

Appendix A - Regulations and outcomes

Please see attached extract from the CQC Guidance Document

	Outcome 1	Outcome 2	Outcome 3	Outcome 4	Outcome 5	Outcome 6	Outcome 7	Outcome 8	Outcome 9	Outcome 10	Outcome 11	Outcome 12	Outcome 13	Outcome 14	Outcome 15	Outcome 16	Outcome 17	Outcome 18	Outcome 19	Outcome 20	Outcome 21	Outcome 22	Outcome 23
Regulation 3: Fitness of service provider																		✓					
Regulation 5: Fitness of registered manager																			✓				
Regulation 6: Registered person: general requirements and training																				✓			
Regulation 7: Care and welfare of people who use services				✓																			
Regulation 8: Assessing and monitoring the quality of service provision													✓										
Regulation 9: Safeguarding vulnerable people who use services							✓																
Regulation 11: Management of medicines and medical devices								✓															
Regulation 12: Meeting nutritional needs					✓																		
Regulation 13: Safety and suitability of premises									✓														
Regulation 14: Safety, availability and suitability of equipment										✓													
Regulation 15: Respecting and involving people who use services	✓																						
Regulation 16: Consent to care and treatment		✓																					
Regulation 17: Complaints														✓									
Regulation 18: Records																	✓						
Regulation 19: Fitness of workers											✓												
Regulation 20: Staffing											✓												
Regulation 21: Supporting staff											✓												
Regulation 22: Cooperating with other providers						✓																	
Regulation 24: Financial position																					✓		
Regulation 25: Statement of purpose												✓											
Regulation 26: Notice of absence																						✓	
Regulation 27: Notice of changes																							✓
Regulation 28: Notification of incidents																	✓						
Regulation 29: Miscellaneous															✓								
Regulation 30: Fees etc.			✓																				

Appendix B

Example 1 Section 1: Involvement and information – Regulation 15

1. This section looks at what provider should do to make sure that people using services 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 requirements. It also looks at the information that providers should make available to people so that they know what their rights are, and so that they are able to make informed choices. References are made to relevant core standards.
2. The section covers guidance about compliance on:
 - 2.1. **Respecting and involving people who use services (Regulation 15)**
 - 2.2. Consent and care to treatment (Regulation 16)
 - 2.3. Fees etc. (Regulation 20 – n/a to acute trust)

Regulation 15 - Respecting and involving service users

15.—(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 at all times 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 them, 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 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;
 - (g) provide appropriate opportunities, encouragement and support to service users in relation to promoting their independence, community involvement and the way in which they wish to live their lives; 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.

The outcome for this Regulation is as follows:

Outcome 1

What should people who use services experience?

People using the service:

- 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 and their carers have their views and experiences taken into account in the way the service is provided and delivered.

This is because providers who are compliant with the law will:

- Maintain the privacy, dignity and independence of people who use services. (C7e, C13a, C20b)
- Involve people who use services in decisions about their care, treatment and support, and provide appropriate information about it. (C16, C17)
- Support people to understand the care, treatment and support that they provide to them. (C13b, C13c, C16)
- Be considerate and respectful to the person. (C7e, C13a)
- Encourage people to care for themselves where this is possible, and to decide how they want to live their lives.
- Encourage people to be involved in how the service is run. (C17)

What do we expect providers to do to meet this outcome?

1A Ensure personalised care through involvement

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

- Explaining and discussing their care, treatment and support options.
- Balancing the need for preference and choice against safety and effectiveness, while respecting the right of people to take informed risks.
- Cooperating with independent advocacy services wherever a person using the service has access to one.
- Promoting and respecting their privacy and dignity by:
 - placing the needs, wishes and decisions of the person at the centre of assessment, planning and delivery of care, treatment and support
 - ensuring that the environment allows privacy in which the person's intimate care, treatment and support needs are met
 - having clear procedures, that are followed in practice, that ensure staff understand the concepts of privacy and dignity and how they should be applied to the people who use the service
 - ensuring that confidentiality is maintained at all times
 - taking account of published Government advice about privacy and dignity
 - actively listening to and involving them, or their nominated representative, in decision-making, unless in doing so their care, treatment and support needs would not be met
 - providing information about their care, treatment and support, and their rights, in a way that the person can understand

- ensuring that staff treat people sensitively by understanding and respecting their diversity.

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

- They are listened to.
- They are able, if they want, to assess, plan and carry out their care, treatment and support themselves, or are able to direct staff in doing so.
- 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 achieve these needs is provided.

3. This Regulation includes two more outcomes covering (1B) manage risk through effective procedures about involvement and (1c) promote rights and choices¹ but the detail is not included.

Example 2 Section 3: Safeguarding and safety – Regulation 11

4. This section looks at what providers should do to make sure that people using the service and, where appropriate, 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.

5. 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 and hence be compliant with the law.

6. This section covers guidance about compliance on:

6.1. Safeguarding vulnerable people who use services (Regulation 9)

6.2. **Management of medicines and medical devices (Regulation 11)**

6.3. Safety and suitability of premises (Regulation 13)

6.4. Safety, availability and suitability of equipment (Regulation 14).

Regulation 11 - Management of medicines and medical devices

11.—(1) The registered person must protect service users against the risks associated with the unsafe use and management of medicines and medical devices, by means of—

(a) the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, safe administration and disposal of medicines and medical devices used for the purposes of the regulated activity; and

(b) having regard to any guidance issued by the Secretary of State or appropriate expert body in relation to the safe handling and use of medicines and medical devices.

(2) For the purposes of this regulation, “medical device” has the same meaning as in the Medical Devices Regulations 2002(a).

Outcome 8

What should people who use services experience?

People using the service:

¹ The detail for all Regulations and outcomes is contained in CQC Document: Consultation: Guidance about compliance with the Health and Social Care Act 2008 (Registration Requirements) Regulations 2009

- Will have the medicines they are prescribed, at the times they need them, and in a safe way.
- Will have medical devices maintained and used safely in meeting their care, treatment and support needs.

This is because providers who are compliant with the law will:

- Handle medicines safely and appropriately. (C4d, C7ac)
- Ensure that medicines are prescribed and taken by people safely. (C1a, C1b, C4d, C5b, C7ac, C11a, C11b)
- Manage, maintain and use medical devices safely. (C1a, C1b, C4b, C7ac)
- Follow published guidance about how to use medicines and medical devices safely. (C4b, C4d)

8B Manage risk through effective procedures about medicines handling

Where people who use services receive support or assistance with their medication, the provider has:

In relation to medicines:

- Clear procedures in practice for medicines handling that include obtaining or purchasing, storage, prescribing, dispensing, preparation, administration and monitoring. Wherever they are required these procedures include:
 - how 'as required' (PRN) medicines are handled
 - ensuring that staff handling medicines have the competency and skills needed
 - 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 adverse event, error and near-miss reporting that encourage local and, where applicable, national reporting, learning, from mistakes and promoting an open and fair culture of safety
 - acts upon any patient safety and drug alerts relating to medicines
 - an up-to-date list of all the medicines taken by the person being produced when they begin to use the service.
- Evidence that they comply with the requirements of the Medicines Act 1968 and the Misuse of Drugs Act 1971, and associated regulations, and the Safer Management of Controlled Drugs Regulations 2006.
- 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 of incidents relating to controlled drugs
 - sharing concerns about controlled drugs handling.

In relation to medical devices:

- Clear procedures, that are followed in practice, monitored and reviewed, for the use of medical devices. Wherever they are required these procedures include:
 - ensuring that staff involved with using them have the competency and skills needed
 - the arrangements for adverse event, error and near-miss reporting that encourage local and, where applicable, national reporting, learning from mistakes and promoting an open and fair culture of safety

- acting upon any Medical Devices Bulletins.

People who use services benefit from a service that:

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

7. This Regulation includes two other sub-outcomes relating to (8A) Providing personalised care through the effective use of medicines and (8C) Promote rights and choices not covered here.

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Appendix C – cross reference of outcomes to core standards

Section and outcomes	Regulation	Core Standard	Lead
1: Involvement and information			
Outcome 1 – Respecting and involving people who use services (see also appendix B)	15	C7e, C13a, b, c, C16, C17, c20b	DNCL
Outcome 2 – Consent to care and treatment	16	C13b, C13c, C16	DNCL
Outcome 3 – Fees etc	30	Not expected to apply to acute trusts	n/a
2: Personalised care, treatment and support			
Outcome 4 – Care and welfare of people who use services	7	C3, C5a, b, c, d, C7e, C13a, C22 and C23	DNCL/MD
Outcome 5 – Meeting nutritional needs	12	C15a, b	DoF
Outcome 6 – Cooperating with other providers	22	C2, C6, C7e, c9, C13b, C13c, C16, C18, C24	COO/DNCL
3: Safeguarding and safety			
Outcome 7 – Safeguarding vulnerable people who use services	9	C2, C5a, C6, C7e, C11a, C11b, C11c	DNCL/DHR
Outcome 8 – Management of medicines and medical devices (see also appendix B)	11	C1a, C1b, C4b, C4d, C7ac, C16	DNCL/MD
Outcome 9 – Safety and suitability of premises	13	C4e, C7ac, C7e, C13a, C16, C18, C20a, C20b, C21	DNCL/DoF
Outcome 10 – Safety, availability and suitability of equipment	14	C1a, C1b, C4b, C4c, C13a, C11a, C11b, C11c	DNCL/DHR
4: Suitability of staffing			
Outcome 11 – Making sure that people who use services are supported	19, 20 and	C5b, C5c, C7ac, C8b, C11a, C11b, C11c,	DHR/DNCL

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Section and outcomes	Regulation	Core Standard	Lead
by arrangements for fitness of workers, staffing and supporting staff	21		
5: Quality and management			
Outcome 12 - Statement of purpose	25	none	DNCL
Outcome 13 - Assessing and monitoring the quality of service provision	8	C3, C5a, C5d, C7ac, C7b, C8a, C16, C17,	DNCL/MD
Outcome 14 - Complaints	17	C7ac, C7b, C7e, C8a, C14a, C14b,	DNCL
Outcome 15 - Miscellaneous	29	C7ac, C14a, C14b	DNCL
Outcome 16 - Notification of incidents	28	Does not apply to NHS	
Outcome 17 - Records	18	C9, C13b, C13c	DNCL
6: Suitability of Management			
Outcome 18 - Fitness of service provider	3	Does not apply to NHS	
Outcome 19 - Fitness of registered provider	5	Does not apply to NHS	
Outcome 20 - Registered person: general requirements and training	6	Does not apply to NHS	
Outcome 21 - Financial position	24	NHS trusts/FT will be exempted from this regulation as they have other mechanisms to assure their financial position	
Outcomes 22 and 23 - notifications of absence and change	26 & 27	Do not apply to NHS	

