

Guidance about compliance

Here's the detailed guidance about compliance, based on the service types that you've selected.

- Community health care services (CHC)
- Doctors consultation services (DCS)
- Doctors treatment services (DTS)

Involvement and information

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

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

Outcome 1 Respecting and involving people who use services

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Respecting and involving service users

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

(a) the dignity, privacy and independence of service users; and

(b) that service users are enabled to make, or participate in making, decisions relating to their care or treatment.

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

(a) treat service users with consideration and respect;

(b) provide service users with appropriate information and support in relation to their care or treatment;

(c) encourage service users, or those acting on their behalf, to

(i) understand the care or treatment choices available to the service user, and discuss with an appropriate health care professional, or other appropriate person, the balance of risks and benefits involved in any particular course of care or treatment, and

(ii) express their views as to what is important to them in relation to the care or treatment;

(d) where necessary, assist service users, or those acting on their behalf, to express the views referred to in sub-paragraph (c)(ii) and, so far as appropriate and reasonably practicable, accommodate those views;

(e) where appropriate, provide opportunities for service users to manage their own care or treatment;

(f) where appropriate, involve service users in decisions relating to the way in which the regulated activity is carried on in so far as it relates to their care or treatment;

(g) provide appropriate opportunities, encouragement and support to service users in relation to promoting their autonomy, independence and community involvement; and

(h) take care to ensure that care and treatment is provided to service users with due regard to their age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

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What should people who use services experience?

People who use services:

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

Those acting on behalf of people who use services:

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

about their care, treatment and support.

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Ensure personalised care, treatment and support through involvement

1A. People who use services are involved in and receive care, treatment and support that respects their right to make or influence decisions because the service:

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

1B. People who use services have their care, treatment and support needs met because:

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

Manage risk through effective procedures about involvement

1C. People who use services receive care, treatment and support where clear procedures are followed in practice, monitored and reviewed. These procedures ensure that:

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

1D. People who use services benefit from a service that:

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

Promote rights and choices

1E. People who use services, or others acting on their behalf, are supported to make informed choices about their care, treatment and support because they are:

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

1F. People who use services receive care, treatment and support that is provided in a way that ensures their independence is promoted by:

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

1G. People who use services receive care, treatment and support that is provided in a way that ensures their human rights and diversity are respected by:

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

1H. People who use services are provided with information about:

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

1I. People who use services, or others acting on their behalf, are given encouragement, support and opportunities to:

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

1J. People who use services, can influence how the service is run as they are given opportunities to take part in decision making through:

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

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Additional guidance for your selected service types

1K. People who use services can be confident that:

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

Outcome 2 Consent to care and treatment

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

Consent to care and treatment

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

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

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Manage risk through effective consent procedures

2A. Where they are able, people who use services receive the examination, care, treatment and support they agree to. This is because clear procedures to get valid consent are followed in practice, monitored and reviewed. Wherever consent is required these procedures include:

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

informed decision.

- Where treatment is refused explaining the risks and benefits of refusing and the alternative options.
- Respecting and taking account of a decision by the person who uses the service to refuse or withdraw consent.
- Following any advance decision made in line with the Mental Capacity Act 2005 that the person using the service may have made, wherever this is known by the provider.
- The arrangements for taking account of restrictions authorised under the deprivation of liberty safeguards.
- The regular review of consent decisions taking into account the changing needs of the person who uses the service.
- Specific arrangements for seeking consent when a person is taking part in health and care-related research.

2B. People who use services benefit from staff who understand:

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

2C. There are clear procedures that are followed in practice, monitored and reviewed about decision making for people who are unable to give, or choose to withhold, consent for each individual care, treatment and support activity, including:

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

2D. People who use services benefit from a service that:

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

2E. People are able to make a decision about whether or not to give consent because:

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

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Additional guidance for your selected service types

2F. People who use services give valid consent because:

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

2G. People who use imaging services who do not have symptoms indicating that imaging is required must:

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

Outcome 3 Fees

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Fees etc.

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

(a) specifying the terms and conditions in respect of the services to be provided to the service user, including as to the amount and method of payment of fees; and of fees; and

(b) including, where applicable, the form of contract for the provision of services by the service provider.

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

(a) in writing; and

(b) as far as reasonably practicable, provided prior to the commencement of the services to which the statement relates.

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What should people who use services experience?

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

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

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

Manage risk through effective procedures about financial agreements

3A. People who use services, or others acting on their behalf, who pay the provider in full for their care, treatment and support either from private means, money received as a grant, benefit, or an insurance scheme, in order to purchase it:

- Are made aware of the requirement for them to pay for their care, treatment and support and the expected costs.
- Are given the time they need to consider whether they wish to proceed with the care, treatment and support.
- Are not placed under undue pressure to agree to sign an agreement.
- Receive a copy of the agreement they will enter into if they decide to proceed with the care, treatment and support and are given time to consider whether they wish to proceed with it in line with applicable consumer regulations.
- Are given a statement of their account at any time they request it.
- Are given terms and conditions that clarify the actions that will be taken in the event of non payment and/or late payment of fees.
- Receive a final copy of any agreement they sign.
- Are offered a receipt for money they pay to the service.

3B. People who use services whose care, treatment and support funding is paid to the service provider by a third party purchaser but where the person or others acting on their behalf makes a contribution to the provider from their own private means:

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

3C. People who use services who enter into a separate arrangement with a service provider because they choose to pay for additional care, treatment and support which is not contracted on their behalf by a third party purchaser:

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

3D. People who use services benefit from a service that:

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

Promote rights and choices

3E. People who use services who pay the provider in full for their care, treatment and support **and** people who use services who enter into a separate arrangement with a service provider because they choose to pay for care, treatment and support that is not contracted on their behalf by a third party purchaser:

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

3F. People who use services whose care, treatment and support funding is paid to the service provider by a third party purchaser but where the person makes a contribution from their own private means and which is collected by the provider on behalf of a third party purchaser:

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

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Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Personalised care, treatment and support

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

Outcome 4 Care and welfare of people who use services

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Care and welfare of service users

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

(a) the carrying out of an assessment of the needs of the service user; and

(b) the planning and delivery of care and, where appropriate, treatment in such a way as to—

(i) meet the service user's individual needs,

(ii) ensure the welfare and safety of the service user,

(iii) reflect, where appropriate, published research evidence and guidance issued by the appropriate professional and expert bodies as to good practice in relation to such care and treatment, and

(iv) avoid unlawful discrimination including, where applicable, by providing for the making of reasonable adjustments in service provision to meet the service user's individual needs.

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

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

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

4A. People who use services have safe and appropriate care, treatment and support because their individual needs are established from when they are referred or begin to use the service. The assessment, planning and delivery of their care, treatment and support:

- Is centred on them as an individual and considers all aspects of their individual circumstances, and their immediate and longer term needs.
- Is developed with them, and/or those acting on their behalf.
- Reflects their needs, preferences and diversity.
- Identifies risks, and says how these will be managed and reviewed.
- Ensures risk assessments balance safety and effectiveness with the right of the person who uses the service to make choices, taking account of their capacity to make those choices and their right to take informed risks.
- Ensures that plans of care, treatment and support are implemented, flexible, regularly reviewed for their effectiveness, changed if found to be ineffective and kept up to date in recognition of the changing needs of the person using the service.
- Maintains their welfare and promotes their wellbeing by taking account of all their needs, including:
 - physical
 - mental
 - social
 - personal relationships
 - emotional
 - daytime activity.
- Ensures continuity in their care, treatment and support as a result of effective communication between all of those who provide it, including other providers.
- Enables people to maintain, return to, or manage changes to their health or social circumstances.
- Is undertaken to reduce the risk of deterioration in their health status.
- Encourages the prevention and early detection of ill health, including relapse, wherever there are real factors that present a risk to their health and welfare.
- Enables them to make healthy living choices concerning exercise, diet and lifestyle.

Manage risk through effective procedures

4B. People who use services benefit from a service that:

- Reflects on the findings of their service reviews.
- Learns from adverse events, incidents, errors and near misses that have occurred within the service so that the risk of these being repeated is reduced to a minimum.
- Informs them, or others acting on their behalf, if an adverse event, incident or error has occurred in their care, treatment or support that has caused, or may result in, harm and offers a full explanation of what happened along with an appropriate apology or expression of regret.
- Implements and acts upon the recommendations of safety and risk alerts and notices.
- Makes plans in advance of a foreseeable emergency, to ensure the needs of people who use the services will continue to be met before, during and after the emergency. These plans include:
 - defined roles and accountabilities
 - contingency arrangements to respond to additional demands while maintaining the essential standards of quality and safety.
- Takes into account relevant guidance, including that from the Care Quality Commissions Schedule of Applicable Publications (see appendix B), and;
 - any other good practice guidance which relates to the care, treatment and support provided by the service and which is published by a professional or expert body that is relevant.

4C. People who use services can be confident that:

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

4D. People who use services can be confident that:

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

Promote rights and choices

4E. People who use services:

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

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Additional guidance for your selected service types

4H. People who use services can be confident that:

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

4I. Children who use services are:

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

4J. Women undergoing a termination of pregnancy know that:

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

4K. People who use services who are at the end of their life will have their care, treatment and support needs met because, wherever possible:

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

4M. People who use services benefit from a service that:

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

4P. People with a learning disability who use services:

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

4R. People who use services have their needs met through the care programme approach:

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

Outcome 5 Meeting nutritional needs

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider

- Additional prompts for your selected service types

What do the regulations say?

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

Meeting nutritional needs

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

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

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

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What should people who use services experience?

People who use services:

- Are supported to have adequate nutrition and hydration.

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

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

Ensure personalised care by providing adequate nutrition, hydration and support

5A. Where the service provides food and drink, people who use services have their care, treatment and support needs met because:

- Staff identify where the person who uses services is at risk of poor nutrition, dehydration or has swallowing difficulties, when they first begin to use the service and as their needs change.
- Action is taken where any risk of poor nutrition or dehydration is identified including any difficulty in swallowing or the impact of any medicines, and a referral is made to appropriate services.
- They know that their medical dietary and hydration requirements are identified and reviewed.
- Their plan of care includes how any identified risks will be managed.
- Relevant staff know what a balanced diet is.
- Staff involved in food preparation produce food to help facilitate a healthy, balanced diet.
- They have food and drink that:
 - are handled, stored, prepared and delivered in a way that meets the requirements of the Food Safety Act 1990
 - are presented in an appetising way to encourage enjoyment
 - are provided in an environment that respects their dignity
 - meet the requirements of their diverse needs
 - take account of any dietary intolerances they may have.
- They can be confident that staff will support them to meet their eating and drinking needs with sensitivity and respect for their dignity and ability.
- They are enabled to eat their food and drink as independently as possible.
- All assistance necessary is provided to ensure they actually eat and drink, where they want to but are unable to do so independently.
- They have supportive equipment available to them that allows them to eat and drink independently, wherever needed.
- They are helped into an appropriate position that allows them to eat and drink safely, wherever needed.
- They are not interrupted during mealtimes unless they wish to be or an emergency situation arises.
- They will have any special diets or dietary supplements that their needs require arranged on the advice of an appropriately qualified or experienced person.
- They have access to specialist advice and techniques for receiving nutrition where their needs require it.
- The service takes into account relevant guidance, including that from the Care Quality Commissions Schedule of Applicable Publications (see appendix B).

5B. Where the service provides food and drink, but not when this is in the person's own home or Shared Lives arrangement, people have their care, treatment and support needs met because:

- A nutritional screening is carried out to identify where they are at risk of poor nutrition or dehydration when they first begin to use the service and at regular intervals.
- Where a full nutritional assessment is necessary because the nutritional screening identified risk of poor nutrition and dehydration, this is carried out by staff with the appropriate skills, qualifications and experience.
- They have their food and drink intake monitored when they are at risk of poor nutrition or dehydration and action is taken as necessary.
- They are not expected to wait for the next meal if their care, treatment and support means they missed a planned mealtime.
- The person can choose a balanced diet that is relevant to them as an individual, taking account of their nutritional status and previous wishes.

Promote rights and choices

5C. Where the service provides food and drink, people who use services can make decisions about their food and drink because they:

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

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Additional guidance for your selected service types

5D. People who use services benefit from clear procedures followed in practice, monitored and reviewed to ensure they:

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

5E. People who use services:

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

Outcome 6 Cooperating with other providers

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Cooperating with other providers

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

(a) so far as reasonably practicable, working in cooperation with others to ensure that appropriate care planning takes place;

(b) subject to paragraph (2), the sharing of appropriate information in relation to—

(i) the admission, discharge and transfer of service users, and

(ii) the co-ordination of emergency procedures; and

(c) supporting service users, or persons acting on their behalf, to obtain appropriate health and social care support.

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

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

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

Ensure personalised care through adequate coordination of services

6A. People who use services can be confident that when their care, treatment or support is provided by more than one service, team, individual or agency or is transferred from one service, team, individual or agency to another, this is organised so that:

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

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

6B. People who use services can be confident that when information about their care, treatment and support needs to be passed to another service, team, individual or agency this is organised so that:

- The information includes everything the other service, individual, team or agency will need to ensure the needs of the person who uses services are met safely, even when the transfer of information is required urgently. As a minimum this includes:
 - their name
 - gender
 - date of birth
 - address
 - unique identification number where one exists
 - emergency contact details
 - any person(s) acting on behalf of the person who uses services, with contact details if available
 - records of care, treatment and support provided up to the point of transfer
 - assessed needs
 - known preferences and any relevant diverse needs
 - previous medical history that is relevant to the person's current needs, including general practitioner's contact details
 - any infection that needs to be managed
 - any medicine they need to take
 - any allergies they have
 - key contact in the service the person is leaving
 - reason for transferring to the new service
 - any advance decision
 - any assessed risk of suicide and homicide and harm to self and others.
- The information is transferred in time to make sure that there is no delay to the assessment of needs by the other service, team, individual or agency.
- There are no interruptions to the continuity of care, treatment and support for the person who uses services.

Lead effectively to manage risk

6C. People who use services can be confident that when more than one service, team, individual or agency is involved at the same time in their care, treatment and support, or are planned to be in the future, the services provided are organised so that:

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

6D. People who use services benefit from a service that:

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

6E. People who use services can be confident that when more than one service, team, individual or agency is involved at the same time in their care, treatment and support or are planned to be in the future, the transfer of information is organised so that:

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

Promote rights and choices

6F. People who use services can be confident that when more than one service, team, individual or agency are involved at the same time in their care, treatment and support, or are planned to be in the future, the services provided are organised so that:

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

6G. People who use services can be confident that when information about their care, treatment and support is, or needs to be, passed to another service, team, individual or agency this is organised so that the person or others acting on their behalf:

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

6H. People who use services know that they:

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

6I. People who use services are supported to access the care, treatment and support they need by a provider who:

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

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Additional guidance for your selected service types

6M. When children who use services are moving to access adult services, these are organised so that:

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

Safeguarding and safety

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

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

This section covers guidance about compliance on the following regulations:

- Safeguarding people who use services from abuse
- Cleanliness and infection control
- Management of medicines
- Safety and suitability of premises
- Safety, availability and suitability of equipment.

Outcome 7 Safeguarding people who use services from abuse

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Safeguarding service users from abuse

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

(a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and

(b) responding appropriately to any allegation of abuse.

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

(a) unlawful; or

(b) otherwise excessive.

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

(a) sexual abuse;

(b) physical or psychological ill-treatment;

(c) theft, misuse or misappropriation of money or property; or

(d) neglect and acts of omission which cause harm or place at risk of harm.

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

- Take action to identify and prevent abuse from happening in a service.
- Respond appropriately when it is suspected that abuse has occurred or is at risk of occurring.
- Ensure that Government and local guidance about safeguarding people from abuse is accessible to all staff and put into practice.
- Make sure that the use of restraint is always appropriate, reasonable, proportionate and justifiable to that individual.

- Only use de-escalation or restraint in a way that respects dignity and protects human rights, and where possible respects the preferences of people who use services.
- Understand how diversity, beliefs and values of people who use services may influence the identification, prevention and response to safeguarding concerns.
- Protect others from the negative effect of any behaviour by people who use services.
- Where applicable, only use Deprivation of Liberty Safeguards when it is in the best interests of the person who uses the service and in accordance with the Mental Capacity Act 2005.

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Prompts for all providers to consider

Lead effectively to reduce the potential of abuse

7A. People receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur. The provider minimises the risk and likelihood of abuse occurring by:

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

7B. People who use services benefit from a service that:

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

7C. People who use services are protected as staff and others involved in carrying on the regulated activity are not:

1. Able to benefit financially or inappropriately gain from a person who uses services; unless it is in line with their services arrangements which should take account of other relevant professional guidance.
2. Involved in writing wills or bequests of people who use services.
3. Able to use property of people who use services for personal use.
4. Able to borrow money from, or lend money to people who use services.
5. Able to sell or dispose of goods belonging to people who use services for their own gain.

Ensure personalised care

7D. People who use services receive care, treatment and support from all staff who:

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

7E. People who use services receive care, treatment and support from staff who, in relation to safeguarding:

- Know how to identify, report and respond appropriately to suspected or actual abuse because there are clear procedures that are followed in practice, monitored and reviewed.
- Recognise the impact that diversity, beliefs and values of people who use services can have.
- Are aware of and understand what abuse is, including the differences between supporting children and adults who are at risk of abuse.
- Understand the risk factors for abuse and what they must do if a person is being abused, suspected of being abused, is at risk of abuse or has been abused.
- Follow the referral process and timescales as described in all relevant local and national multi-agency procedures when responding to suspected abuse. They will take account of circumstances of the person using the service to identify and respond appropriately to other potential risk of abuse.
- Understand the roles of other organisations who may be involved in responding to suspected abuse to the extent that is appropriate to their role.
- Contribute to actions required including sharing information and attending forums.
- Work collaboratively with all relevant services, teams and agencies to safeguard and protect the welfare of people who use services.
- Cooperate and work collaboratively with all relevant services, teams and agencies during any investigative process.
- Take part in regular reviews of the care, treatment and support outcomes against specific plans for people who use services.
- Are confident to report any suspicions without fear that they will suffer as a result.
- Are confident to report concerns without worrying about consequences as they are aware of their rights under the Public Interest Disclosure Act 1998.
- Follow the protection plan agreed through the multi-agency procedures in order to reduce the risk of further abuse after an actual or suspected case of abuse.

7F. People who use services receive care, treatment and support from all staff who, in relation to restraint:

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

7G. People who use services receive care, treatment and support from staff who, in relation to responding to behaviour that presents a risk to themselves or others:

- Understand the value of a stimulating environment, meaningful activity and effective communication in preventing behaviour that presents a risk,

taking into account that over-stimulation can sometimes adversely impact the behaviour of people who use services.

- Understand what can potentially trigger behaviour that presents a risk for each person or to others.
- Have the skills and knowledge to respond at an early stage and do so to reduce the likelihood of this behaviour happening or re-occurring.
- Respond in a person-centred way.
- Have the opportunities to talk about how they prevent and manage behaviour with others so that learning is shared and the risk of further incidents is reduced.

7H. People who use services benefit from practice where the use of restraint and management of behaviour that presents a risk is:

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

7I. People who use services that have been abused or are suspected of being abused (or where appropriate, people acting on their behalf) are:

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

Promote rights and choices

7J. People who use services have access to information about:

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

7K. People who use services:

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

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Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 8 Cleanliness and infection control

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Cleanliness and infection control

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

(a) service users;

(b) persons employed for the purpose of the carrying on of the regulated activity; and

(c) others who may be at risk of exposure to a health care associated infection arising from the carrying on of the regulated activity,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

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

(a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;

(b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and

(c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—

(i) premises occupied for the purpose of carrying on the regulated activity,

(ii) equipment and reusable medical devices used for the purpose of carrying on the regulated activity, and

(iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection.

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Cleanliness and infection control

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

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

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 9 Management of medicines

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Management of medicines

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

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Providing personalised care through the effective use of medicines

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

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

Manage risk through effective procedures about medicines handling

9B. Where people who use services receive care, treatment and support that involves medicines, the provider has:

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

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

9C. People who use services benefit from a service that:

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

Promote rights and choices

9D. People who use services benefit from a service that:

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

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Additional guidance for your selected service types

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

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

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

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

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

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

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

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

Outcome 10 Safety and suitability of premises

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Safety and suitability of premises

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

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

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

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

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What should people who use services experience?

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

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

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

Ensure the premises are adequate

10A. People who use services and others who work in or visit the premises can be confident that in relation to design and layout, the provider:

- Ensures the premises are suitable for the regulated activity.
- Takes account of identified risks.
- Meets the requirements of The Health and Safety at Work Act 1974 and associated regulations and The Regulatory Reform (Fire Safety) Order 2005 and other relevant legislation.
- Ensures the premises protect people's rights to privacy, dignity, choice, autonomy and safety.
- Ensures the premises have space, heating, lighting and ventilation that conform to relevant and recognised standards.
- Ensures the premises are accessible to people who need to enter the premises and meet the appropriate requirements of the Disability Discrimination Act 1995.
- Ensures the premises are free from preventable offensive odours.
- Ensures the premises are designed and operated in a way that takes account of guidance from expert bodies in relation to specific needs.
- Takes account of the safety needs of people who enter or use the premises, including the safety of children and other vulnerable people where they are permitted to enter.
- Ensures there is space for a relative, carer or friend to be able to be with a child who uses services.
- Ensures that all safety precautions are in place and tested with regard to all specialist equipment and engineering systems that are physically fixed to the premises.
- Ensures care is taken to maintain a suitable and comfortable environment for treatment having regard to the impact from equipment in use.
- Ensures the premises reflect Department of Health published guidance.

Lead effectively to manage risk about the premises

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

10B. In relation to design and layout:

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

10C. In relation to security of premises and grounds:

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

10D. In relation to maintenance of premises and grounds, renewal and service continuity:

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

10E. People who use services, and staff understand:

- What to do in the event of an emergency.

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Additional guidance for your selected service types

10F. People who use services and others who work in or visit the premises can be confident that in relation to design and layout, the premises:

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

10G. People who work, visit or use services can be confident that, in relation to design and layout:

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

10H. People who work, visit or use services can be confident that, in relation to maintenance and renewal:

- There are clear procedures, followed in practice, monitored and reviewed, which cover:
 - what will happen in the event of electricity, water or gas supply failure
 - what will happen in the event of a fire or flooding
 - other emergencies that occur on the premises
 - how the situation will be managed should IT or communication systems, which are integral to the premises, fail.
- There are systems in place to ensure that the dcor of the building is maintained and refreshed.
- The management of risk includes the prevention and control of Legionella.

10I. People who use services and others who work in, or visit the premises can be confident that in relation to design and layout the premises:

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

Outcome 11 Safety, availability and suitability of equipment

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Safety, availability and suitability of equipment

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

(a) properly maintained and suitable for its purpose; and

(b) used correctly.

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

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

(4) For the purposes of this regulation—

(a) equipment includes a medical device; and

(b) medical device has the same meaning as in the Medical Devices Regulations 2002(a).

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What should people who use services experience?

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

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

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

Ensure equipment is adequate

11A. People are safe because where equipment is provided or used as part of the regulated activity, the equipment is:

- Available in sufficient quantities to meet the needs of people who use the service.
- Safe to be used.
- Suitable for its stated purpose.
- Compliant with all relevant laws.
- Installed, used and maintained correctly with reference to the specifications, manufacturers instructions, legislation and appropriate guidance from expert bodies.
- Properly maintained, tested, serviced and renewed under a recorded programme.
- Stored safely and securely to prevent theft, damage or misuse.

11B. Peoples needs are met because staff using any equipment do so in a way that has regard to their dignity, comfort and safety and promotes their independence by:

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

Manage risk through effective procedures about equipment suitability

11C. People are safe because where equipment is provided as part of the regulated activity, there are clear procedures followed in practice, monitored and reviewed. Wherever necessary these include:

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

11D. Where people who use services receive care, treatment or support that involves the use of medical devices, the provider has:

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

11E. People who use services receive care, treatment and support from a service that:

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

Providing personalised care through the effective use of medical devices

11F. People who use services receive care, treatment and support that:

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

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Additional guidance for your selected service types

11G. When equipment is used in a persons own home:

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

11H. People who use services receive care, treatment and support that:

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

Suitability of staffing

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

This section covers guidance about compliance on the following regulations:

- Requirements relating to workers
- Staffing
- Supporting workers.

Outcome 12 Requirements relating to workers

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Requirements relating to workers

21. The registered person must—

(a) operate effective recruitment procedures in order to ensure that no person is employed for the purposes of carrying on a regulated activity unless that person

(i) is of good character,

(ii) has the qualifications, skills and experience which are necessary for the work to be performed, and

(iii) is physically and mentally fit for that work;

(b) ensure that information specified in Schedule 3 is available in respect of a person employed for the purposes of carrying on a regulated activity, and such other information as is appropriate;

(c) ensure that a person employed for the purposes of carrying on a regulated activity is registered with the relevant professional body where such registration is required by, or under, any enactment in relation to—

(i) the work that the person is to perform, or

(ii) the title that the person takes or uses; and

(d) take appropriate steps in relation to a person who is no longer fit to work for the purposes of carrying on a regulated activity including—

(i) where the person is a health care professional, informing the body responsible for regulation of the health care profession in question, or

(ii) where the person is a social care worker registered with the General Social Care Council, informing the Council(a).

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Manage quality by employing the right people

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

12A. In relation to recruitment:

- Are honest, reliable, trustworthy and treat the people who use services with respect.
- Are not discriminated against during the application or recruitment process.
- Are qualified and competent to carry out their role and meet the needs of people who use services.
- Have been subject to the necessary checks as described in schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, so that the provider is assured that the worker is suitable for their role.
- Have been subject to a check that they are registered with the Independent Safeguarding Authority:
 - where they are undertaking a Safeguarding Vulnerable Groups Act 2006 regulated activity or controlled activity; and
 - are required to be registered under the Schemes phasing in arrangements.
- Are only allowed to start work before a full and satisfactory Criminal Records Bureau (CRB) check has been received where the provider has received an ISA Adult First check that confirms the staff member is not barred. In these circumstances the following safeguards are put in place:
 - an appropriately qualified and experienced member of staff is appointed to supervise them
 - wherever it is possible, this supervisor is on duty at the same time as the new worker, or is available to be consulted
 - new workers do not escort people away from the premises unless accompanied by a staff member for whom a full and satisfactory CRB check has been received.

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

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

12B. In relation to qualifications, knowledge, skills and experience:

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

12C. People who use services receive a service from a provider that has the right staff because:

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

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Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 13 Staffing

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Staffing

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

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Lead effectively to ensure there are sufficient staff

13A. People who use services benefit from sufficient staff to meet their needs because the provider:

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

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 14 Supporting workers

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Supporting workers

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

(a) receiving appropriate training, professional development, supervision and appraisal; and

(b) being enabled, from time to time, to obtain further qualifications appropriate to the work they perform.

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

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

(a) evaluate and improve the quality of the services provided; and

(b) safeguard high standards of care by creating an environment in which clinical excellence can flourish.

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Lead effectively to support staff

14A. People who use services receive care, treatment and support from staff who are competent to carry out their roles, because:

- All staff receive a comprehensive induction that takes account of recognised standards within the sector and is relevant to their workplace and their

role.

- Induction is undertaken when they start their job and is completed before they are allowed to work unsupervised.
- The induction for new staff includes at least:
 - the aims, objectives and purpose of the service
 - information on the people whose care, treatment and support the staff member will be involved in providing and any specific communication needs
 - the rights of people who use the service
 - the policies and procedures of the service
 - the action to be taken in an emergency
 - the health and safety risk assessments and any necessary health surveillance, necessary for their work
 - how to report adverse events, incidents, errors and near misses
 - the arrangements for the staff members own support and supervision
 - the support and the safety arrangements where they are required to work alone
 - the arrangements for reporting where the service falls below essential standards of quality and safety
 - An orientation to the systems, culture and terminology of the health and or social care sectors in England, where the staff member has been recruited from outside the UK.
- The learning and development needs of staff are identified based on the needs of people who use services and the skills needed from staff to ensure that the service meets essential standards of quality and safety.
- Staff have a learning and development plan in place from the point of induction based upon the needs identified and how those needs will be met. This takes account of recognised standards in the sector.
- The service has a learning and development plan which leads to the development of a programme of activity that meets mandatory, sector body and professional requirements for the designated roles and enables staff to meet their professional registration and development requirements.
- Staff are enabled to take part in learning and development that is relevant and appropriate so that they can carry out their role effectively.
- Where it applies, staff are supported to take accredited training.
- The staff learning and development programme takes account of the working patterns of staff.
- Where learning and development is delivered by a trainer, that person has demonstrated that they are competent to do so and, where an accreditation scheme applies, are accredited to act as a trainer for the course being provided.
- The programme of learning and development is supported by appropriate resources.
- Where necessary, the service works with relevant training providers to ensure the programme is delivered effectively.
- A record is kept of those attending the learning and development activities that staff attend.
- The competency of staff to provide care, treatment and support is assessed in light of their learning and development, and support is provided to them where gaps are identified.
- The learning and development plan for staff is reviewed and adjusted to meet the changing needs of the people who use the service and to ensure that the service is fully able to meet essential quality and safety standards.
- Staff receive the learning and development opportunities they need to carry out their role and keep their skills up to date.
- They take into account relevant guidance, including that from the Care Quality Commissions Schedule of Applicable Publications (see appendix B).

14B.Children who use services can be confident that:

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

14C. People receive a service from a provider that supervises its staff, because:

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

14D. People receive a service from a provider that supports its staff because:

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

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Additional guidance for your selected service types

14F. People who use services can be confident that:

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

14G. Children who use services:

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

14H. Children who use services:

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

14J. People who use services:

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

Quality and management

This section looks at what providers should do to manage risk in order to ensure that essential standards of quality and safety are maintained, and what

information they must give to the Care Quality Commission about certain important events.

This section covers guidance about compliance on the following regulations:

- Statement of purpose
- Assessing and monitoring the quality of service provision
- Complaints
- Notification of death of service user
- Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983
- Notification of other incidents
- Records.

Outcome 15 Statement of purpose

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Statement of purpose

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

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

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

SCHEDULE 1 INFORMATION TO BE INCLUDED IN THE STATEMENT OF PURPOSE

1. The aims and objectives of the service provider in carrying on the regulated activity.
2. The kinds of services provided for the purposes of the carrying on of the regulated activity and the range of service users' needs which those services are intended to meet.
3. The full name of the service provider and of any registered manager, together with their business address, telephone number and, where available, electronic mail addresses.
4. The legal status of the service provider.
5. Details of the locations at which the services provided for the purposes of the regulated activity are carried on.

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

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

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 16 Assessing and monitoring the quality of service provision

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Assessing and monitoring the quality of service provision

10.(1) The registered person must protect service users, and others who may be at risk, against the risks of inappropriate or unsafe care and

treatment, by means of the effective operation of systems designed to enable the registered person to

(a) regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirements set out in this Part of these Regulations; and

(b) identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.

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

(a) where appropriate, obtain relevant professional advice;

(b) have regard to—

(i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by service users, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 19,

(ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the regulated activity,

(iii) the information contained in the records referred to in regulation 20,

(iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a)),

(v) reports prepared by the Commission from time to time relating to the registered persons compliance with the provisions of these Regulations, and

(vi) periodic reviews and special reviews and investigations carried out by the Commission in relation to the provision of health or social care, where such reviews or investigations are relevant to the regulated activity carried on by the service provider;

(c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—

(i) the analysis of incidents that resulted in, or had the potential to result in, harm to a service user, and

(ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;

(d) establish mechanisms for ensuring that—

(i) decisions in relation to the provision of care and treatment for service users are taken at the appropriate level and by the appropriate person (P), and

(ii) P is subject to an appropriate obligation to answer for a decision made by P, in relation to the provision of care and treatment for a service user, to the person responsible for supervising or managing P in relation to that decision; and

(e) regularly seek the views (including the descriptions of their experiences of care and treatment) of service users, persons acting on their behalf and persons who are employed for the purposes of the carrying on of the regulated activity, to enable the registered person to come to an informed view in relation to the standard of care and treatment provided to service users.

(3) The registered person must send to the Commission, when requested to do so, a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with, together with any plans that the registered person has for improving the standard of the services provided to service users with a view to ensuring their health and welfare.

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Lead effectively to manage risk

Providers who are registered with the Care Quality Commission:

16A. In relation to monitoring the quality of services that people who use services receive:

- Have appropriate systems for gathering, recording and evaluating accurate information about the quality and safety of the care, treatment and

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

16B. In relation to making sure people who use services are not harmed as a result of unsafe care, treatment and support:

- Gather information about the risks to peoples health, welfare and safety. This includes people who use the service, the services staff, and anyone else involved in the regulated activities provided by the service.
- Make the necessary changes to the plan of care of a person who uses the service where the information gathered identifies a risk of inappropriate or unsafe care, treatment and support.
- Have a system to continuously identify, analyse and review risks, adverse events, incidents, errors and near misses. Information about this is used to develop solutions and risk reduction actions to ensure any non-compliance, or any risk of non-compliance, with the regulations is resolved as quickly as possible.
- Identify and analyse adverse events, incidents, errors and near misses to establish what caused them.
- Make sure there is a confidential way for staff to raise concerns about risks to people, poor practice and adverse events. Staff understand the reporting system and feel confident to use it, without fear that they will be treated unfairly as a result of raising a concern.
- Involve people who use the service, others acting on their behalf, staff and all those who provide support in decisions about taking appropriate risks in a way that complies with relevant legislation.
- Provide people who use services with information about:
 - risks to their health, welfare and safety
 - any preventative or protective measures they should follow or use
 - their own responsibilities for contributing to safety.

16C. In relation to reporting on quality, risk, and improvement plans to ensure compliance with the regulations:

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

16D. In relation to decision-making arrangements:

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

16E. Providers who are registered with the Care Quality Commission:

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

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 17 Complaints

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Complaints

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

(2) In particular, the registered person must—

(a) bring the complaints system to the attention of service users and persons acting on their behalf in a suitable manner and format;

(b) provide service users and those acting on their behalf with support to bring a complaint or make a comment, where such assistance is necessary;

(c) ensure that any complaint made is fully investigated and, so far as reasonably practicable, resolved to the satisfaction of the service user, or the person acting on the service users behalf; and

(d) take appropriate steps to coordinate a response to a complaint where that complaint relates to care or treatment provided to a service user in circumstances where the provision of such care or treatment has been shared with, or transferred to, others.

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

(a) complaints made pursuant to paragraph (1); and

(b) responses made by the registered person to such complaints.

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What should people who use services experience?

People who use services or others acting on their behalf:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Lead effectively to manage complaints

17A. People who use services and those acting on their behalf can be confident that their comments and complaints are listened to and dealt with effectively because:

- There are clear procedures followed in practice, monitored and reviewed, for receiving, handling, considering and responding to comments and complaints, and a named contact who is accountable for doing so.
- The complaints process is available, understood and well publicised, and reflects established principles of good complaint handling. The process will ensure:
 - that the details of the complaint, and the desired outcome, have been properly understood
 - that advice and advocacy support is available to those who wish or need such support
 - that what is required to resolve the complaint, and the likely timescale, is explained.
- Investigations are both proportionate and sufficiently thorough.
- A documented audit trail of the steps taken and the decisions reached is kept.
- Consideration of the complaint is undertaken by staff who are competent to address the issues raised, provide honest explanations that are based on facts and include the reasons for the decisions made.
- Whenever possible complaints are reviewed by someone not involved in the events leading to the complaint.
- Comments and complaints are investigated and resolved to the satisfaction of the person raising the complaint unless:
 - the complaint falls outside of the remit of the providers responsibility
 - the complaint cannot be upheld.
- The service has clear procedures followed in practice, monitored and reviewed for dealing with unreasonably persistent complainants in a fair and consistent manner, but ensures that the point they make is properly considered.
- The service encourages and supports a culture of openness that ensures any comment or complaint is listened to and acted on.
- The organisation ensures that a full record of the complaint is logged in line with the services procedures.
- The information from complaints is used to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
- The person knows how to contact the Care Quality Commission in order to inform the Commission of concerns they may have about the carrying on of the regulated activity.

17B. People who use services whose care, treatment and support is shared with more than one provider, or has been transferred to another provider, know that their comments and complaints are listened to because:

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

17C. Providers who are registered with the Care Quality Commission:

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

17D. People who use services benefit from a service that:

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

Promote rights and choices

17E. People who use services or those acting on their behalf are able to use the comments and complaints process because:

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

of their right to refer the matter to the next stage of the complaints system, including the Health Service Ombudsman, Local Government Ombudsman or Independent Sector Complaints Adjudication Service, where these options apply.

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 18 Notification of death of a person who uses services

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Notification of death of service user

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

(a) whilst services were being provided in the carrying on of a regulated activity; or

(b) as a consequence of the carrying on of a regulated activity.

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

(a) occurred—

(i) whilst services were being provided in the carrying on of a regulated activity, or

(ii) as a consequence of the carrying on of a regulated activity; and

(b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care or treatment.

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

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

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

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What should people who use services experience?

People who use services:

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

This is because:

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

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Prompts for all providers to consider

Informing the Care Quality Commission

18A. The regulations say that a registered person (provider or manager) must send notifications about deaths to the Care Quality Commission without delay.

18B. Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 16.

18C. English NHS trusts send these notifications to the National Patient Safety Agency (NPSA), who will send them on to the Care Quality Commission. All other providers send their notifications directly to the Commission.

18D. These notifications must not identify the person they are about, or enable them to be identified. Individuals should be referred to using a code that is unique to them. Services must keep a record of these codes and who they refer to, in case the Care Quality Commission needs to make further enquiries.

18E. The death of a person who is detained, or liable to be detained, under the Mental Health Act 1983 is not notified under this outcome. Please refer to outcome 19 in these circumstances.

English NHS trusts only

18F. English NHS trusts inform the Care Quality Commission without delay of any death of a person using the service that occurred:

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

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

Providers that are not English NHS trust

18G. All providers that are **NOT** English NHS trusts inform the Care Quality Commission without delay of ALL deaths of a person using the service where they die while receiving, or as a result of, the care, treatment or support provided by the service.

18H. Notifications about deaths must include the following:

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

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

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

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

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

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

(a) under the Mental Health Act 1983 (“the 1983 Act”); or

(b) pursuant to an order or direction made under another enactment (which applies in relation to England), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

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

(3) In this regulation—

(a) references to persons “liable to be detained” include a community patient who has been recalled to hospital in accordance with section 17E of the 1983 Act, but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42, 73 or 74 of the 1983 Act;

(b) “community patient” has the same meaning as in section 17A of the 1983 Act;

(c) “hospital” means a hospital within the meaning of Part 2 of that Act; and

(c) “unauthorised absence” means unauthorised absence from a hospital.

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What should people who use services experience?

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

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Informing the Care Quality Commission

19A. The regulations say that a registered person (provider or manager) must send notifications about deaths and unauthorised absences of patients detained or liable to be detained under the Mental Health Act 1983 to the Care Quality Commission without delay.

19B. Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 16.

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

19D. These notifications must not identify the person they are about, or enable them to be identified. Individuals should be referred to using a code that is unique to them. Services must keep a record of these codes and who they refer to, in case the Care Quality Commission needs to make further enquiries.

19E. Notification about the death of a person using the service must be made where the person dies while receiving, or as a result of, the care, treatment or support provided by the service.

19F. The death of a person detained, or liable to be detained, under the Mental Health Act 1983 is only notified under this outcome, and not notified under outcome 18.

19G. Unauthorised absences of a person liable to be detained under the Mental Health Act 1983 become notifiable when the person is still absent after midnight on the day their absence began.

Deaths

19H. All notifications about deaths and unauthorised absences of a person detained or liable to be detained under the Mental Health Act 1983 must include the following:

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

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

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

Unauthorised absence

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

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

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 20 Notification of other incidents

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Notification of other incidents

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

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

- (a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—
 - (i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,
 - (ii) changes to the structure of a service user's body,
 - (iii) the service user experiencing prolonged pain or prolonged psychological harm, or
 - (iv) the shortening of the life expectancy of the service user;
 - (b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—
 - (i) the death of the service user, or
 - (ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);
 - (c) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation, including the result of such a request;
 - (d) any application made to a court in relation to depriving a service user of their liberty pursuant to section 16(2)(a) of the 2005 Act;
 - (e) any abuse or allegation of abuse in relation to a service user;
 - (f) any incident which is reported to, or investigated by, the police;
 - (g) any event which prevents, or appears to the service provider to be likely to threaten to prevent, the service provider's ability to continue to carry on the regulated activity safely, or in accordance with the registration requirements, including—
 - (i) an insufficient number of suitably qualified, skilled and experienced persons being employed for the purposes of carrying on the regulated activity,
 - (ii) an interruption in the supply to premises owned or used by the service provider for the purposes of carrying on the regulated activity of electricity, gas, water or sewerage where that interruption has lasted for longer than a continuous period of 24 hours,
 - (iii) physical damage to premises owned or used by the service provider for the purposes of carrying on the regulated activity which has, or is likely to have, a detrimental effect on the treatment or care provided to service users, and
 - (iv) the failure, or malfunctioning, of fire alarms or other safety devices in premises owned or used by the service provider for the purposes of carrying on the regulated activity where that failure or malfunctioning has lasted for longer than a continuous period of 24 hours.
- (3) Paragraph (2)(f) does not apply where the service provider is an English NHS body.
- (4) Where the service provider is a health service body, paragraph (1) does not apply if, and to the extent that, the registered person has reported the incident to the National Patient Safety Agency.
- (5) In this regulation—
- (a) "the 2005 Act" means the Mental Capacity Act 2005;
 - (b) "abuse", in relation to a service user, means—
 - (i) sexual abuse;
 - (ii) physical or psychological ill-treatment;
 - (iii) theft, misuse or misappropriation of money or property; or
 - (iv) neglect and acts of omission which cause harm or place at risk of harm;
 - (c) "health care professional" means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999 applies;
 - (d) "registration requirements" means any requirements or conditions imposed on the registered person by or under Chapter 2 of Part 1 of the Act;
 - (e) "standard authorisation" has the meaning given under Part 4 of Schedule A1 to the 2005 Act;
 - (f) "supervisory body" has the meaning given in paragraph 180 (in relation to a hospital in England) or paragraph 182 (in relation to a care home) of Schedule A1 to the 2005 Act;
 - (g) (g) for the purposes of paragraph (2)(a)—
 - (i) "prolonged pain" and "prolonged psychological harm" means pain or harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days, and
 - (ii) a sensory, motor or intellectual impairment is not temporary if such an impairment has lasted, or is likely to last, for a continuous period of at least 28 days.

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What should people who use services experience?

People who use services:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Informing the Care Quality Commission

20A. The regulations say that a registered person (provider or manager) must send notifications about incidents that affect people who use services to the Care Quality Commission without delay.

20B. Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 16.

20C. English NHS trusts send SOME of these notifications to the National Patient Safety Agency (NPSA), who will send them on to the Care Quality Commission. This guidance says when NHS trusts should send notifications to the NPSA, and when they send them directly to the Care Quality Commission.

20D. Other providers send ALL notifications directly to the Care Quality Commission.

20E. These notifications must not identify individual people, or enable them to be identified. Individuals must be referred to using a code that is unique to them. Services must keep a record of these codes and who they refer to, in case the Care Quality Commission needs to make further enquiries.

20F. The two kinds of incidents and events that must be notified to the Care Quality Commission are:

- **Incidents affecting a person who uses the service:**
 - Injuries
 - Applications to deprive someone of their liberty under the Mental Capacity Act
 - Allegations of abuse.
- **Events involving the service in a way that could affect all of the people who use it:**
 - Incidents reported to the police
 - Events that stop or may stop the service from operating safely and properly.

20G. In all cases the notifications about an incident affecting a person must include:

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

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

Injuries

20H. Providers tell the Care Quality Commission without delay about events that lead to:

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

20I. These serious injuries include:

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

- permanent injury
- any of the outcomes, harms or pain described above.

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

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

20J. Providers of hospitals, care homes or care homes with nursing tell the Care Quality Commission without delay about any application by the service to a **Supervisory Body** to deprive an adult of their liberty.

20K. Providers of all services tell the Care Quality Commission without delay about any application by the service to the **Court of Protection** to deprive an adult of their liberty.

20L. All notifications about an application to deprive an adult of their liberty must include:

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

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

20M. Providers inform the Care Quality Commission without delay about:

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

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

Allegations of abuse

20N. Providers inform the Care Quality Commission without delay of:

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

20O. In relation to where the alleged or possible victim of abuse is an **adult** the notification must include details of the allegation, including:

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

20P. In relation to where the alleged or possible victim of abuse is a **child or young person** under 18 years, the notification must include details of the allegation, including:

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

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

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

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

Incidents reported to or investigated by the police

20R. Providers inform the Care Quality Commission without delay of:

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

The above requirement does not apply to English NHS trusts.

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 21 Records

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Records

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

(a) an accurate record in respect of each service user which shall include appropriate information and documents in relation to the care and treatment provided to each service user; and

(b) such other records as are appropriate in relation to—

(i) persons employed for the purposes of carrying on the regulated activity, and

(ii) the management of the regulated activity.

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

(a) kept securely and can be located promptly when required;

(b) retained for an appropriate period of time; and

(c) securely destroyed when it is appropriate to do so.

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What should people who use services experience?

People who use services can be confident that:

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

This is because providers who comply with the regulations will:

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

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Prompts for all providers to consider

Manage risk through effective procedures about records

21A. People who use services can be confident that their personal records for their care, treatment and support are properly managed because:

- The service has clear procedures that are followed in practice, monitored and reviewed, to ensure personalised records and medical records are kept and maintained for each person who uses the service.
- Records about the care, treatment and support of people who use services are updated as soon as practical.
- Verbal communications about care, treatment and support are documented within personal records as soon as is practical.
- Records about care, treatment and support are clear, factual and accurate and maintain the dignity and confidentiality of the people who use services.
- Records are securely stored and transferred internally between departments and externally to other organisations, when required.
- Protocols exist with other organisations for secure information sharing.
- Records about people who use services are used to plan appropriate care, treatment and support to ensure their rights and best interests are protected and their needs are met.
- The record of the current interaction is linked with any previous records that exist for that person, whenever the service is able to reliably identify the person.
- They, or others acting on their behalf, and relevant staff, are aware of and can access, and where appropriate, contribute to the record.
- They are assured that safe and secure records management arrangements will continue to be in place for the legally required period should the registered provider close operations.
- Where a request for access to a record is made, all legislation and guidance in respect of Freedom of Information Act 2000 and the Data Protection Act 1998 is followed by all staff.
- Wherever they are relevant to the service, the following records are kept and for the periods of time stated:
 - risk assessments; retain the latest risk assessment until a new one replaces it
 - purchasing excluding medical devices and medical equipment; 18 months
 - general operating policies and procedures; retain the current version and previous version for three years
 - any incidents, events or occurrences that require notification to the Care Quality Commission; three years
 - use of restraint or the deprivation of liberty; three years
 - detention; three years
 - maintenance of the premises; three years
 - maintenance of equipment; three years
 - electrical testing; three years
 - fire safety; three years
 - water safety; three years
 - medical gas safety, storage and transport; three years

- o money or valuables deposited for safe keeping; three years
 - o staff employment; three years following date of last entry
 - o duty rosters; four years after the year to which they relate
 - o purchasing of medical devices and medical equipment; 11 years
 - o final annual accounts; 30 years.
- Takes into account relevant guidance, including that from the Care Quality Commissions Schedule of Applicable Publications (see appendix B).

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Additional guidance for your selected service types

21B. People who use services can be confident that:

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

Suitability of management

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

This section covers guidance about compliance on the following regulations:

- Requirements where the service provider is an individual or partnership
- Requirement where the service provider is a body other than a partnership
- Requirements relating to registered managers
- Registered person: training
- Financial position
- Notification of absence
- Notification of changes.

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

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

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

Requirements where the service provider is an individual or partnership

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

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

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

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

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

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

(a) of good character;

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

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

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What should people who use services experience?

People who use services:

- Have their needs met by the service because it is provided by an appropriate person.

This is because providers who comply with the regulations will:

- Register with the Care Quality Commission the appropriate people or persons who:
 - o are of good character
 - o are physically and mentally able to perform their role
 - o have the necessary qualifications, skills and experience to carry on the regulated activity or, where it is an organisation, supervise its management.

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Prompts for all providers to consider

The following prompts relate to all registered providers who are an individual or a partnership. These prompts do not apply where the service provider is a body other than an individual or partnership.

Lead effectively to manage risk of inappropriate providers

22A. People who use services receive care, treatment and support from a provider who has demonstrated that it:

- Is honest, reliable and trustworthy.
- Is competent to run the service.
- Is physically and mentally able to do the job, with plans of support for individuals to show what arrangements will be put in place including any reasonable adjustments to enable them to do their job, wherever necessary.
- Is appropriately skilled with the qualifications, knowledge and experience required to manage the regulated activity, where there is no separate registered manager.
- Has been subject to the necessary checks as described in schedule 3 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, so that the provider is assured that the worker is suitable for their role.
- Has been subject to a check that they are registered with the Independent Safeguarding Authority where:
 - they are undertaking a Safeguarding Vulnerable Groups Act 2006 regulated activity or controlled activity
 - they are required to be registered under the Schemes phasing in arrangements.
- Is able to respond to any registered manager requests for resources in order to meet essential standards of quality and safety.
- Is able to empower the registered manager, where one is employed, and appropriately delegate authority to them so that they can effectively run the service on a day-to-day basis.

22B. In relation to meeting the needs of people who use services, providers:

- Anticipate and understand the possible outcomes of their decisions and actions on peoples lives.
- Influence and negotiate to achieve the essential standards of quality and safety for people who use services by understanding the importance of putting them at the centre and encouraging choice and control.
- Know and understand how to safeguard people.
- Have knowledge and understanding of how equal opportunities and a respect for human rights and diversity are put in to practice when delivering the service.
- Put into practice the aims and objectives described in the statement of purpose and explain how the service will achieve these.
- Recognise when particular knowledge and skills are needed and take appropriate action.

22C. In relation to their legal responsibilities, providers:

- Inform the Care Quality Commission about any and all:
 - convictions, cautions, warnings, reprimands and bind overs they receive
 - actions taken against them by a regulatory and/or professional body
 - voluntary insolvency arrangements and circumstances made by an individual.
- Have appropriate knowledge of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (Part 3 and Part 4) and the consequences of failing to take action on set requirements.
- Make sure that the service complies with relevant laws and takes into account relevant statutory codes of practice.
- Supply all necessary information that the Care Quality Commission may request as required by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (Part 3 and Part 4).
- Cooperate effectively with any statutory agencies investigations.

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 23 Requirement where the service provider is a body other than a partnership

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

- Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Requirement where the service provider is a body other than a partnership

5. (1) This regulation applies where the service provider is a body other than a partnership.

(2) The body must give notice to the Commission of the name, address and position in the body of an individual (in these Regulations referred to as the nominated individual) who is employed as a director, manager or secretary of the body and who is responsible for supervising the management of the carrying on of the regulated activity by the body.

(3) The registered person must take all reasonable steps to ensure that the nominated individual is—

(a) of good character;

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

(c) able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

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What should people who use services experience?

People who use services:

- Have their needs met because the management is supervised by an appropriate person.

This is because providers who comply with the regulations will:

- Have a nominated individual who:
 - is of good character
 - is physically and mentally able to perform their role
 - has the necessary qualifications, skills and experience to supervise the management of the regulated activity.

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Prompts for all providers to consider

The following prompts relate to all providers who are a body other than an individual or a partnership. These prompts do not apply where the service provider is an individual or partnership.

Manage quality by notifying an appropriate nominated individual

23A. People who use services receive a service whose management is supervised by a nominated individual who:

- Has been notified in writing to the Care Quality Commission.
- Is of good character as they are honest, reliable and trustworthy.
- Is physically and mentally able to do the job, with a plan of support that sets out any reasonable adjustments where necessary. This means they:
 - do not present a risk to people who use services because of any illness or medical condition they have
 - are not placed at risk by the work they will do because of any illness or medical condition they have.
- Is appropriately skilled with the qualification(s), knowledge and experience to supervise the management of the regulated activity. This means the nominated individual:
- Has been subject to the necessary checks as described in schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, so that the provider is assured that the nominated individual is suitable for their role.
- Has been subject to a check that they are registered with the Independent Safeguarding Authority:
 - where they are undertaking a Safeguarding Vulnerable Groups Act 2006 regulated activity or controlled activity; and
 - are required to be registered under the Schemes phasing in arrangements.
- Has their qualifications, knowledge and skills updated on a regular basis.
- Has an awareness and knowledge of diversity and human rights and apply in practice the competencies to support peoples diverse needs and human rights.
- Is aware of the services policies, procedures, legislation and standards.
- Knows who they are able to contact when expert advice is needed.
- Is able to respond to any registered manager requests for resources in order to meet essential standards of quality and safety.
- Is able to empower the registered manager, where one is employed, and appropriately delegate authority to them so that they can effectively run the service on a day-to-day basis.

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 24 Requirements relating to registered managers

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

- Regulation 6 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Requirements relating to registered managers

6.(1) A person (M) shall not manage the carrying on of a regulated activity as a registered manager unless M is fit to do so.

(2) M is not fit to be a registered manager in respect of a regulated activity unless M is—

(a) of good character;

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

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

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What should people who use services experience?

People who use services:

- Have their needs met because it is managed by an appropriate person.

This is because providers who comply with the regulations will:

- Have a registered manager who:
 - is of good character
 - is physically and mentally able to perform their role
 - has the necessary qualifications, skills and experience to manage the regulated activity.

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Prompts for all providers to consider

The following prompts relate service, or a part of the service, is managed by a Registered Manager.

This only applies to registered NHS providers where the Care Quality Commission has decided to apply a registered manager condition.

Lead effectively to manage risk of inappropriate managers

24A. People who use services receive a service from a manager who has demonstrated that they:

- Are of good character as they are honest, reliable and trustworthy.
- Are physically and mentally able to do the job, with a plan of support, showing any reasonable adjustments, where necessary. This means the manager:
 - does not present a risk to people who use services because of any illness or medical condition they have
 - is not placed at risk by the work they will do because of any illness or medical condition they have.
- Have the qualifications, knowledge and experience to manage the regulated activity.
- Are appropriately skilled, including as a minimum:
 - effective communication skills to enable good communication with their staff and the people who use their service
 - basic management skills to ensure that the service is delivered to meet essential standards of quality and safety.
- Has been subject to the necessary checks as described in schedule 3 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, so that the provider is assured that the nominated individual is suitable for their role.
- Has been subject to a check that they are registered with the Independent Safeguarding Authority:
 - where they are undertaking a Safeguarding Vulnerable Groups Act 2006 regulated activity or controlled activity.
 - and are required to be registered under the Schemes phasing in arrangements.
- Show that they are registered with the relevant professional regulators and/or professional bodies where appropriate, and comply with their requirements and codes of practice.
- Show qualifications and competencies recognised by the relevant sector body or, where these don't apply, are able to demonstrate relevant skills and experience.
- Have appropriate knowledge of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (Part 3 and Part 4) and the consequences of failing to take action on set requirements.
- Anticipate and understand the possible outcomes of their decisions and actions on people's lives and take appropriate action.
- Use resources effectively.
- Have delegated responsibility to make decisions where needed.
- Delegate appropriately by:
 - knowing what can or cannot be delegated
 - knowing what can be delegated to whom
 - understanding the competencies of staff and what is appropriate for them to do
 - having clear descriptions of each member of staff's role so that it is clear what should be delegated to whom
 - ensuring that staff have the time they need to complete any newly delegated tasks.
- Ensure that people are safeguarded from abuse.
- Have knowledge and understanding of how equal opportunities and a respect for human rights and diversity are put in to practice when delivering the service.
- Understand the importance of the delivery of the service in a person centred way, by ensuring that people who use services have choice and control.
- Put into practice the statement of purpose.
- Have plans of support that will show what arrangements will be put into place and any reasonable adjustments to enable a particular person to do their job.
- Make appropriate use of resources and highlight any areas of concerns to the provider, where relevant.
- Inform the Care Quality Commission about any:
 - convictions, cautions, warnings, reprimands and bind overs they receive
 - any action taken against them by a professional body.

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 25 Registered person: training

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

- Regulation 7 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Registered person: training

7.(1) If the service provider is

(a) an individual, the individual must undertake;

(b) a partnership, it must ensure that one of the partners undertakes; or

(c) a body other than a partnership, it must ensure that the nominated individual undertakes,

(i) from time to time such training as is reasonably practicable and appropriate to ensure that there are the necessary experience and skills available for carrying on the regulated activity.

(2) The registered manager must undertake from time to time such training as is appropriate to ensure that the manager has the experience and skills necessary for managing the carrying on of the regulated activity.

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What should people who use services experience?

People who use services:

- Have their care, treatment and support needs met because there is a competent person leading the service.

This is because providers who comply with the regulations will:

- Undertake appropriate training.

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Prompts for all providers to consider

Manage risk through effective procedures for learning and development

25A. People who use services benefit from a service that is competently run and has effective systems to meet the requirements of the regulations. This is because the registered persons undertake the training necessary to ensure they:

- Have the relevant skills and experience and apply these in their work.
- Apply up-to-date knowledge to effectively meet the needs of people who use services, including taking into account staffing and premises requirements.
- Have a clear organisational structure with well defined, transparent and consistent lines of responsibility.
- Have effective processes and systems to identify, manage, monitor and report risks, which must include systems to gather information from people who use services, professionals, and published audits and reports.
- Use this information to reduce unacceptable risks and keep this under review.
- Have a clear understanding of the services policies, procedures, legislation and standards.

25B. In addition, where the registered person is in day-to-day charge of the service, people who use services benefit from effective management. This is because the registered persons:

- Have plans in place to keep their knowledge and skills up to date and participate in appropriate training and activities. This training ensures that they:
 - provide effective care, treatment and support to the people who use their service
 - uphold and promote the rights of the people who use their service
 - are able to meet the diverse needs of people who use their service and follow current legislation
 - put into practice the statement of purpose.

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Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 26 Financial position

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

Regulation 13 of the Care Quality Commission (Registration) Regulations 2009

Financial position

13.—(1) Subject to paragraph (2), the service provider must take all reasonable steps to carry on the regulated activity in such a manner as to ensure the financial viability of the activity for the purposes of—

- (a) achieving the aims and objectives set out in the statement of purpose; and
- (b) meeting the registration requirements prescribed pursuant to section 20 of the Act.

(2) This regulation does not apply where the service provider is—

- (a) an English local authority; or
- (b) a health service body.

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What should people who use services experience?

People who use services:

- Can be confident that the service provider is able to meet the financial demands of providing safe and appropriate services.

This is because providers who comply with the regulations will:

- Have the financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards.

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Prompts for all providers to consider

Ensure quality through adequate finances

26A. People who use services are confident that the provider has:

- The financial resources needed to provide and continue to provide the services as described in the statement of purpose to the required standards.
- Wherever it is available, insurance and suitable indemnity arrangements to cover potential liabilities arising from death, injury, or other causes, loss or damage to property, and other financial risks.

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 27 Notifications notice of absence

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

- Regulation 14 of the Care Quality Commission (Registration) Regulations 2009

Notice of absence

14.—(1) Subject to paragraphs (7) and (8), where—

- (a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or
- (b) the registered manager,

proposes to be absent from carrying on or managing the regulated activity for a continuous period of 28 days or more, the registered person must give notice in writing to the Commission of the proposed absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) must be given no later than 28 days before the proposed absence commences or within such shorter period as may be agreed with the Commission and must contain the following information in relation to the proposed absence—

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for the management of the carrying on of the regulated activity during the period of absence;
- (d) the name, address and qualifications of the person who will be responsible for the management of the carrying on of the regulated activity during that absence;
- (e) in the case of the absence of the registered manager, the arrangements that have been, or are proposed to be, made for appointing another person to manage the carrying on of the regulated activity during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence referred to in paragraph (1) arises as the result of an emergency, the registered person must give notice of the absence to the Commission within 5 working days of its occurrence specifying the matters set out in paragraph (2)(a) to (e).

(4) Where—

- (a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or
- (b) the registered manager,

has been absent for a continuous period of 28 days or more, and the Commission has not been given notice of the absence, the registered person shall forthwith give notice in writing to the Commission specifying the matters set out in paragraph (2)(a) to (e).

(5) The registered person must notify the Commission of the return to duty of the service provider or (as the case may be) the registered manager not later than 7 working days after the date of that return.

(6) In this regulation “working day” means any day other than a Saturday, a Sunday, Christmas Day, Good Friday or a day which is a bank holiday in England and Wales within the meaning of the Banking and Financial Dealings Act 1971.

(7) Subject to paragraph (8), this regulation does not apply where the service provider is a health service body.

(8) Where the service provider is a health service body and is subject to a registered manager condition pursuant to regulation 5 or section 12(3) or (5) of the Act, this regulation shall have effect in relation any absence, proposed absence or return to duty of that registered manager.

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What should people who use services experience?

People who use services:

- Can have confidence that, if the person(s) in charge of their service is absent, it will continue to be properly managed and be able to meet their needs.

This is because providers who comply with the regulations will:

- Inform the Care Quality Commission:
 - about any significant planned absences from the service
 - about any significant unplanned absences
 - how the service will be run while they are away
 - when they return from a significant absence.

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Prompts for all providers to consider

The following guidance relates to all registered providers.

The regulations say that a registered person who is an individual (provider or manager) must send these notifications to the Care Quality Commission. Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 16.

Inform the Care Quality Commission of absences of a registered person

People who use services receive a service from a provider (where the provider is an individual) and/or registered manager who has made appropriate arrangements to cover their absence:

27A. In relation to planned absences of a registered provider who is in day-to-day charge of the service or of a registered manager:

- Registered persons give the Care Quality Commission 28 days notice if they are going to be absent from the service for 28 or more days.
- Where an absence is planned less than 28 days before it begins, registered persons inform the Care Quality Commission without delay before the absence begins.

27B. In relation to an emergency absence of a registered provider who is in day-to-day charge of the service or of a registered manager that is likely to last more than 28 days:

- Inform the Care Quality Commission of the absence within five working days after it began.

27C. In relation to all notices of absence of a registered provider who is in day-to-day charge of the service or of a registered manager:

- Tell the Care Quality Commission:
 - the reason for the absence, and how long it will last, if it is known
 - who will run the service while the registered person is away
 - the name, address and qualifications of the person who will be responsible for the service while the registered person is away.
- If the length of the absence is unknown, propose to the Care Quality Commission how long the situation will continue before a new manager will be proposed for registration.

27D. In relation to returning from an absence of a registered provider who is in day-to-day charge of the service or of a registered manager:

- Inform the Care Quality Commission that they have returned to work no later than seven days after their return.

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types

Outcome 28 Notifications notice of changes

- What do the regulations say?
- What should people who use services experience?
- Prompts for all providers to consider
- Additional prompts for your selected service types

What do the regulations say?

- Regulation 15 of the Care Quality Commission (Registration) Regulations 2009

Notice of changes

15.—(1) Subject to paragraph (2), the registered person must give notice in writing to the Commission, as soon as it is reasonably practicable to do so, if any of the following events takes place or is proposed to take place—

(a) a person other than the registered person carries on or manages the regulated activity;

(b) a registered person ceases to carry on or manage the regulated activity;

(c) the name of a registered person (where that person is an individual) changes;

(d) where the service provider is a partnership, any change in the membership of the partnership;

(e) where the service provider is a body other than a partnership—

(i) a change in the name or address of the body,

(ii) a change of director, secretary or other similar officer of the body, or

(iii) a change of nominated individual;

(f) where the service provider is—

(i) an individual, the appointment of a trustee in bankruptcy in relation to that individual, or

(ii) a company or partnership, the appointment of a receiver, manager, liquidator or provisional liquidator in relation to that company or partnership.

(2) Paragraph (1)(e)(ii) does not apply where the service provider is a health service body.

(3) In this regulation, “nominated individual” means the individual who is employed as a director, manager or secretary of the body and whose name has been notified to the Commission as being the person who is responsible for supervising the management of the carrying on of the regulated activity by that body.

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What should people who use services experience?

People who use services:

- Can be confident that, if there are changes to the service, its quality and safety will not be adversely affected.

This is because providers who comply with the regulations will:

- Inform the Care Quality Commission:
 - when the person who manages or carries on the service changes
 - when the registered details of the service and any individual, partnership or organisation who manage or carry it on, change
 - when the registered person becomes financially insolvent
 - when the service closes.

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Prompts for all providers to consider

The following guidance relates to all registered providers.

The regulations say that a registered person (provider or manager) must send these notifications to the Care Quality Commission. Where the registered person delegates this task to another member of staff, this must be included in the written description of decision-making arrangements required under Outcome 1.

Inform the Care Quality Commission

People who use services receive a service from a registered provider and/or manager who has made appropriate arrangements to notify the Care Quality Commission of changes:

28A. In relation to the people who manage or carry on the service:

- Registered providers tell the Care Quality Commission of any plans for a person other than a registered person to carry on or manage the service as soon as possible before they do so.
- Where a person other than a registered person begins to carry on or manage the service and it has not been possible to tell the Care Quality Commission before they start to do so, they tell the Care Quality Commission about the planned change without delay.

28B. In relation to the registered details of the service:

- Providers tell the Care Quality Commission as soon as possible about:
 - where a registered person is an **individual**; any changes to their name
 - the appointment a new registered manager, and
 - the name of the new registered manager
 - the date they will begin work
 - where the service provider is a **partnership**; any changes to the membership of a partnership
 - where the service provider is an **organisation**; any changes to the organisations:
 - name
 - business address
 - officers (such as to the directors or secretary)
 - nominated individual.

The requirement to notify changes to officers does not apply to English NHS trusts

28C. In relation to changes to financial solvency:

- Inform the Care Quality Commission when:
 - where the provider is an **individual or member of a partnership that is not a limited liability partnership**; they have been made bankrupt or their estate has been sequestrated; or
 - where the provider is an organisation or limited liability partnership; that an administrator, receiver, liquidator or provisional liquidator has been appointed.

This requirement does not apply to English NHS trusts

28D. Where a provider cannot tell the Care Quality Commission about any of these changes before they are made or take place, they do so without delay afterwards.

Additional guidance for your selected service types

There is no additional guidance in this section for your selected service types