy services.

Decision tree: Termination of pregnancies



Services in slimming clinics

Description

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

- Consist of advice or treatment and **include** the prescription of medicines for the purpose of weight reduction, **and**
- Are provided by, or under the supervision of, a registered medical practitioner.

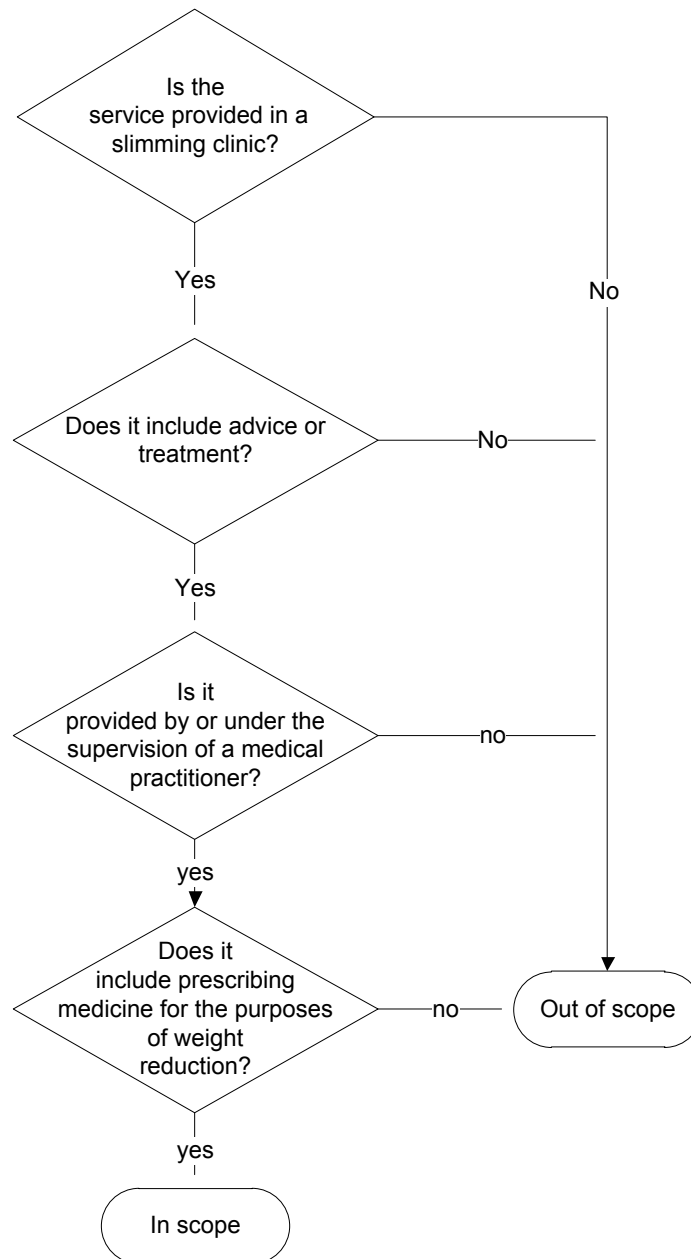
In order to be registerable, "clinic" in this activity means it must be carried out in a physical location rather than being a remote website service.

This regulated activity applies if advice or treatment is being provided by or under the supervision of a medical practitioner, **and** the service **includes** the prescription of medicines for weight reduction.

It may still be necessary to register for other regulated activities. For example, the regulated activity of 'treatment of disease, disorder or injury' may apply if treatment is also being provided for a condition that is not an obesity/weight disorder.

This activity does not apply in cases where a slimming clinic is not prescribing medicines for the purpose of weight loss. As an example, a slimming clinic that provides diet plans written by or authorised by a medical practitioner will not be required to register unless that service or clinic also prescribes medicine for the purpose of weight loss.

Decision tree: Services in slimming clinics



Nursing care

Description

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

Nursing care means any service provided by a nurse and involving:

- a) The provision of care, or
- b) The planning, supervision or delegation of the provision of care, other than any services which, by their nature and the circumstances in which they are provided, do not need to be provided by a nurse.

If nursing care is provided as a necessary part of another activity, then 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 nurse will involve another regulated activity. For example, health visiting may include vaccination (which will be included in the activity of 'treatment of disease disorder or injury'), or a test that is included in 'diagnostics and screening procedures'. Sexual health advisory services may be carried out by a doctor or other health care professional and are not required to be carried out solely by a nurse. Similarly, smoking cessation services may be carried out by an appropriately trained person and not necessarily by a nurse.

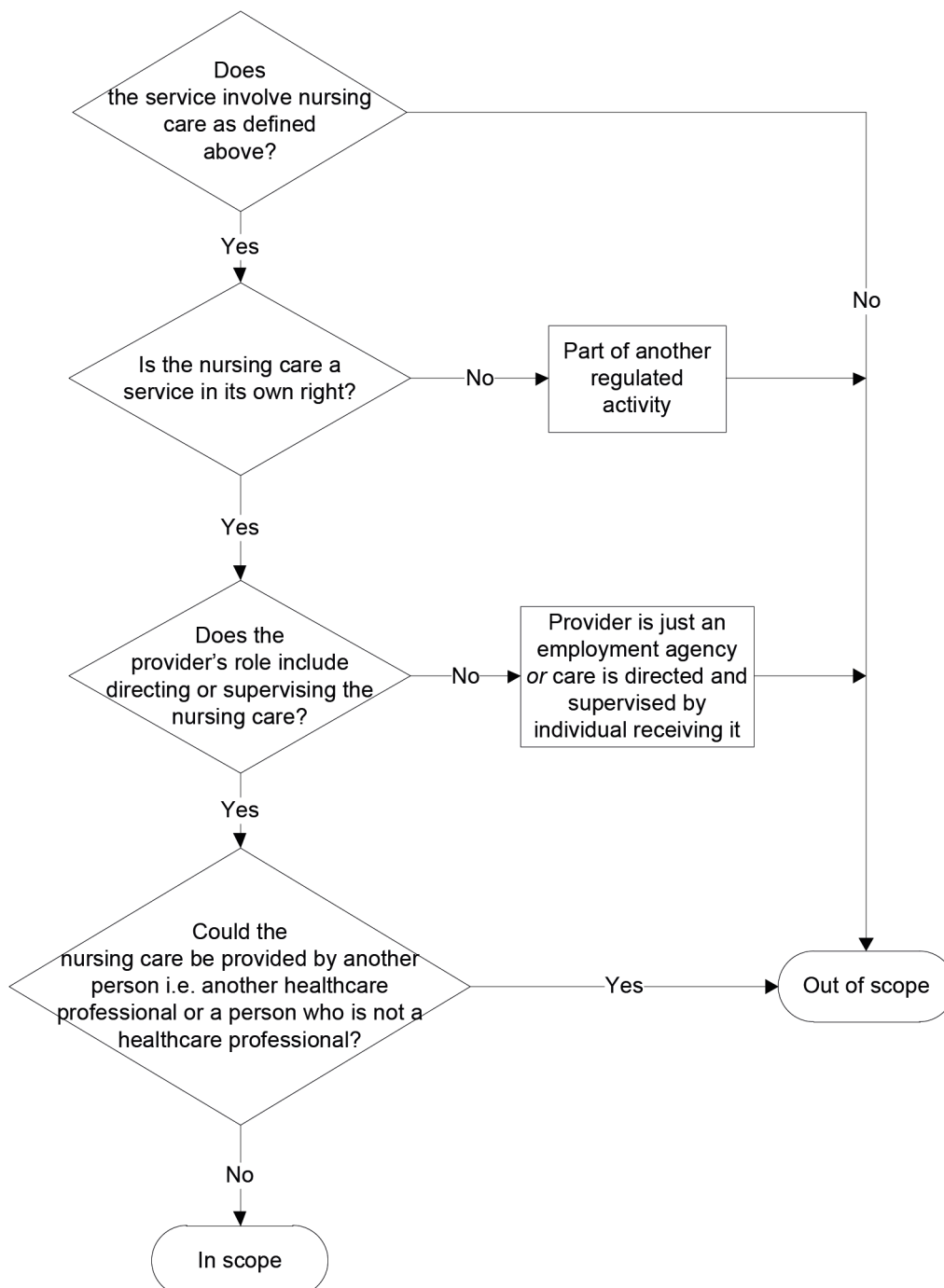
Exemptions

- The supply of nurses by an employment agency or employment business to another service provider is not a regulated activity. Nurses' agencies providing agency or locum nurses may not have to register. This exemption only applies where the agency is not responsible for directing or supervising the role of the nurse in any way.
- Introductory services, through which an individual is put in contact with nurses, from which the individual may select a nurse who he/she will then employ or use, are exempt. This might be, for example, where a nurse is introduced to someone who directs their own care through private funding or a personal budget arrangement. This exemption requires that the provider of the introductory service has no ongoing role in the direction or control of the

service that is subsequently provided to the individual. Where a person makes a private arrangement and secures a nurse for his/her own care, under his/her direction, the service provided is exempt even if it did not involve an introductory agency or employment agency. This may include, for example, where an individual uses a personal budget or a self-pay arrangement.

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

Decision tree: Nursing care



Family planning services

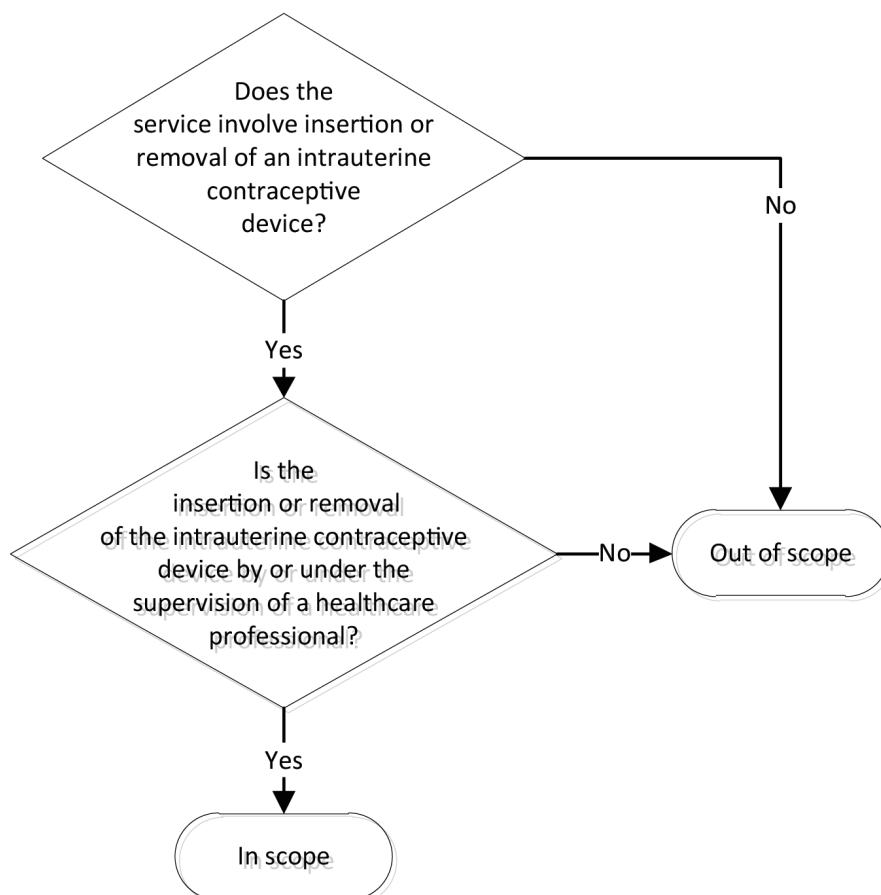
Description

This regulated activity involves services for the insertion or removal of an intrauterine contraceptive device by, or under the supervision of, a health care professional.

This activity includes insertion or removal of all types of intrauterine contraceptive device regardless of whether they are an intrauterine system or intrauterine device.

Providers may need to register for other regulated activities such as 'treatment of disease, disorder or injury' if, for example, they are providing treatment for sexually transmitted infections or menstrual disorders alongside the family planning services.

Decision tree: Family planning services



Glossary of terms

Cosmetic surgery

Cosmetic surgery is not defined, but the procedures that are captured are described as being carried on by a health care professional for cosmetic purposes and involving the insertion of instruments or other equipment into the body. The following procedures are **not** included:

- Piercing.
- Tattooing.
- Subcutaneous injections to enhance appearance.
- Removal of hair roots or small blemishes by application of heat using an electric current.

Health care professional in relation to 'surgical procedures' and midwifery services

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

- Health Professions Council.
- Nursing and Midwifery Council.
- General Medical Council.
- General Dental Council.
- General Pharmaceutical Council.
- General Osteopathic Council.
- General Optical Council.
- General Chiropractic Council.

or any professional in due course 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 is permitted by that body to provide or supervise the provision of the regulated activity in question.

Listed health care professional in relation to 'treatment of disease, disorder or injury'

A listed health care professional is defined for the purpose of this regulated activity only, 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.

who is permitted by their relevant registration body to provide or supervise the activity in question.

Local anaesthesia

Local anaesthesia is defined as any form of anaesthesia other than general, spinal or epidural.

Nursing care

Nursing care is defined as any services provided by a registered nurse and involving the provision of care or the planning, supervision or delegation of the provision of care.

Note: this does not include any services, which, having regard to their nature and the circumstances in which they are provided, do not need to be provided by a registered nurse.

Personal care

The definition of personal care is broader than that used in previous registration systems. It covers:

- a) Physical assistance given to a person in connection with:
 - i. Eating or drinking (including the administration of parenteral nutrition);
 - ii. Toileting (including in relation to menstruation);
 - iii. Washing or bathing;
 - iv. Dressing;
 - v. Oral care, and
 - vi. The care of skin, hair and nails (with the exception of nail care provided by a chiropodist or podiatrist), and
- b) The prompting and supervision of a person to do any of the types of personal care listed above, where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision.

Prompting and supervision

Prompting and supervision is where staff prompt **and** directly supervise a person when they are carrying out the above actions (i)–(vi) and where the person is unable to make a decision for themselves in relation to performing such an activity without someone prompting them. Supervision will normally include direct observation of the action as it is carried out or otherwise checking on how it being carried out, but 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, then the services will be classed as providing the provision of personal care.

Shared Lives schemes

Shared Lives schemes are defined as schemes carried on (whether or not for profit) by a local authority or other person for the purposes of recruiting and training adult Shared Lives carers; making arrangements for the placing of service users with Shared Lives carers; and supporting and monitoring placements. Schemes of this type are referred to as Shared Lives, Shared Life schemes or Homeshare programmes. Previously these schemes were referred to as Adult Placement Schemes.

Who are Shared Lives carers?

Shared Lives carers are people who provide accommodation and other support for an adult service user in their own home (the placement). They may or may not provide 'personal care'. **Note:** it is the Shared Lives scheme and not the individual carers who must be registered for the regulated activity of personal care.

Triage

Triage means assigning degrees of urgency to diseases, disorders or injuries in order to decide the order and place of treatment for people using the service.

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