

A new system of registration

The scope of registration

About the Care Quality Commission

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

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

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

Introduction

This publication is for people and organisations that provide, or are intending to provide, healthcare or adult social care in England.

It is to help them understand whether they need to register with the Care Quality Commission under the Health and Social Care Act 2008 (the Act). It is not a definitive description of the law and is a guide so should not be regarded as an interpretation of the law, but it aims to help those providing services and answer as many of their questions as possible.

This is the second edition of our guidance. It supersedes and replaces the earlier guidance dated November 2009. The main changes that we have made are as follows.

- We have added more detail so as to reflect queries made by NHS trusts who applied for registration in January 2010. By learning from their questions, we hope the guidance will anticipate the needs of new applicants.
- We have now set out our guidance on regulated activities to reflect a decision path for each. This provides more clarity so that applicants can check whether their services are covered by just one regulated activity, or whether they will need to register for more than one. We recommend that providers go through each decision path in order, as a structured process for making sure that they consider every activity that they may need to register.
- We have included a new section on when managers need to register. (This requirement did not apply to NHS trusts who were under an obligation to apply in January 2010.)
- We have removed sections on matching activities to locations, and on reflecting activities in the 'statement of purpose' that providers must prepare. This is because we have issued separate guidance on these as part of our guidance for providers on completing their application. This can be found on our website at www.cqc.org.uk. As a general point, we recommend that this scope guidance should be read alongside our other guidance on completing an application in the registration section of our website.

In section 1, we describe what is meant by a “provider” and a “ manager” who, generally, need to consider making an application.

In sections 2 and 3, we provide guidance on how Schedules 1 and 2 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 apply. We refer informally to these as the “scope regulations”, as they set the scope of which regulated activities fall within the new registration system. Section 2 sets out the general exemptions. If any of these apply, there is no need to register for the time being for the activities that are exempted. 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 which trigger the need for registration and to treat this document as a guide to the regulations but not a substitute for them. The regulations are currently published online at www.opsi.gov.uk/si/dsis2010.

The previous Care Standards Act system of categorising providers by organisation type or service type no longer apply: there are no categories for domiciliary care, care homes, dentistry and so on, and the need for registration depends on what activity is provided within those services rather than their common name. The ‘service types’ set out in our *Essential standards of quality and safety* publication similarly should not be confused with regulated activities: they represent a way of matching guidance about compliance to services after those services have been identified as providing regulated activities.

For a more general background to the new registration system, please read our booklet *Guide for providers of healthcare or adult social care*.

1

Who has to register?

The Act allows for the registration of service providers and managers.

Providers

A service provider can be an individual, a partnership or an organisation (for example, a company, a charity, an NHS trust or a local authority). It is the legal entity (whether this is an individual, partnership or organisation) that provides the regulated activity to people that must register. Individual locations, such as care homes within a corporate group, are not registered separately.

A provider must register if any of the regulated activities is carried out in England. There are separate arrangements for regulating health and social care in other UK territories, with close and regular coordination between the regulators. Where a provider from a neighbouring country occasionally delivers services in England (for example, an ambulance service), we will take a proportionate and reasonable approach.

Managers

A manager is an individual who is in day to day charge of a service provider's regulated activity, or a service provider's regulated activity in a particular location. The circumstances in which a manager must register are set out in the Care Quality Commission (Registration) Regulations 2009. They are as follows:

- The service provider must have a registered manager if they are a non-NHS body. Health Service bodies such as trusts do not require a registered manager unless we impose a condition so as to require one, but others, including independent organisations who work under contract to the NHS, do.
- The service provider must meet one of these conditions:
 - they must be a body of persons which is corporate (i.e. a company) or unincorporated (i.e. a partnership)or
 - if the service provider is an individual, that individual is either not a fit person to manage the regulated activity or does not intend to take on the role of a manager in day to day charge of how the regulated activity is provided.

In order 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 reasonable adjustments or plans that may be needed to enable them to do so; suitably qualified, skilled and experienced; and able to provide certain information. This will normally involve an interview. The information that must be available is:

- proof of identity
- Criminal Records Bureau disclosure
- 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).

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. We will, however, manage our relationship across the brand and ensure that the way we communicate our assessments will enable people 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. Again, we will communicate our assessments so 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, this creates a new partnership, which is a new legal entity requiring a new registration. However, we will take a proportionate approach to managing this situation.

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 may need to register, depending on the individual case.

Section 75 agreements

Section 75 agreements enable NHS bodies and local authorities to delegate or cooperate in functions and resources, 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. 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.

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 us. This does not mean that a provider cannot be dual registered: what it means is that there cannot be double accountability for the same activity. A provider may be registered with Ofsted for activity A, and also 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 wherever this sort of situation arises, we and Ofsted will monitor our different parts of the service so as to avoid duplication and overlap. In addition, CQC and Ofsted work closely together so as to share expertise and coordinate activity, for example with joint inspection or single inspection that collects information for both regulators.

Hosting arrangements

Where an activity is carried on by A, but hosted by B, then A will need to register, regardless of its host. For example, independent providers of healthcare in prisons must register, not the host prison; a private dialysis unit in the grounds of an NHS hospital, will need to register in its own right if it provides a regulated activity.

However, in these situations hosts are advised to set out in agreements with the service provider what the extent of their role is (for example, through a contract or service level agreement). If the boundary of responsibilities is left unclear, hosts may sometimes end up *de facto* having responsibilities for activities taking place in premises that are under their control, in the absence of anyone else being responsible for them.

Renting arrangements

By the same token, 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 in an NHS hospital, doctors sometimes rent consulting rooms for private outpatient appointments. Where these doctors provide a consultation within a service that is managed by the hospital, and the doctors have agreed 'practising privileges', it will be covered by the hospital's registration. (Practising privileges are a system by which doctors who work in independent hospitals, but are not directly employed by them, agree to a hospital's policies for promoting the quality of treatment and care.)

However, in this example, 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 the granting of practising privileges.

Alternatively, doctors may practise in outpatient departments under their own arrangements, with the hospital only acting as landlord. In that case, where the doctor is carrying on regulated activities independently of the hospital, the doctor must register (unless they are exempt for other reasons – see section 2).

Again, landlords are advised to set out in agreements with the service provider what the extent of their role is (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* having responsibilities 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. 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 is a hospital imaging service in which the x-ray and scanning department is equipped, staffed and operated by a subcontractor. These services are typically seamless and people who use the services may be unaware that they are subcontracted. They will, however, need to register in addition to their host hospital, even though they provide a service that is part of a pathway of care entirely within the registered hospital.

The only circumstance in which they might not need to register is likely to be where responsibility for service delivery is totally with the client. In this instance, the subcontractor acts only as a supplier of equipment or a staffing agency, with the client in charge of, and responsible for, all aspects of how the service is actually run. But the provider must register if the subcontractor retains 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, and so on).

Secondments and similar service level agreements

Occasionally a service is provided with staff from another provider 'loaned' to it through a secondment or agreement for a certain proportion of their time to be devoted to it. In these cases it is not a joint service (which might require both parties to register) but the staff member's employer is acting as if in the capacity of a staffing agency so that, once the member of staff has been seconded to the service provider it is the service provider who manages them and the service that they are part of. In that situation, the original employer would not need to register for the service provided by the provider who receives the 'loaned' or seconded staff.

Each case will need to be considered individually as there are many different ways of organising the service. All that we have provided here are illustrations and examples of scenarios. 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 the service user 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 who therefore needs to register.

2

General exemptions from registration

If a general exemption applies to a service, the provider of that service will not need to register for the activities that are exempted. There are two types of general exemption:

- Those with a time limit on the exemption: in which case, providers will need to register in respect of the activities when the time limit is reached.
- Those that do not currently have a time limit on exemption.

Many regulated activities also have specific exemptions that apply only in certain circumstances. These are described in section 3. Where a provider is exempted from the need to register for regulated activity A, they still need to check their responsibility with regard to regulated activities B, C, D and so on.

Exemptions with a time limit

Primary dental services

Providers of primary dental services are exempt until 1 April 2011. But in practice, the effect of this exemption only covers those services delivered in wholly private dental clinics, and clinics that provide services to the NHS as 'independent contractors' to primary care trusts. Dental services provided directly by primary care trusts themselves, or by hospitals, are not included within this exemption. A primary care trust 'provider arm' or a hospital that provides dental service will need to register. In this scenario, we remind readers that the need to register is in relation to regulated activities and not types of service or organisation as in every day speech. There is no regulated activity specific to 'dentistry'. Providers of dental care will need to consider their services against the full range of regulated activities (such as, 'treatment of disease, disorder or injury', 'surgical procedures', 'diagnostic and screening procedures', etc).

Independent ambulance services

Independent providers of ambulance services (of all kinds, including both 'blue light' and planned transport) are exempt from registration until 1 April 2011. All non-NHS ambulance services are exempt until this date. This includes independent sector services that are fully contracted to other registered providers (for example, an air ambulance service run by a voluntary sector organisation on behalf of an NHS trust). It includes any form of treatment that would otherwise be registerable, if it takes place in a vehicle operated by a non-NHS ambulance provider. All references to vehicles in

relation to ambulances include air and water ambulances, as well as road vehicles.

As noted above in relation to dentistry, the need to register is not related to the type of organisation or common understanding of an ambulance service. When the exemption ends, providers will need to review their service against all regulated activities (in particular, 'treatment of disease, disorder or injury' and 'transport services'). Any regulated activities that they currently provide which are not covered by the exemption described above, will also need registration.

Primary medical services

Providers of NHS primary medical services are exempt until 1 April 2012. The exemption covers NHS primary medical care under contracts made by a primary care trust, strategic health authority or the Secretary of State (known as GMS, PMS, APMS and Section 3 contracts). This will exempt all providers who provide primary medical care as 'independent contractors' to the NHS until that date. The exemption generally includes 'extended practice' into areas that may not traditionally have been considered primary care and may not be covered by primary care contracts

However, NHS primary medical services that are directly provided by an NHS trust or by organizations, other than an individual GP, for whom providing NHS primary medical services is not the sole or main purpose (for example a corporate provider that provides a large variety of different services), must be included within those providers' registrations in April 2010 (if an NHS trust) or October 2010 (all other cases). Most providers of NHS primary medical services also provide some private services, such as self-pay travel vaccinations. These will not trigger the need to register where the above exemption applies.

Most NHS providers of primary medical services also provide some private services, such as self-pay travel vaccinations. These will not trigger the need to register where the above exemption applies.

Providers that consist of doctors who practise privately without a surgery or consulting room (for example, home visiting services and internet-based services, known as independent medical agencies) are exempt if the providers also provide treatment to people under the NHS. The provider in this case may be any form of undertaking, including an organisation, a partnership or a self-employed individual.

The exemptions relating to primary medical care and private medical practice are particularly complex. Further information is available on our website at www.cqc.org.uk/guidanceforprofessionals/registration/nhsprimarymedicalcare.cfm.

Exemptions currently without a time limit

Doctors in independent practice

Doctors who practise privately in a surgery or consulting room are exempt if they (as individuals) also have some NHS practice there or elsewhere. For a group of doctors in private practice, working together as one organisation or partnership, they must all meet this criterion in order to be exempt from registration – that is, all of the individual doctors must have some NHS practice in order for the organisation or partnership as a whole to be exempt. If any one of them is wholly private, without any NHS practice, then the whole organisation or partnership must register.

The exemption does not apply if the private practice in a surgery or consulting room includes any services on the following list. These services override the exemption above based on NHS practice for doctors in private practice. If any of these services are provided, then the exemption is cancelled and the private doctor service must register:

- Treatment carried out under anaesthesia or intravenously administered sedation (this includes any treatment under any form of anaesthesia, but minor ‘lumps and bumps’ are excluded – see the guidance on ‘surgical procedures’ in section three for more information on how lumps and bumps are defined).
- Dental treatment carried out under general anaesthesia.
- Obstetric services and, in connection with childbirth, medical services.
- The termination of pregnancies.
- Cosmetic surgery (again, see the guidance on ‘surgical procedures’ in section three for more information on the types of cosmetic surgery which are exempt).
- Haemodialysis or peritoneal dialysis.
- Endoscopy.
- The provision of hyperbaric therapy, which is the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber that is gradually pressurised with compressed air, where such therapy is carried out by or under the supervision or direction of a medical practitioner.

Independent midwives

Independent midwives are exempt if 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 the guidance in section three on ‘maternity and midwifery services’.

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

Where a person makes their own arrangement for nursing care or personal care, and the nurse or carer works for them without an agency or employer involved in managing or directing the care that the nurse or carer provides, the nurse or carer does not need to register for that service.

Individual user trusts, set up to make arrangements for nursing care or personal care on behalf of someone who lacks capacity to do it for themselves, are also exempt. This exemption is 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 (often known as introductory agencies) but do not have any role in managing or directing the care that a nurse or carer provides when an individual employs them for their care.

These exemptions are also described in section three of this guidance, under the activities of 'personal care' and 'nursing care'.

Third party exemptions

The regulations exempt the services below. We have grouped them together because they represent services which may be organised through a third party, and the third party may be the provider's "customer", unlike most other services which are organised directly between the provider and the person who uses the service. That is however our way of grouping them as a convenient way to understand them; the regulations merely list them.

- Occupational health schemes, 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 through police authorities.
- 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 such as BUPA.
- Medical services organised by a Government department (for example, medical assessments to determine eligibility for social security benefits).

Other exemptions

The following are also exempt:

- Any health or social care service carried out by a carer who cares for a member of their family or someone in a personal relationship, and 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) and primary pharmacy services (for example, high street pharmacists).
- School nurses who are employed and managed by the school, and providing 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 primary care trust's registration.)
- First aid by first aid organisations or non-healthcare professionals who are trained in first aid, or by healthcare professionals in response to an urgent or emergency situation (as opposed to their ordinary, planned roles).

In general, the various exemptions mean that the following services, which used to require registration under the Care Standards Act 2000, are not required to register under the new system:

- 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.
- Use of non-surgical lasers and intense pulsed lights (used mainly in beauty salons) if they are used only for services which do not constitute regulated activities (e.g. for purely cosmetic purposes). However, clarification by distinguishing between cosmetic use and therapeutic use often requires case by case consideration using the guidance in the next section of this document.

3

Activities that are covered by registration

How to use this section of the guidance

Providers who are not exempted by the general exemptions set out in section 2, must register all regulated activities that they provide. In this section, we explain what each regulated activity covers.

The regulated activities are set out one by one in this section, in the order that they appear in the regulations. Our guidance for each is set out in three parts for each regulated activity.

- First, there is a description of what the activity involves.
- Second, we reference the key definitions used.
- Third, we set out a flow chart as a decision path that we suggest are the steps that a provider should go through in considering whether their services will fall within the regulated activity. We recommend that, for completeness, providers should go through these for all activities.

Note that, in this document, where the word ‘treatment’ is used in a general sense, it should not be interpreted as shorthand for the activity of ‘treatment of disease, disorder or injury’. Instead, it relates to the general definition of treatment within the regulations.

At this point, we remind readers that the regulations are complicated and this document is a guide to them but not a substitute. We recommend that providers should also check their service against the regulations: it is ultimately providers’ responsibility to check their need to register against the regulations, and this document cannot give more than guidance and help with navigating and interpreting the regulations. Providing a regulated activity without registration for it is a serious offence.

A few questions are separated out in the guidance as additional questions, and do not have yes/no answers. These are designed to help consideration of whether the activity covers the whole of a provider’s service or just part of it, in a few cases where feedback suggests a risk of providers applying for too few activities. If the activity only covers part of the service, the provider may have to register for multiple activities in order to cover it fully.

How regulated activities relate to each other

Registration for each regulated activity is formally a separate registration in its own right even though, for convenience, CQC allows multiple registrations to be covered in one application form.

It will be entirely normal for many providers to register for multiple activities, to the extent that providers should not expect only to register for one. Most activities include some aspects that are very broad (and so may overlap with other activities) and some aspects that are very specific. It is for this reason that we recommend that providers need to consider their service against every activity, and we have set this guidance out in a highly structured way so as to enable that.

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

The only cases where registration for one activity will remove the need to register for another, are:

- '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' or where it is part of 'accommodation and nursing or personal care in the further education sector'.

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 elsewhere. 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

The complete list of regulated activities is:

1. Personal care
2. Accommodation for people who require nursing or personal care
3. Accommodation for people who require treatment for substance misuse
4. Accommodation and nursing or personal care in the further education sector
5. Treatment of disease, disorder or injury
6. Assessment or medical treatment for people detained under the Mental Health Act 1983
7. Surgical procedures
8. Diagnostic and screening procedures
9. Management of supply of blood and blood derived products
10. Transport services, triage and medical advice provided remotely
11. Maternity and midwifery services
12. Termination of pregnancies

13. Services in slimming clinics
14. Nursing care
15. Family planning services.

1. 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, in the place where they are living. This might capture, for example, a domiciliary care agency.

Providers do not need to register for this activity where they are registered to provide service users with accommodation together with the personal care. Where the provider provides 'accommodation for persons who require nursing or personal care' or 'accommodation and nursing or personal care in the further education sector' they will not need to register additionally for the activity of 'personal care' within that service. However, each service needs to be considered in its own right and where personal care is provided that is not together with accommodation it cannot be covered by the registration for that service if it is separate. In addition, CQC will normally impose conditions on a provider so as to restrict an activity to a given location. These conditions will mean that where a provider runs a care home at location A and a domiciliary care service from location B, a registration for 'accommodation for persons who require nursing or personal care' at A will not cover the provision of 'personal care' from B, which needs to be registered in its own right.

This activity may be combined with any other activities that are provided to service users (such as nursing care or diagnostic and screening procedures). It may form part of a list of activities that a provider is registered for.

This activity covers the direct provision of personal care. This does not include providing 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.

This activity does not cover personal care in prisons, or similar custodial establishments (such as immigration removal centres). Hospitals where patients may be detained under the Mental Health Act are not counted as custodial settings.

Definitions

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;

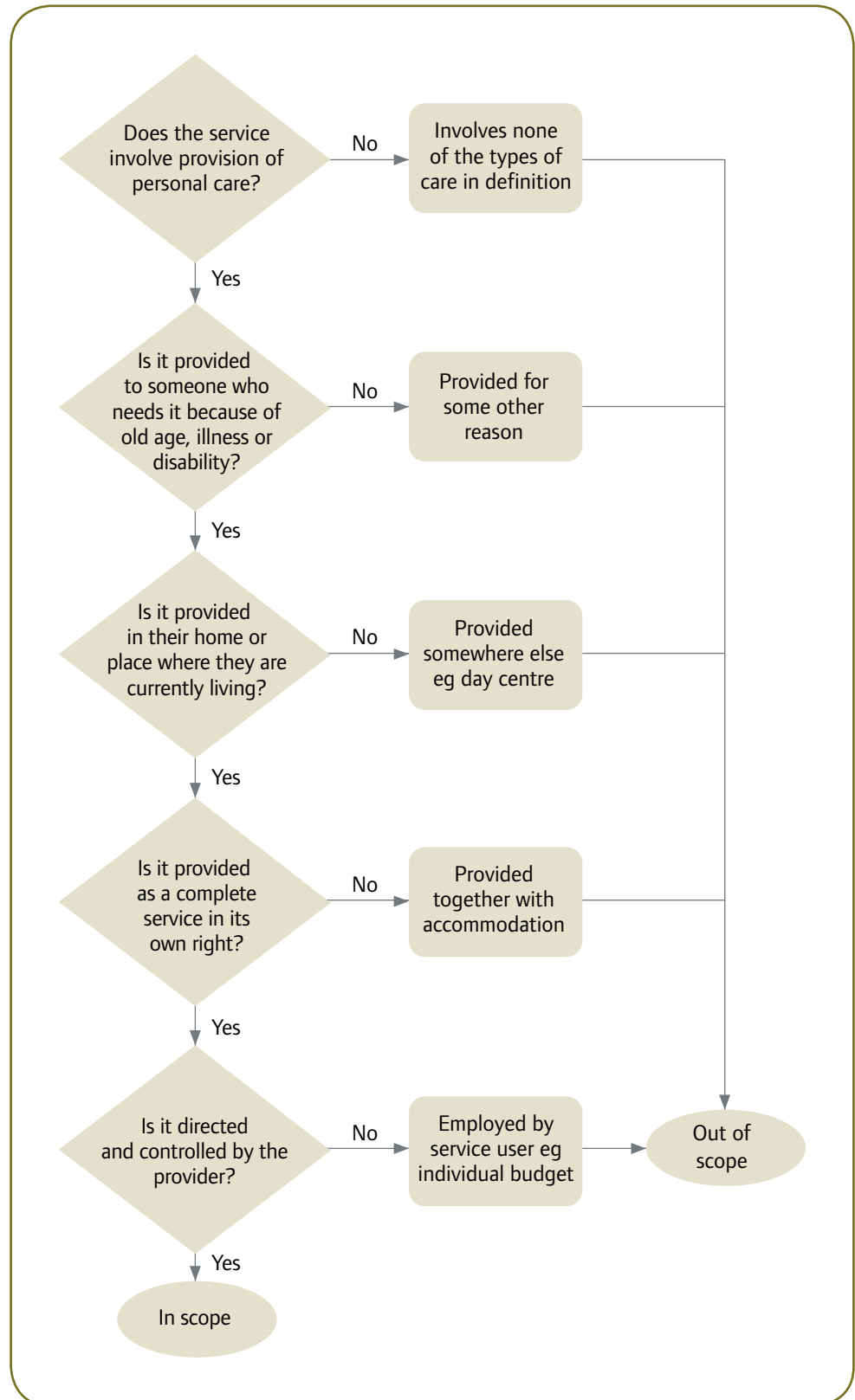
- (iv) Dressing;
- (v) Oral care; and
- (vi) The care of skin, hair and nails (with the exception of nail care provided by a chiropodist or podiatrist);

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” means that services where staff prompt and directly supervise a person when they are carrying out the above actions (i)-(vi). Supervision will normally include direct observation of the action as it is carried out or otherwise checking on how it carried out, but will not normally include merely encouraging someone to perform the activity, or checking at some point afterwards on whether it has been done.

Decision flow chart for 'personal care'



2. Accommodation for people who require nursing or personal care

Description

The regulated activity consists of providing 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. We have further advice on this issue at www.cqc.org.uk in the section called ‘guidance for professionals’.

The provision of residential accommodation includes arranging accommodation through Shared Lives schemes (previously known as adult placement schemes), and these schemes will be captured where they arrange accommodation with personal care. The individuals who directly provide the personal care together with accommodation in their own home, to someone who lives there with them under one of these schemes, are not captured. In other words, an individual Shared Lives carer will not need to register, but the provider of the Shared Lives scheme will.

This activity is registerable wherever it is provided. Previous exemptions, such as the “28 day rule” for short-term, small Shared Lives schemes, no longer apply; nor does the “five year rule” exemption for placements for an 18-year-old which started more than five years previously when he/she was under 13.

This activity cannot be combined with a registration for the regulated activities of ‘personal care’ or ‘nursing care’ in the same service. This is because those activities can form part of this one and it would be redundant to register for them twice in one service. It can however be combined with other activities. For example, a care home that also has intermediate care or palliative care services, may need to consider the need to register in addition for ‘treatment of disease, disorder or injury’. This activity does not cover schools and the further education sector: a separate activity (below) is designed to reflect further education providers, while school services are generally registered with Ofsted.

Definitions

Personal care is included in the earlier sections on definitions.

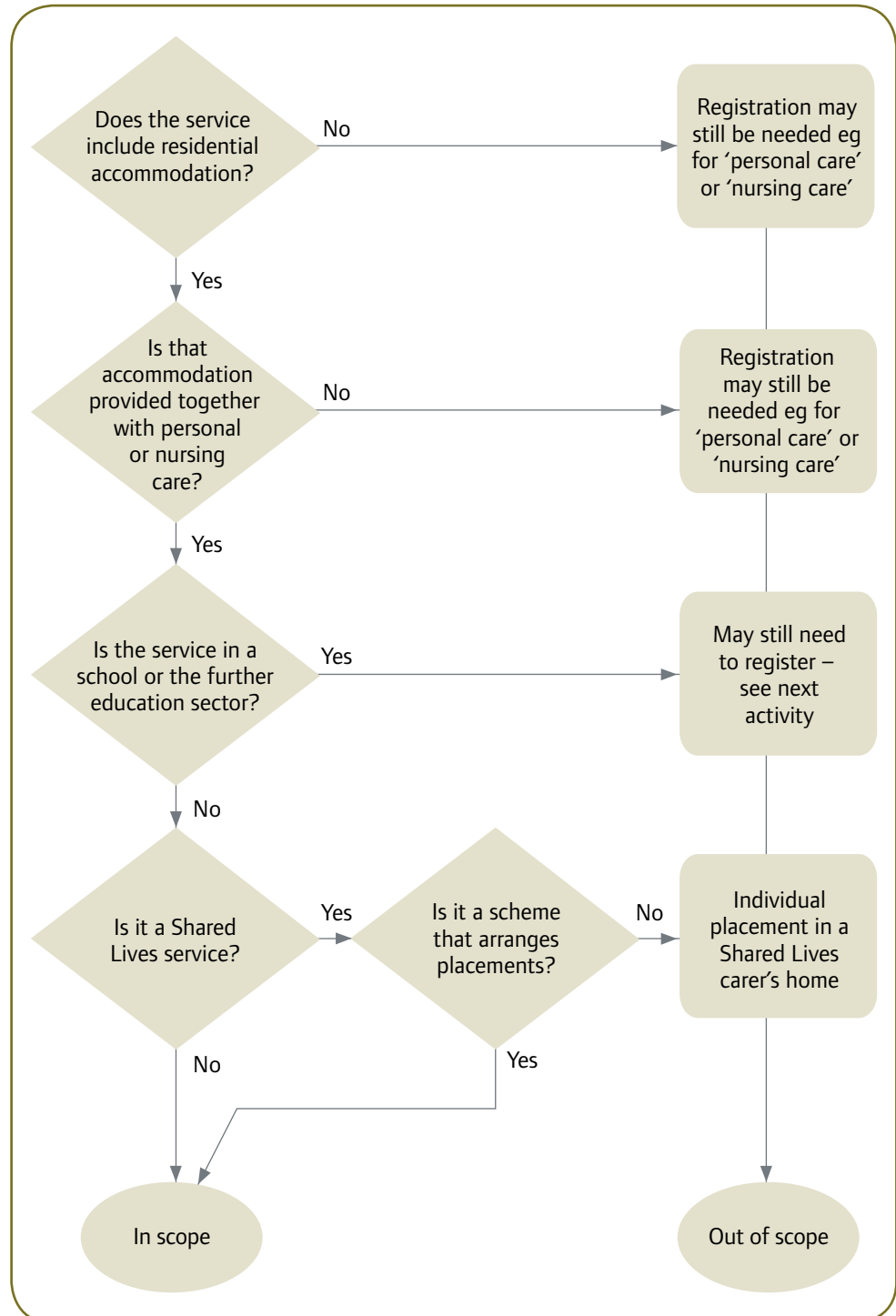
Nursing care is defined as any services provided by a registered nurse and involving the provision of care or the planning, supervision or delegation of the provision of care. However this does not include any services which, having regard to their nature and the circumstances in which they are provided, do not need to be provided by a registered nurse.

The regulations refer to adult placement schemes, although in normal usage these are called Shared Lives schemes. Adult placement 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 placement carers;

making arrangements for the placing of service users with adult placement carers; and supporting and monitoring placements.

Similarly, the regulations refer to adult placement carers, who in every day language nowadays are normally called Shared Lives carers. An adult placement carer is an individual who provides (or intends to provide), personal care for service users together with, where necessary, accommodation in the individual's home.

Decision flow chart for 'accommodation for people who require nursing or personal care'



3. Accommodation for people who require treatment for substance misuse

Description

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

Because this concerns “residential” accommodation, it is not the same as inpatient detoxification treatment. The accommodation has to be “together with” treatment. This does not necessarily mean that the treatment be provided in the same place as the accommodation (it could be on a different site), or even by the same provider (as this activity is about providing accommodation, not about providing treatment). However the accommodation and the treatment must be linked to the extent the accommodation is for someone who requires treatment. That is, acceptance of that treatment will be a requirement for the accommodation.

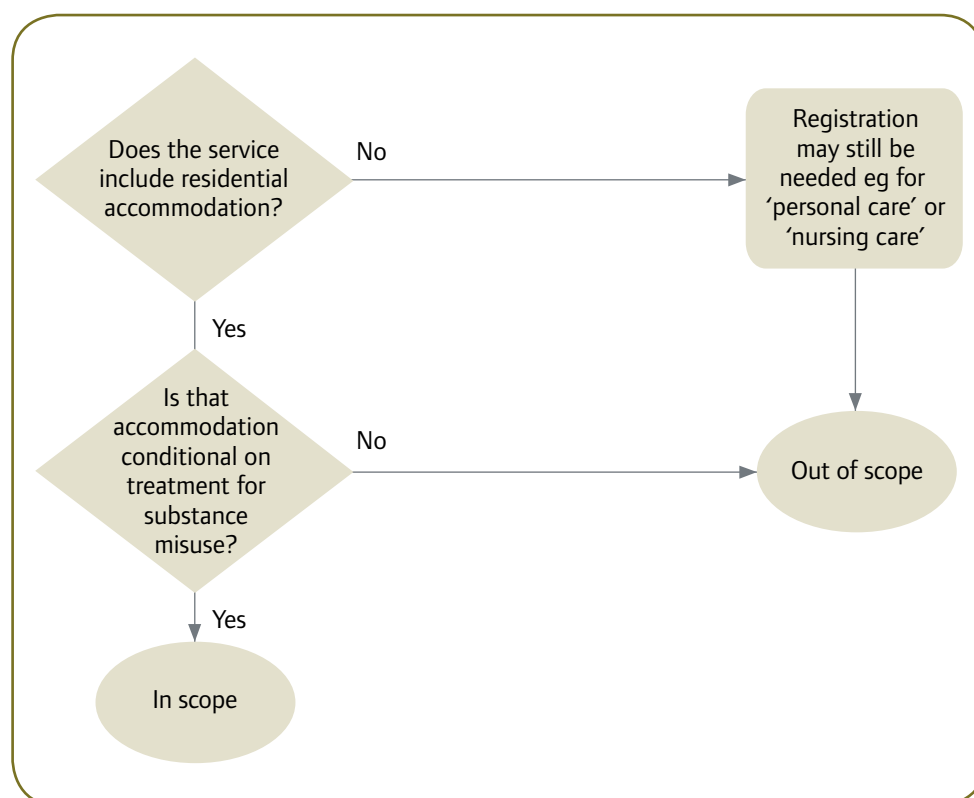
This activity does not include reference to any other regulated activity. If any other activities are provided as part of the service, they may require additional registration. For example, whoever provides the treatment to the people receiving accommodation, is likely to have to register for ‘treatment of disease, disorder or injury’.

Definitions

The definition of treatment is that it includes (but is not limited to):

- A diagnostic or screening procedure carried out for medical purposes.
- The ongoing assessment of a service user’s mental or physical state.
- Nursing, personal and palliative care.
- The giving of vaccinations and immunisations.

Decision flow chart for 'accommodation for people who require treatment for substance misuse'



4. Accommodation and nursing or personal care in the further education sector

Description

This activity is very similar to 'accommodation for people who require nursing or personal care', and will generally include the type of residential care services that care homes and care homes with nursing provide. However, in this case it is with the condition that the regulated activity must be provided in an institution within the further education sector.

Furthermore, the number of people to whom personal care or nursing care is provided, must be at least 10% of the total number of students in the institution in the further education sector who are provided with education and accommodation. We will normally judge this by considering student numbers over 12 months, rather than just on a single day.

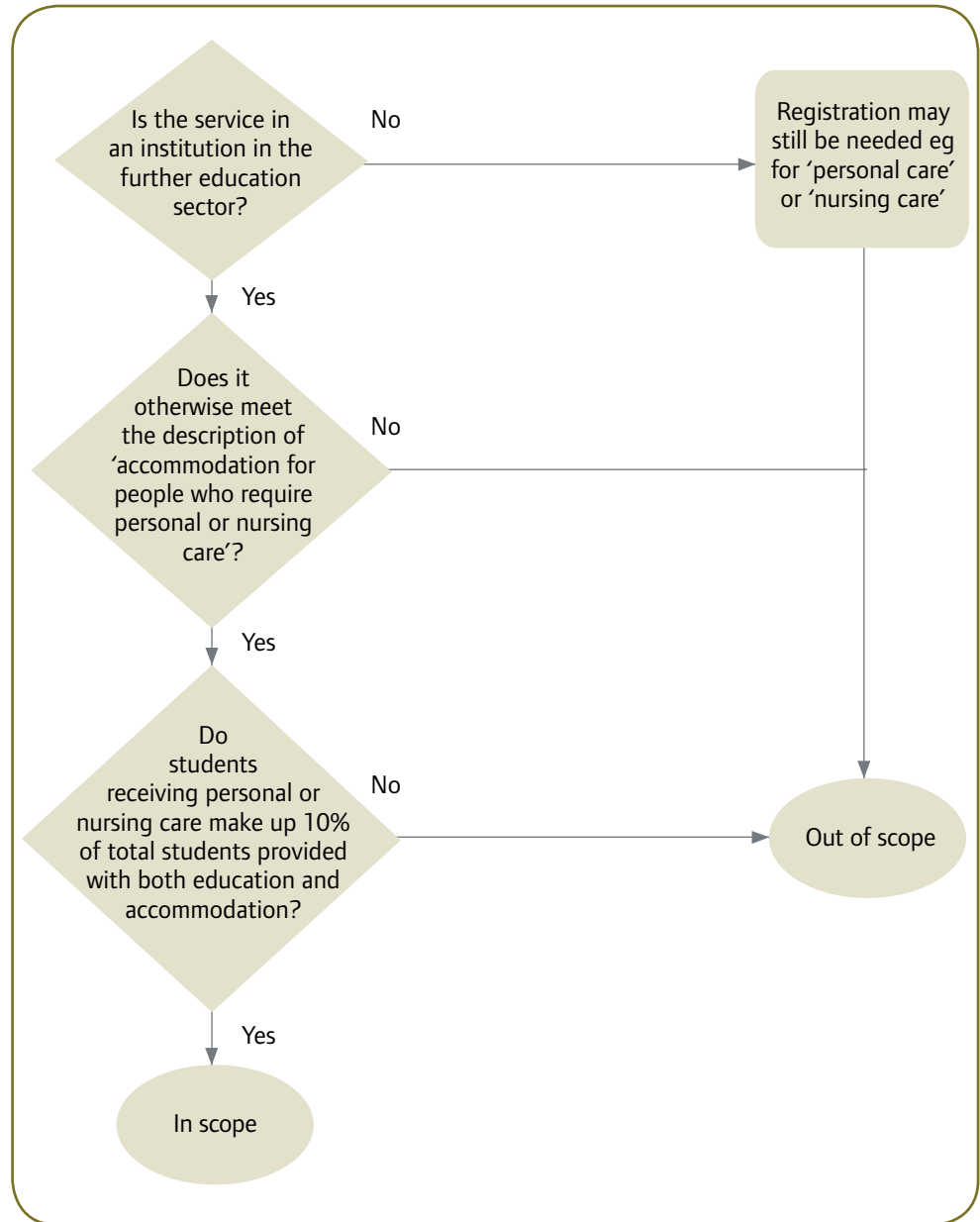
A service registered for this activity does not usually need registration for the regulated activities of 'personal care', 'accommodation for persons who require personal or nursing care' or 'nursing care' as those are generally contained within this activity already. Registration for this activity may be in combination with other regulated activities however, such as 'treatment for disease, disorder or injury'.

Definitions

Personal care and nursing care are defined as in the definitions sections above.

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.

Decision flow chart for 'accommodation and personal or nursing care in the further education sector'



5. Treatment of disease, disorder or injury

Description

This activity allows for a treatment service that is (a) provided by a healthcare professional (or social worker in the case of mental health treatment) or by a multi-disciplinary team including one, and (b) related to disease, disorder or injury. It will include a wide range of treatment such as emergency treatment, ongoing treatment for long-term conditions, and treatment and care for mental health problems and learning disabilities; but it will not include

treatment that is not for disease, disorder or injury, such as purely cosmetic interventions. It applies to treatment of disease, disorder or injury in any setting, ranging from hospitals to clinics, hospices, ambulances and community services.

The principle is that a provider will require registration for this regulated activity if the service includes treatment, is carried out by or under the supervision of a listed professional, and is intended to treat disease, disorder or injury. However, there may be occasions when the person providing treatment is not acting in the capacity of a healthcare professional, even if holding a professional qualification (for example, a beautician undertaking an aesthetic service who is also qualified as a nurse). Equally, there may be times when it is unclear if the service constitutes treatment (for example, some interventions which are normally aesthetic, such as laser hair removal, may also be undertaken in response to a clinical disorder), or it may be unclear if it is for a disorder (for example, being overweight may not always be considered formally to be a disorder). These scenarios will however be rare, and will need consideration on a case by case basis.

Healthcare professionals are defined – for the purpose of this activity only – by a list (see below). If a multi-disciplinary team includes one of these healthcare professionals (or a social worker in the case of mental health treatment or care), then the activity will be within scope as a provider of the activity. For example, clinical psychologists, occupational therapists, physiotherapists and speech and language therapists are not included in the list, and so standalone services run by these professionals are not required to register. But where such professionals work in multi-disciplinary teams with anyone from the list below, the service will need to be registered and the registered provider must ensure compliance in all aspects of the treatment provided, including the components provided by these professionals, if it provides treatment for a disease, disorder or injury.

The inclusion of a registered social worker along with healthcare professionals is only relevant where the social worker is involved in the treatment of a mental disorder. Where social care staff are involved in mental health care which is not treatment (for example, in care home or supported living services), those will still be subject to registration if they fall into the definition of other regulated activities such as ‘accommodation for persons who require nursing or personal care’.

Healthcare professionals and social workers are only relevant to this regulated activity where they are involved in it in their capacity as a healthcare professional or social worker. For example, a psychiatrist may also be qualified as a psychotherapist. Where he or she practises as a psychiatrist – a registered medical practitioner – it may be captured by this activity. Where he or she practises as a psychotherapist, it would not be captured by this activity unless it is combined with treatment by others from the list of healthcare professionals or social workers. That is because “psychotherapist” does not feature on the list of healthcare professionals and while an individual is practising in that capacity, any other qualifications that they may have but are not currently using, are not relevant. This principle will apply in the same way to many other services in addition to the example given (for example,

where a doctor undertakes aesthetic procedures but, in doing so, is acting in the role of a beautician rather than using medical qualifications).

The activity is not for all types of treatment. It does not include surgical procedures; diagnostic or screening procedures; assessment or medical treatment for patients who are detained under the Mental Health Act; or services in slimming clinics. Those activities must be registered separately in their own right (although they will normally be registered in addition to this activity).

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' will still require registration in these cases in its own right, in addition to any other activities that the provider may need to register for that service. Where those services are provided by another body (such as a primary care trust), the guidance on hosted services earlier in this document will apply.

'Treatment of disease, disorder or injury' may also be provided, sometimes as a secondary purpose, in research settings. It is still registerable in those cases.

'Treatment of disease, disorder or injury' does not include alternative and complementary treatments. This means that they are never included in this activity. Osteopathy and chiropractic are not included in this exemption and are not counted as alternative and complementary treatments. In practice, osteopathy and chiropractic will not normally be captured but that is for a different reason: it is because they will normally be provided by an osteopath or a chiropractor, who do not feature in the list of healthcare professionals below. But because they are not specifically exempt, then just like any other type of treatment, they will still fall within this regulated activity if they are provided by a healthcare professional from the list, or if they are provided as part of a multi-disciplinary team that includes a healthcare professional from the list.

Treatment provided in a sports ground or gymnasium (so long as it is only for people taking part in, or attending, sporting activities or events), and treatment provided through temporary arrangements for sporting or cultural events (such as festivals, or the Olympic Games), are also exempt from this activity. This means that they are never included in this activity (they may however be captured within other activities, for example if they include diagnostic procedures). This will include "exercise on prescription" type schemes where the exercise constitutes a treatment, and it is within a sports ground or gymnasium (these would of course be exempt anyway if they do not involve a listed professional).

The final two exemptions in this activity are for treatment that is covered by other regulatory regimes.

- 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.

- IVF treatment where it is covered by a licence from the Human Fertilisation and Embryology Authority (HFEA). This only applies to the aspects covered by an HFEA licence. Any other aspects of IVF which are provided, but which are not regulated by HFEA, may still require registration under this activity. Those other aspects may fall into this activity and/or other activities, such as ‘diagnostic and screening procedures’.

The scope regulations do not restrict ways in which this activity may be combined with others. A complex hospital provider, for example, may need to register for a number of regulated activities in addition to this one.

Definitions

The definition of treatment is as in earlier definitions sections, i.e. that it includes (but is not limited to):

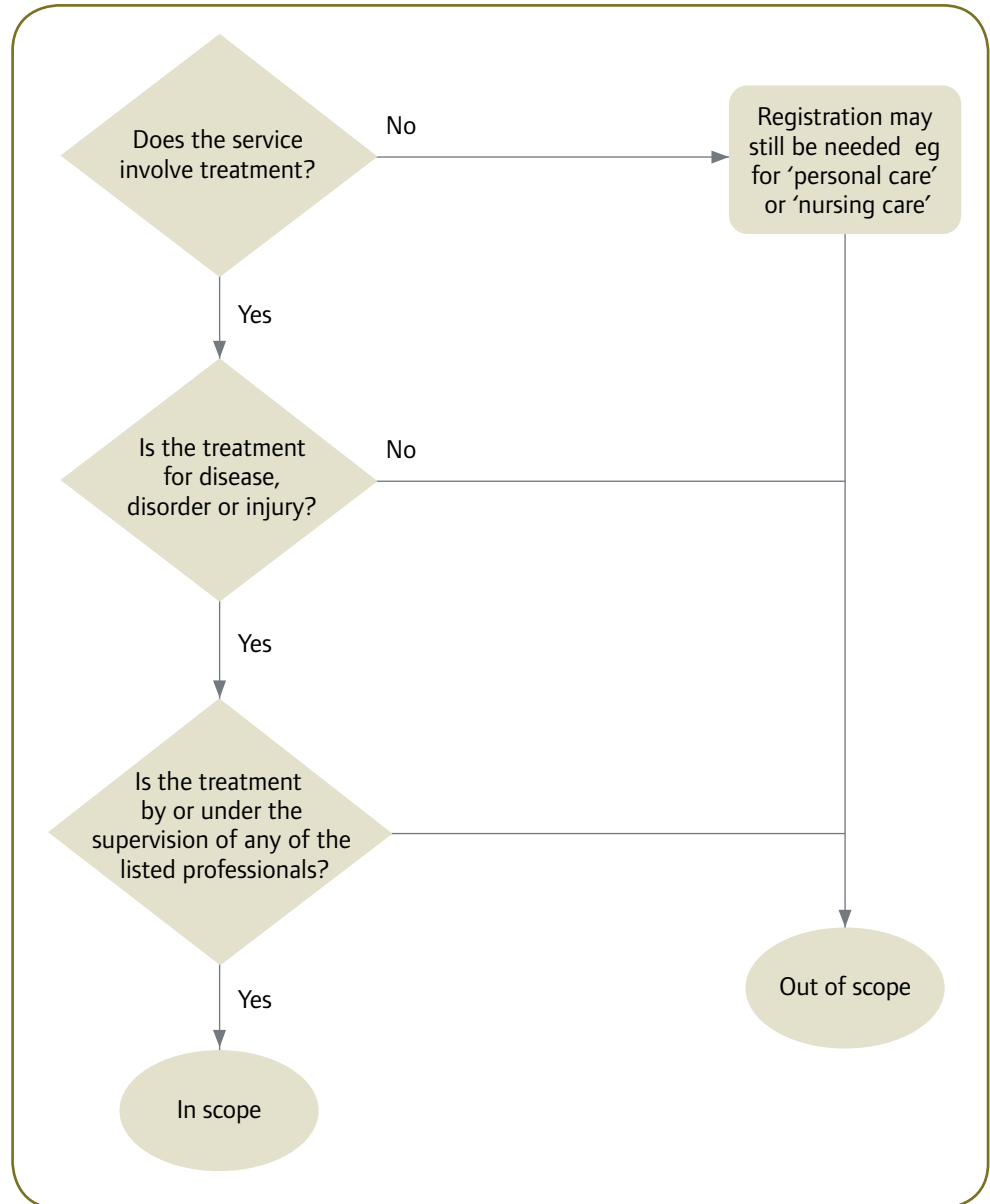
- A diagnostic or screening procedure carried out for medical purposes.
- The ongoing assessment of a service user’s mental or physical state.
- Nursing, personal and palliative care.
- The giving of vaccinations and immunisations.

A mental disorder is defined as any disorder or disability of the mind, including dependence on alcohol or drugs.

A healthcare professional is defined, uniquely and for the purpose of this 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.

Decision flow chart for 'treatment of disease, disorder or injury'



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

Description

This activity concerns where people are detained or recalled for treatment (not including surgery) or assessment under the Mental Health Act 1983. This activity also applies where a person is detained in a hospital under another enactment and that detention is deemed to take place under the Mental Health Act 1983. It applies to hospitals, rather than any other settings, and it excludes detention to a place of safety under sections 135 or 136 of that Act (for example, neither a police station nor an accident/emergency department designated as a place of safety will not be captured as part of this activity).

Registration for this activity may be required for any assessment or medical treatment of people under the Mental Health Act's provisions for detention and recall. It could therefore apply to providers other than specialist mental

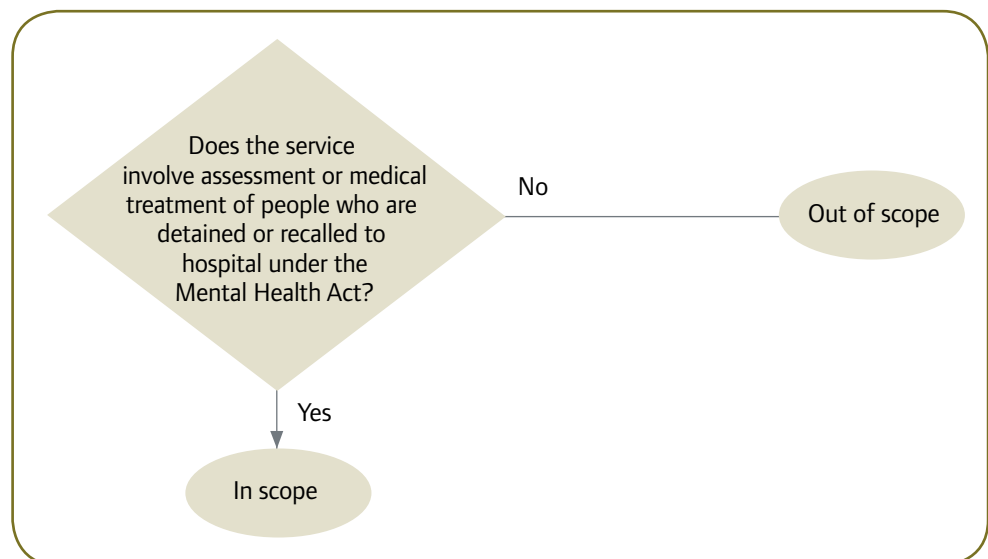
health hospitals (for example, acute hospitals) but only where there is assessment or treatment related to mental health – see the definition of medical treatment below.

The activity can be combined with registration for any other activities.

Definitions

Medical treatment, as included uniquely in this activity only, is defined in the Mental Health Act as including nursing, psychological intervention and specialist mental health habilitation, rehabilitation and care; and to be construed as a reference to medical treatment the purpose of which is to alleviate, or prevent a worsening of, a mental disorder or one or more of its symptoms or manifestations.

Decision flow chart for ‘assessment of medical treatment for people detained under the Mental Health Act 1983’



7. Surgical procedures

Description

This activity covers surgical procedures if they are:

- For the purpose of treating disease, disorder or injury; or cosmetic surgery; or for religious observance (eg circumcision), and
- Carried out by a healthcare professional.

Minor surgical procedures are however 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 (procedures sometimes referred to as “lumps and bumps”), and
 - which involves the use of local anaesthesia (or no anaesthesia).

or

- Undertaken by any healthcare professional but are limited to:
 - nail surgery and nail bed procedures on the foot (eg minor podiatric procedures – not the same as the “lumps and bumps” described above), and
 - involve the use of local anaesthesia (or no anaesthesia).

The way that this activity is set out does not create any limits on how it may be provided in combination with other activities. It covers surgical “procedures”, which may not constitute the entirety of the treatment and care that a service provides, and combination with other activities is likely to be the norm rather than the exception. For example, use of imaging techniques in surgery may require registration for ‘diagnostic and screening procedures’ and where there are consultations or treatment that go beyond surgical procedures, that may require registration for ‘treatment of disease, disorder or injury’.

This activity does however cover all pre- and post-operative care associated with the procedures. That care must be associated with the procedures. In relation to pre-operative care this might include, for example, assessment by an anaesthetist shortly in advance of the procedures (where that assessment is an assessment of safety and suitability directly related to the procedures) but would not include an initial consultation with a surgeon before the procedures had been decided.

Similarly in relation to post-operative care, the activity must be related to the procedures 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. It will not include unplanned use of intensive care, for example.

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.

To summarise, the key principles are:

- 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 healthcare teams that may be taking place at the same time.

Surgical procedures carried out for religious reasons, such as circumcision, are included where carried out by a healthcare professional. Where a religious leader is also a healthcare professional, we will assume that he or she is acting in his/her capacity as a healthcare professional for the surgical procedures, on the grounds that a registered healthcare professional's code of practice will prohibit them from disregarding the need for appropriate skills, experience, equipment and facilities for this procedure and they cannot 'opt out' of their core duties and responsibilities as a registered professional.

Definitions

A healthcare professional is someone who is registered with the Health Professions Council, Nursing and Midwifery Council, General Medical Council, General Dental Council, General Pharmaceutical Council, General Osteopathic Council, General Optical Council or General Chiropractic Council, and any professional in due course who is included within a "Section 60" order of the Health Act 1999.

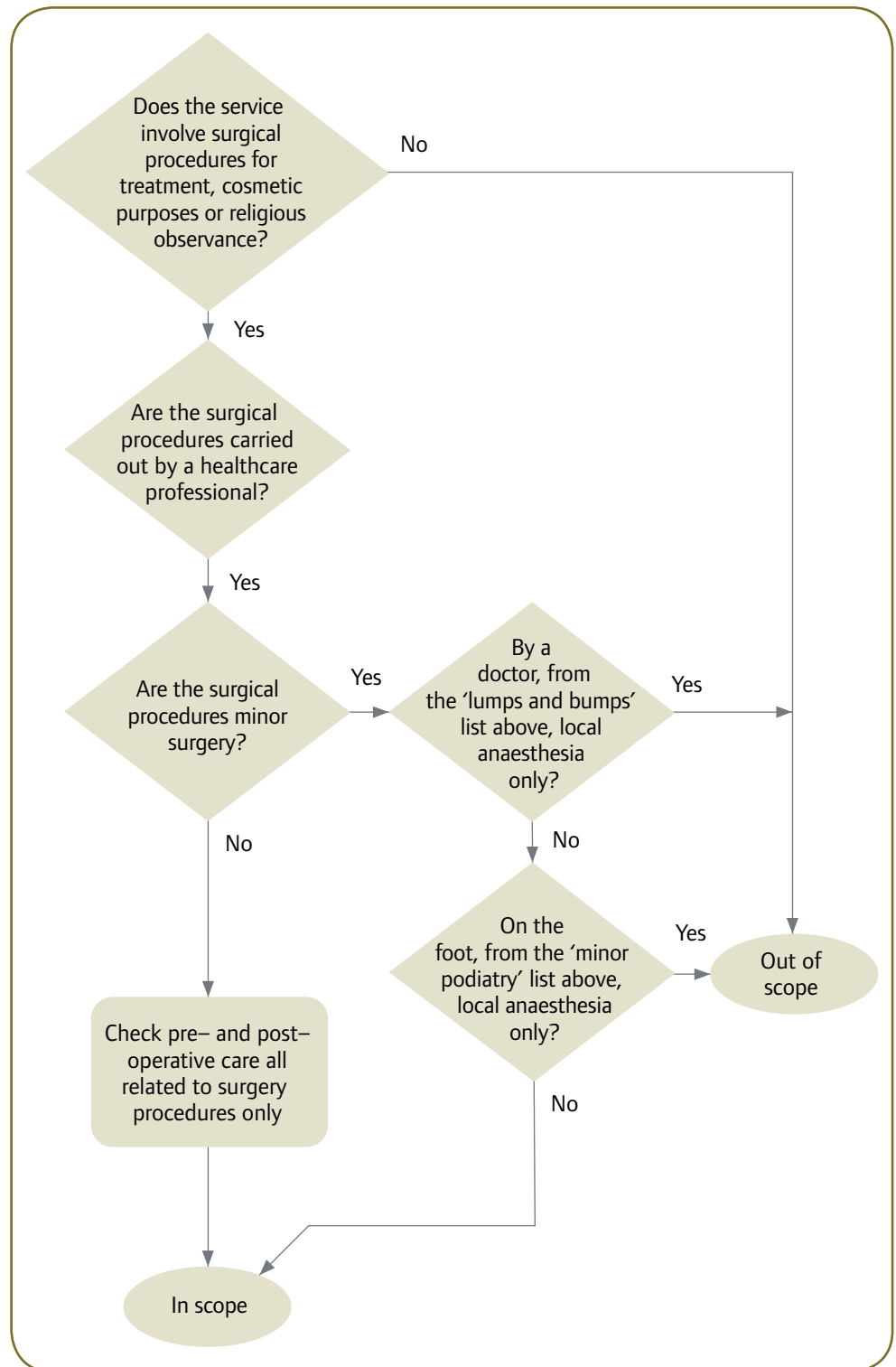
A medical practitioner is a doctor who is registered with the General Medical Council.

Local anaesthesia is defined, so that it means any form of anaesthesia other than general, spinal or epidural, with regional nerve blocks also not counted as local anaesthetic.

Cosmetic surgery is not defined as such but the procedures that are captured are described as being for cosmetic purposes and involving the insertion of instruments or other equipment into the body. For the avoidance of doubt, these do not include:

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

Decision flow chart for 'surgical procedures'



8. Diagnostic and screening procedures

Description

This 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 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, some forms of interventional radiology or treatment involving ultrasound (those may require registration for the activity of 'treatment of disease, disorder or injury').

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

- Equipment, and
- Insertion of that equipment into the body, and
- Use of that equipment to either view inside of the body (eg imaging), or gather physiological data (eg measure or monitor functioning).

The activity includes many, if not all, 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. This will include taking blood (other than pin prick tests) but will not normally include urine samples, because the sample must be 'removed'. It will also capture the analysis of those samples or biopsies, as it includes any use of equipment to examine cells, tissue or fluids to assess causes or extent of disease, disorder or injury.

So anyone who 'removes' tissue, cells or fluids from the body for diagnostics must register, and so must anyone who uses equipment to analyse those samples. If those are the same provider, 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.

However, analysis must involve the use of 'equipment' such as microscopes, centrifuges, etc. It would not include simple addition of a chemical substance (for example, in occult blood tests). Furthermore, the equipment must be used to examine cells, fluids or tissue taken from the body – such as a microscope. For example, this will not include equipment that is used to examine changes in a chemical substance when that substance interacts with bodily cells, fluids or tissue (such as reagent strip used in a pregnancy test).

Physiological measurement is also captured where it includes use of equipment for measurement or monitoring of the following, in order to monitor the cause or extent of disease, disorder or injury, or response to treatment, in order to inform the planning or delivery of treatment and care:

- Hearing system and balance (audio-vestibular system)
- Heart and vascular system
- Gastro-intestinal system
- Neurological system
- Vision system
- Respiratory system
- Urinary system.

The procedures described above will generally require registration wherever they are provided, including for example use of imaging within surgery or treatment, and use of physiological measurement. This applies whether the procedure is carried out by a healthcare professional or by anyone else. Furthermore, the analysis and reporting of the results of any of these procedures will similarly be captured.

So where diagnostic procedures are provided, all aspects are generally captured. A provider that only provides part of a diagnostic service will still need to register (for example, carrying out scans but not the reporting of them; or just doing the reporting on scans that have been done abroad). Where diagnostic images are reported remotely by a subcontracted provider overseas, the overseas subcontractor will be outside the Care Quality Commission's remit. However, we will hold the client who has made the contract with the subcontractor to account to ensure that they have made appropriate arrangements, including arrangements for quality assurance.

There are also some significant exemptions from this activity.

- The national cancer screening programmes are excluded. Other national screening programmes (eg for chlamydia) are not excluded however and must register if they are providing any aspect of the regulated activity.
- Certain minor procedures are not captured. They are:
 - use of an auroscope (other non-invasive audio testing will also usually be exempt: they will not be captured unless they involve the use of equipment that is used to “measure or monitor physiological data” in the person being tested)
 - the use of pin-prick blood tests which do not need to be sent to a specialist facility for analysis (e.g. to a laboratory).
- The use of x-ray by registered chiropractors, and the use of ultrasound by registered physiotherapists, are excluded from this activity.
- Fitness screening procedures in a gymnasium, related to the use of fitness equipment or fitness activities, are exempt (treadmill tests for clinical purposes however are not).

Standalone genetic testing is not included. The analysis of samples of bodily tissues, cells or fluids in order to determine the existence of a genetically inherited disease or disorder, or the use of such tests to determine the influence of an individual's genetic variation on a drug response, are exempt unless they are provided not on a standalone basis but as part of:

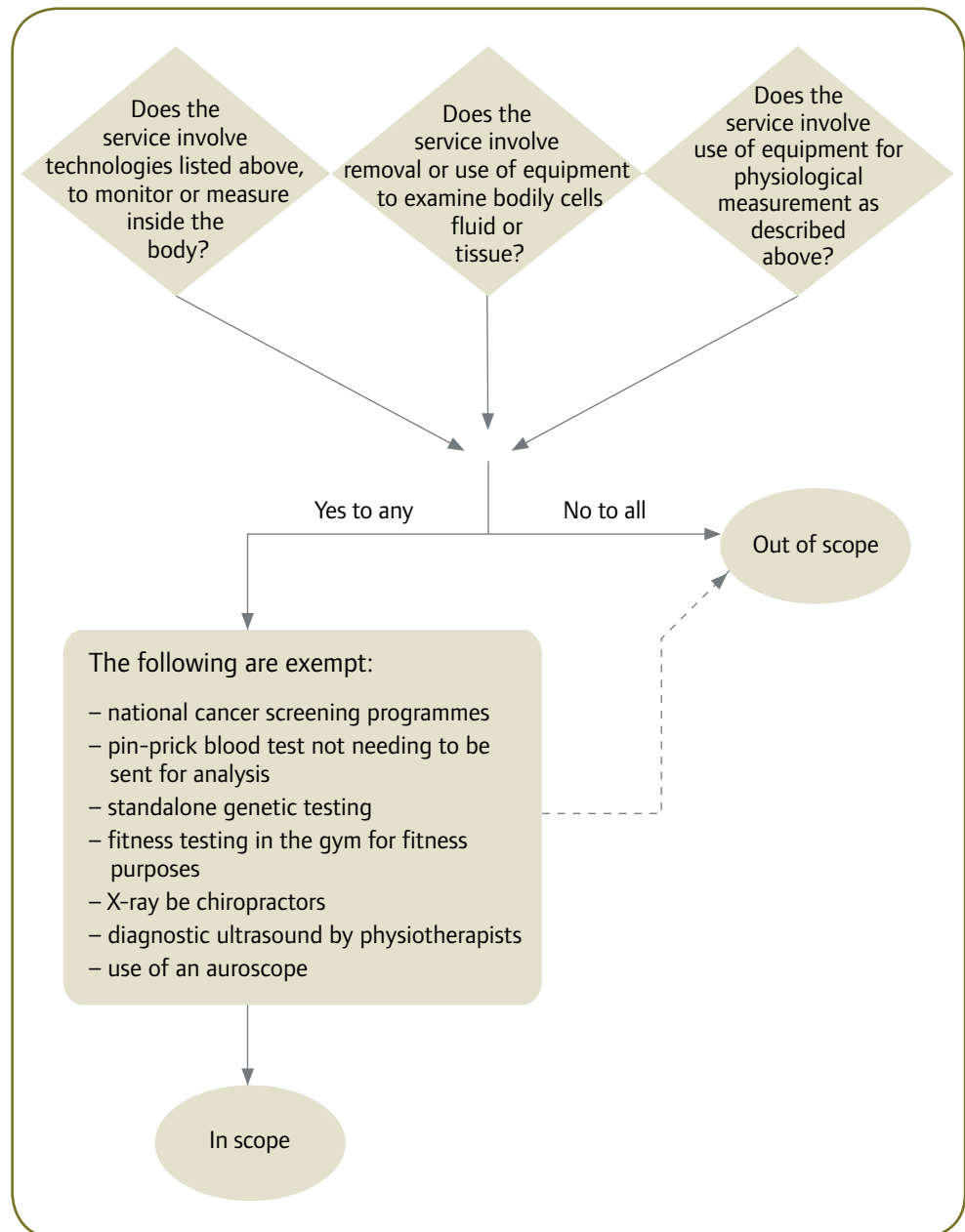
- The planning or delivery of treatment or care.
- A national screening programme (except for the cancer screening programmes which are themselves exempt).

This activity is not set out in a way that impacts on any other activities. A service provider may be registered for it in combination with any number of other activities. This activity is not restricted to services by healthcare professionals.

Definitions

There are no additional definitions for this activity.

Decision flow chart for 'diagnostic procedures'



9. Management of supply of blood and blood-derived products

Description

This activity covers:

- The supply of blood, blood components and blood-derived products for transfusion (for example, this will include supply of blood by NHS Blood and Transplant, a service to supply blood by one provider to another provider or a service from a dedicated unit set up for that purpose, such as

a central or regional facility set up to provide this service to individual hospitals in a corporate group).

- 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).
- 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 side from donors).

In relation to blood and tissue products, this activity concerns the management of supply. That does not include storage of, and access to, 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. Supply of these products outside of a provider's regulated activity – for example, an arrangement for a large hospital to supply bloods or tissue to a smaller one – would however be captured.

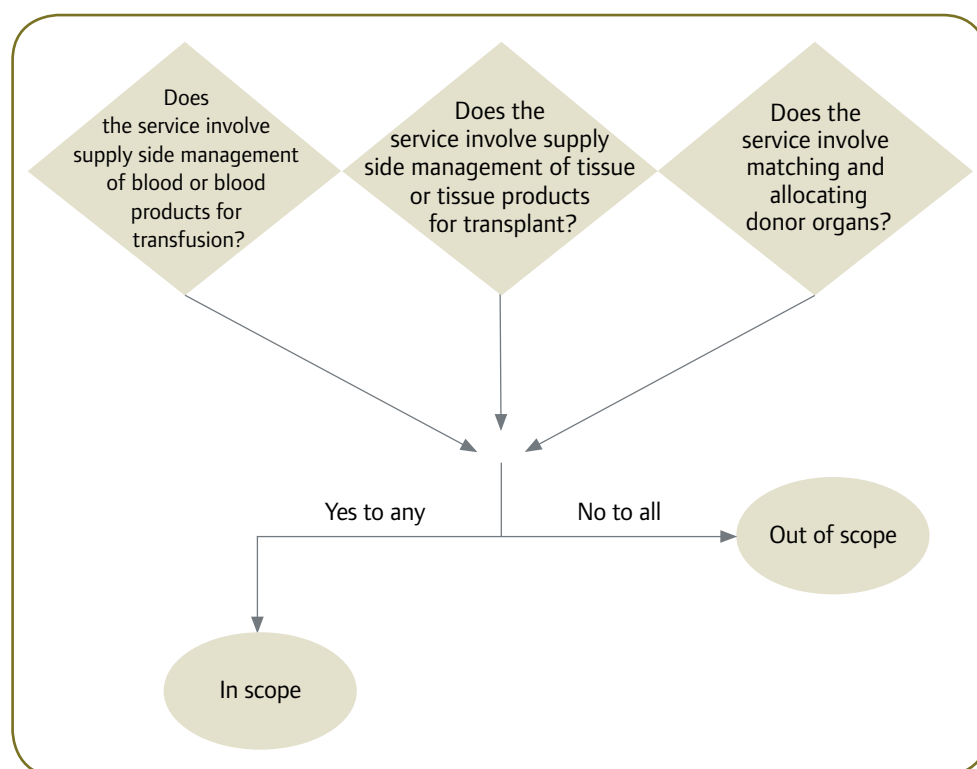
It does not capture autologous transplant, in which tissue is taken from an individual and stored, in order to be implanted back into him/her later. In addition, it does not capture situations in which a provider's role is only to harvest an organ where the patient has chosen to be a donor (for example, harvesting an organ from a deceased patient), where a separate agency such as NHS Blood and Transplant will be responsible for supplying onward to transplantation services.

In relation to donor organs, stem cells or bone marrow, the activity covers the whole of the supply side (matching and allocation, from donation). It does not cover the demand side issues such as managing requests or waiting lists for transplantation (which may, for example, be undertaken as part of transplant coordinators' roles).

Definitions

There are no additional definitions for this activity.

Decision flow chart for 'management of supply of blood and blood derived products'



10. Transport services, triage and medical advice provided remotely

Description

This activity covers two main service types: transport (ambulance) services, and remote clinical advice.

Transport services are captured by this activity where they are in a vehicle which has the transport of people who require treatment as the primary purpose that it is designed for. This will exclude vehicles which have a different primary purpose, such as taxis, volunteers using their private cars, or mortuary vehicles and Dial-A-Ride vehicles which, even though they may be registered with DVLA as ambulances, are not used primarily for people in relation to their treatment. Search and rescue helicopters and coastguards' boats will similarly be excluded as their primary purpose is different, but if they provide any other regulated activity (such as 'treatment of disease, disorder or injury') they may still need to register for that.

The way in which vehicles trigger the need to registration, will require registration for ambulances operated by hospital providers, as well as providers of ambulance only services. The idea of the vehicle being designed for transport of people who require treatment is not limited to the manufacturer's original design concept but includes any way in which the vehicle is made suitable for this purpose (e.g. modification, livery, etc).

This 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'. CQC's view is that this activity will normally cover routine, planned patient transport related to treatment. Where treatment is included, it will normally require additional registration for 'treatment of disease, disorder or injury' and we will take a proportionate and reasonable approach if emergency, unplanned treatment in this context includes some aspects of other activities on an exceptional basis (such as 'diagnostic and screening procedures', 'surgical procedures' or 'maternity and midwifery services').

Remote advice is captured by this activity when:

- The advice is medical (ie clinical in nature), and
- It is responsive, i.e. for immediate attention or action (as opposed to, for example, a service in which questions may be submitted and responses provided at some later time, or general healthcare or lifestyle advice is sought) or it constitutes triage, 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 whose purpose includes immediate telephone or internet-based medical advice will be captured (eg some telemedicine advisory services such as those for people with long-term conditions).
- Ambulance control centres will be captured where they provide triage by means of telephony.

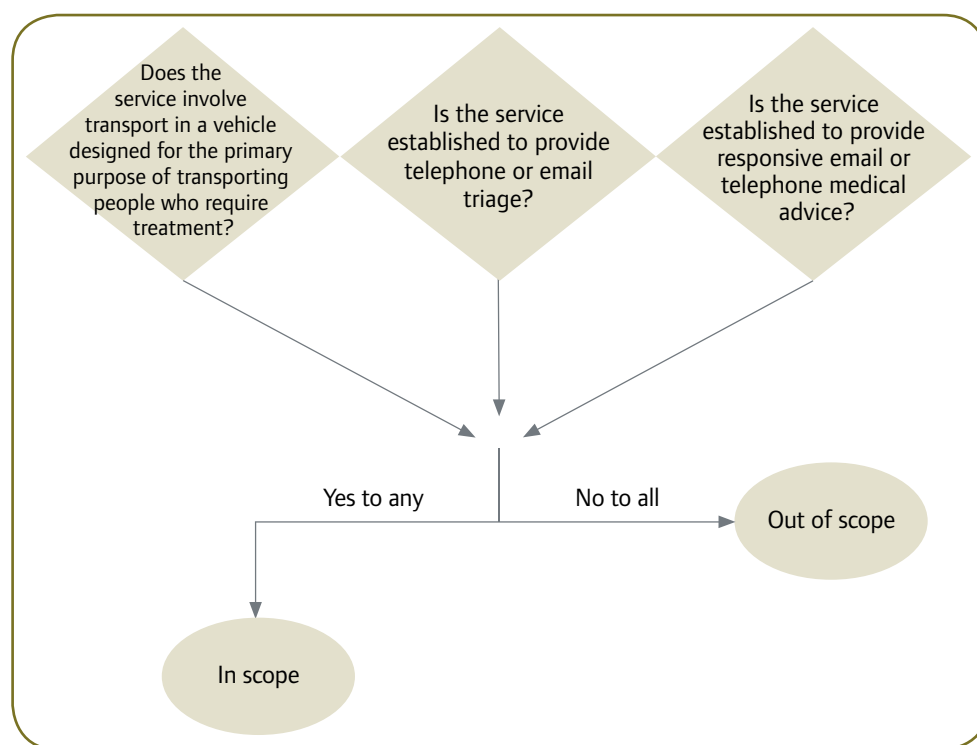
Definitions

A vehicle in this context includes an air ambulance or a water ambulance.

Premises (and therefore any associated requirements of registration) include vehicles.

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.

Decision flow chart for 'transport services, triage and medical advice provided remotely'



11. Maternity and midwifery services

Description

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

Organisations that provide advice, support or education related to childbirth and parenting are not included in this activity, so long as the provision of healthcare is not their main business. This means that a hospital would not become exempt by virtue of providing advice, because its main purpose is healthcare. But an organisation which is not primarily a healthcare provider and which provides this advice (such as the National Childbirth Trust) would not have to register, even if the advice is provided by a healthcare professional.

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' own homes (e.g. not as part of a hospital or clinic based service).

For the avoidance of doubt, this activity does not capture arrangements that local social services authorities may make under schedule 20 of the NHS Act 2006, for the care of pregnant women and women who are breastfeeding.

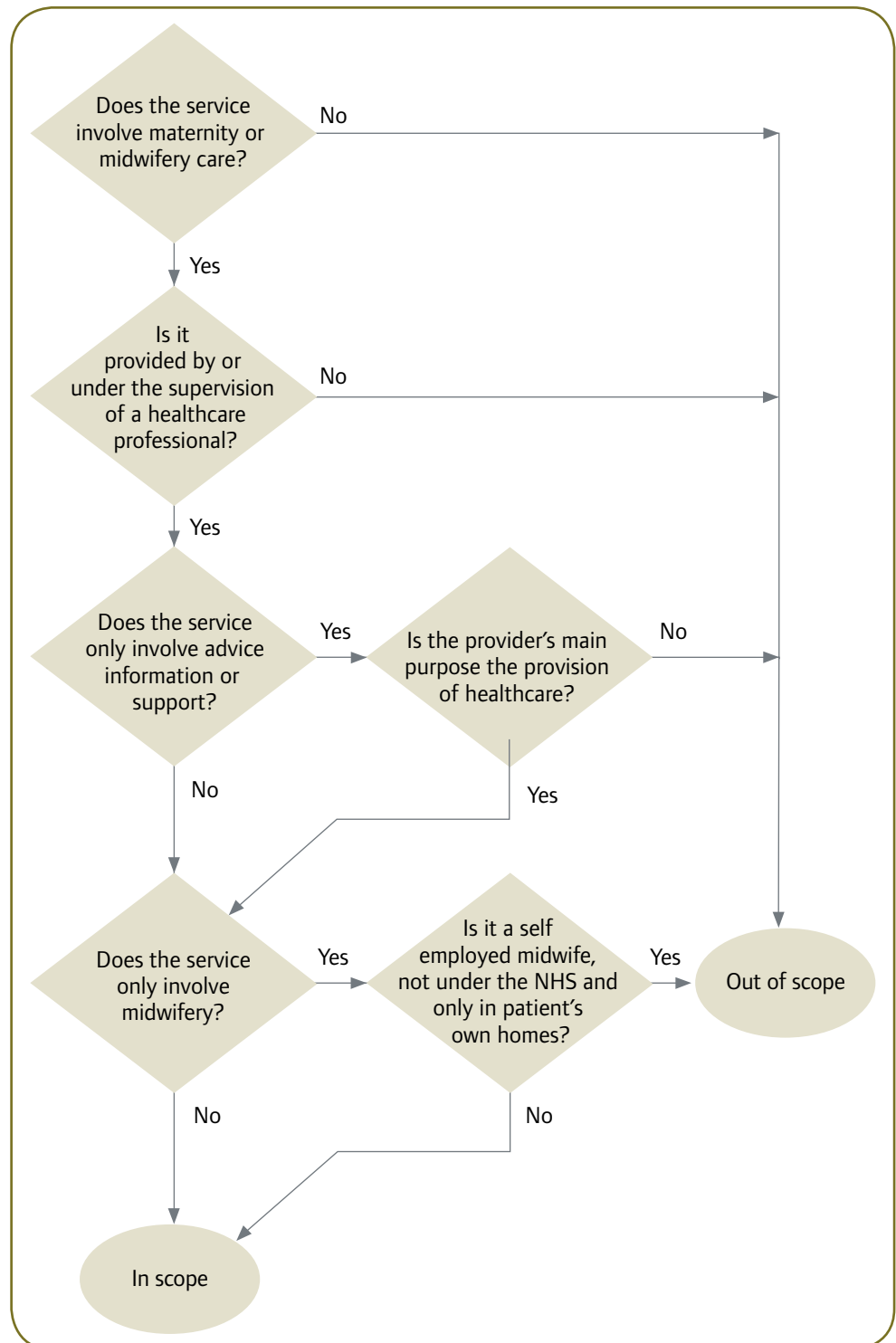
Where antenatal services are provided as part of primary medical care, the current exemptions for primary medical care may apply (see section two of this guidance). But where maternity services are provided as a community or outreach service that is part of the community nursing service (as opposed to a GP practice) or is an outreach service from a hospital, it is likely to need to register even if it is organised so as to be located alongside primary care services.

This activity is not set out in a way that limits how it could be provided in combination with other activities.

Definitions

A healthcare professional is someone who is registered with the Health Professions Council, Nursing and Midwifery Council, General Medical Council, General Dental Council, General Pharmaceutical Council, General Osteopathic Council, General Optical Council or General Chiropractic Council, and any professional in due course who is included within a "Section 60" order of the Health Act 1999 (as set out above under 'surgical procedures').

Decision flow chart for 'maternity care and midwifery'



12. Termination of pregnancies

Description

The termination of pregnancy, by any method such as either surgical or medical, is included in this activity. Advice on termination of pregnancy is not. The "morning after pill" is not a form of termination of pregnancy where it constitutes emergency contraception and has its effect before the earliest stages of implantation. Some medicines used as emergency contraception

may however also be used to terminate a pregnancy. Where they are used in that way (which is normally clearly set out in their licensing and prescribing guidance), their use will require registration under this regulated activity.

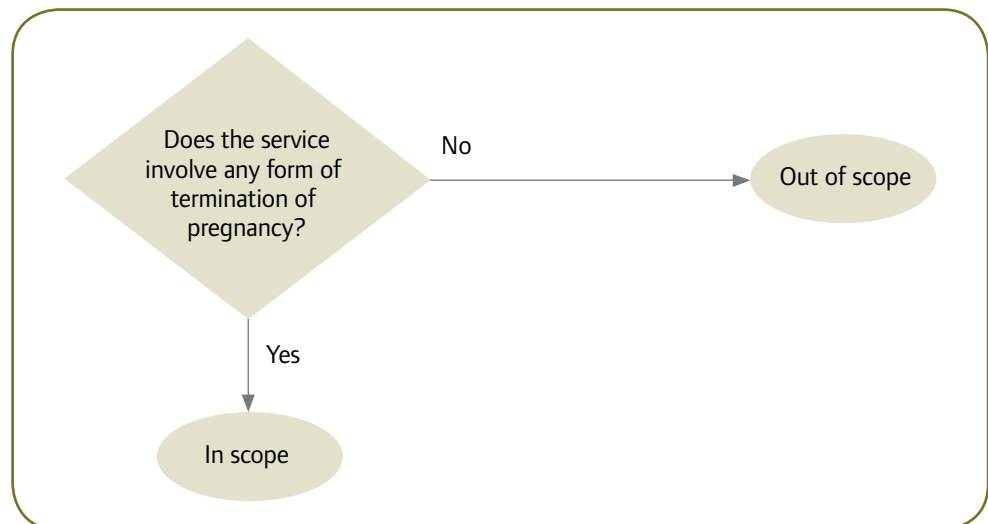
Where the service provider is a non-NHS provider, attention is drawn to regulation 20 of the Care Quality Commission (Registration) Regulations 2009, SI no. 3112, which can be read at www.opsi.gov.uk/si/si200931. These regulations place certain obligations on registered providers. They are also reflected in CQC's *Essential Standards of Quality and Safety*.

This activity is not set out in a way that limits how it could be provided in combination with other activities. Providers may need to register for other services in addition, such as 'surgical procedures' if surgical abortions are performed or 'treatment of disease, disorder or injury' if a termination is provided alongside treatment services.

Definitions

There are no additional definitions for this activity.

Decision flow chart for 'termination of pregnancy'



13. Services in slimming clinics

Description

This activity captures any service provided in a slimming clinic which:

- Consists of advice or treatment, including prescription of medicines for the purpose of weight reduction, and
- Is provided by, or under the supervision of, a registered medical practitioner.

"Clinic" in this activity means a physical location rather than a clinical session or service.

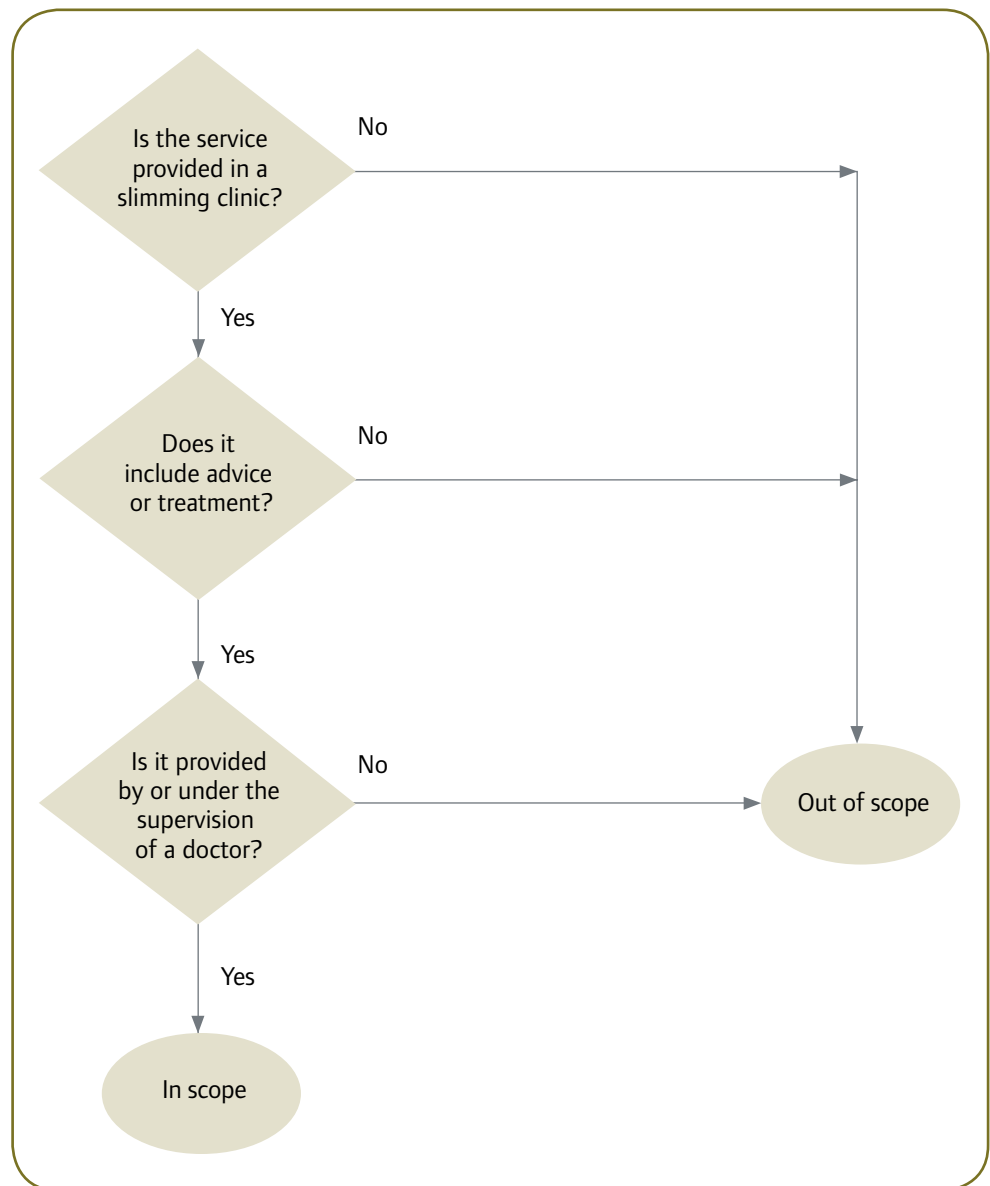
The activity is not set out so as to limit the ways that it could be provided in combination with other activities, for example 'diagnostic and screening procedures'. In particular, the activity mentions treatment (in the general

sense) and only elaborates on this by indicating that it includes prescription of medicines for weight reduction. This means that it may still be necessary to register for the activity of 'treatment of disease, disorder or injury' if the treatment is for a disease, disorder or injury and involves a healthcare professional (see above, earlier in this section). As noted above in relation the regulated activity of 'treatment of disease, disorder or injury', there may be occasions when case by case consideration is needed of whether the service is for overweight and obesity that constitute a disorder, or whether it is for purely aesthetic purposes.

Definitions

There are no additional definitions for this activity.

Decision flow chart for 'services in slimming clinics'



14. Nursing care

Description

This activity captures nursing care, where it is not part of another regulated activity. If nursing care is provided as part of another activity, then this activity cannot apply. The effect is that this activity normally covers services which do not constitute treatment as such, for example health visiting, sexual health advisory services, smoking cessation services, or other services which require a registered nurse's involvement but are not one of the other activities.

If 'nursing care' is provided as part of 'treatment of disease, disorder or injury' at location A, the provider will not need to register for both but only for 'treatment of disease, disorder or injury'. If the provider also runs a 'nursing care' service at location B, which is not part of 'treatment of disease, disorder or injury' or any other activity, then the exemption from registering for 'nursing care' at A does not cover location B, as 'nursing care' is an activity at B in its own right. The provider would have to register for 'nursing care' at location B. Furthermore, if two services are provided from the same location, but are each organized so that they separate in their own right, then each will need registration. For example, a community health centre may be registered for 'treatment of disease, disorder or injury' and may also host a health visiting service, which is separate but just happens to be located in the same place. Since health visitors do not provide a treatment service, the health visiting service would need to be registered for 'nursing care' as it is not part of 'treatment of disease, disorder or injury'.

In addition, this activity has the following exemptions.

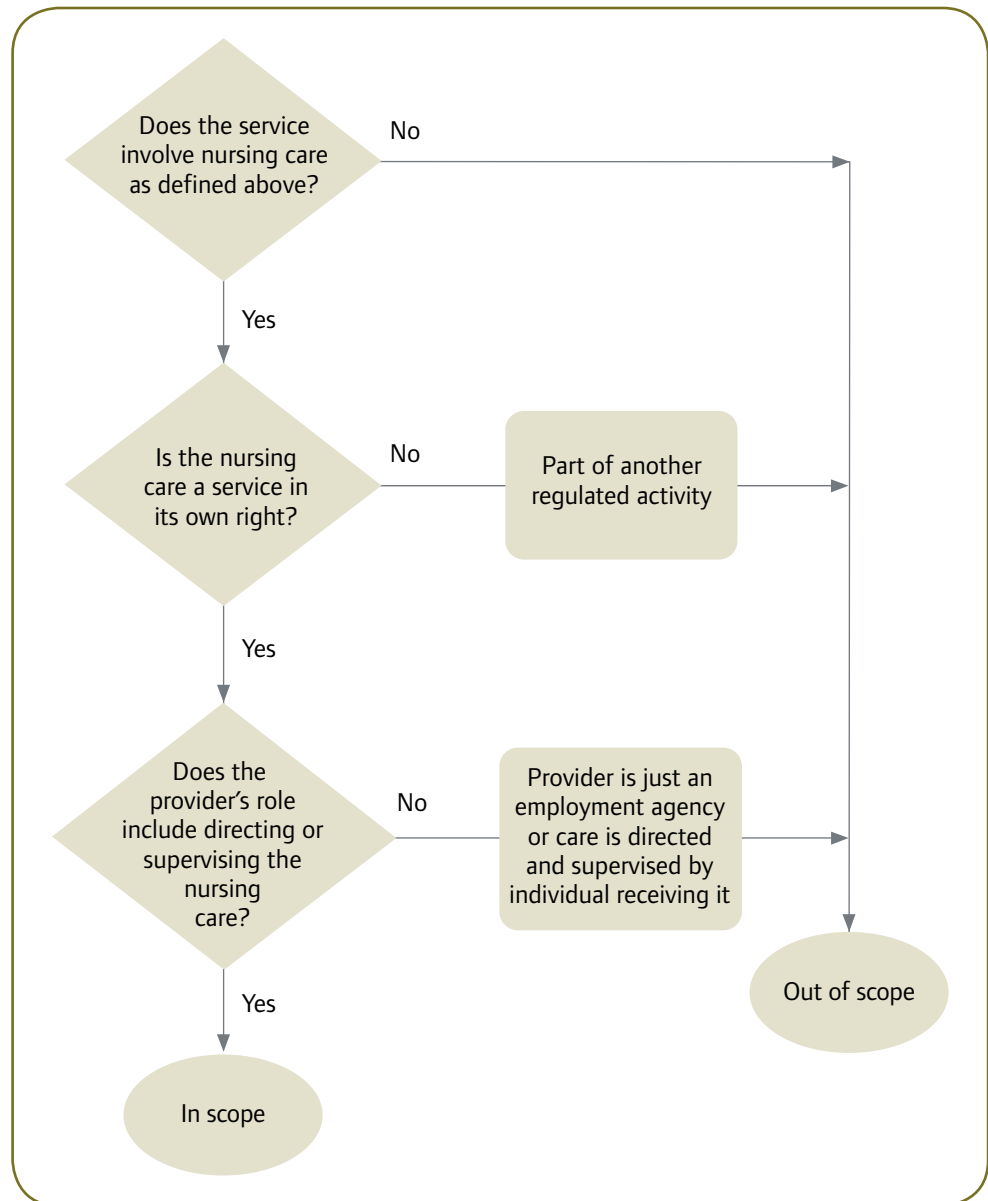
- The supply of nurses on the basis of an employment agency or employment business to another service provider is not captured. Nurses' agencies providing agency or locum nurses who were previously required to register under the Care Standards Act 2000 may no longer have to register because of this exemption.
- Introductory services, through which an individual is put in contact with nurses, from which the individual may select nurses which he/she will then direct, are exempt. This might be, for example, where a nurse is introduced to someone who then 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 an individual makes a private arrangement and secures a nurse for his/her own care, under his/her direction, it 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.

Definitions

Nursing care is defined so that it includes both the provision of care by a registered nurse and the planning, supervision and delegation of care by a

registered nurse. It excludes services that, by their nature or circumstances, do not need to be carried out by a registered nurse.

Decision flow chart for 'nursing care'



15. Family planning services

Description

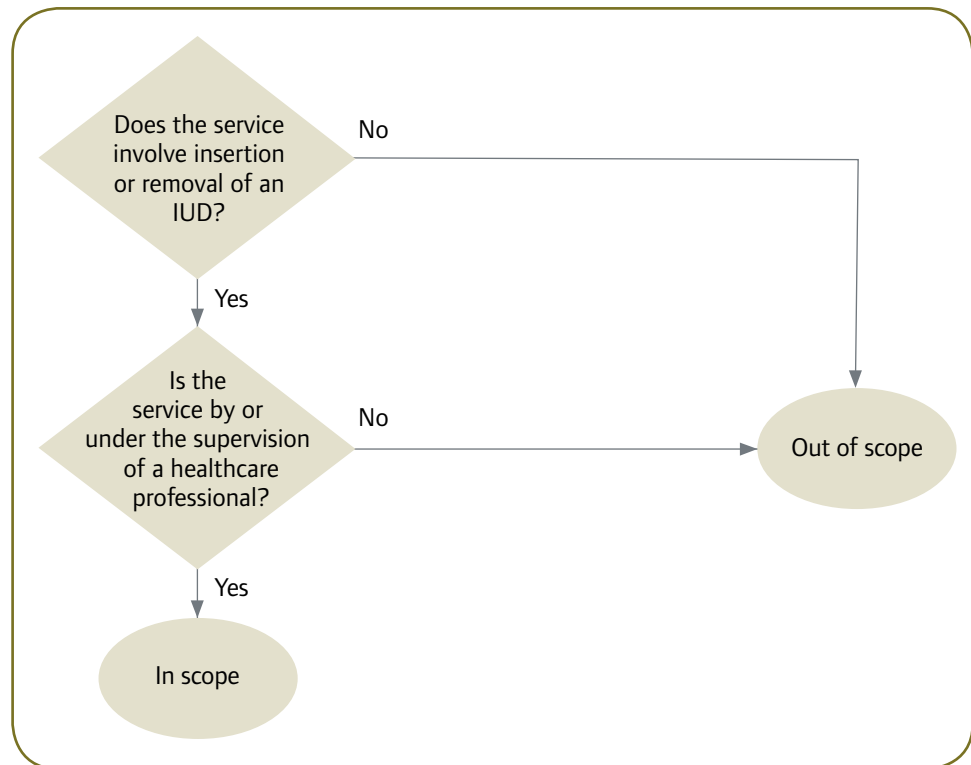
This activity involves services for the insertion or removal of an intrauterine contraception device by, or under the supervision of, a healthcare professional.

The activity singles out this service because it would otherwise usually not be captured within any other activity. It is not set out in a way that limits how it can be provided in combination with other activities.

Definitions

A healthcare professional is as in earlier definitions (see 'surgical procedures').

Decision flow chart for 'family planning services'



16. 'Ancillary' services, and services that fall outside regulated activities

The scope regulations allow for activities (which do not themselves require registration) to be treated as part of a regulated activity if they are carried out wholly or mainly as part of that regulated activity.

In this case, a provider will be registered for a regulated activity; and the other activity, which is ancillary to the regulated activity, will be covered within that registration. This means that a registered provider is accountable for essential levels of quality and safety across the totality of a regulated activity, even where it includes elements that would not otherwise need to be registered. For example, in a hospital with contracted-out catering, the registered provider is responsible for catering as part of its registration, as it is ancillary to regulated activities. They cannot simply disclaim responsibility and claim that standards are the contractor's responsibility.

An ancillary activity cannot be a regulated activity: each always requires registration in its own right.

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