
DRAFT STATUTORY INSTRUMENTS

2009 No.

**The Health and Social Care Act 2008
(Regulated Activities) Regulations 2009**

PART 4

**QUALITY AND SAFETY OF SERVICE PROVISION
IN RELATION TO REGULATED ACTIVITY**

General

8. A registered person must, in so far as they are applicable, comply with the requirements specified in regulations 9 to 24 in relation to any regulated activity in respect of which they are registered.

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.

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 person's 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.

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) The registered person must have regard to any guidance issued by the Secretary of State or an appropriate expert body, in relation to—
- (a) the protection of children and vulnerable adults generally; and
 - (b) in particular, the appropriate use of methods of control or restraint.
- (4) 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.

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.

Management of medicines

- 13.**—(1) 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.

(2) In making the arrangements referred to in paragraph (1), the registered person must have regard to any guidance issued by the Secretary of State or an appropriate expert body in relation to the safe handling and use of medicines.

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 users' 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.

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.

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 in accordance with the technical specifications and guidance issued by the manufacturer, the Secretary of State or appropriate expert bodies.

(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(1).

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.

Consent to care and treatment

18. The registered person must—

- (a) 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; and
- (b) have regard to any guidance issued by the Secretary of State or other appropriate expert body in relation to the matters referred to in paragraph (a).

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.

(1) [S.I. 2002/618](#); the relevant amending instrument is [S.I. 2008/2936](#).

- (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 user's 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.

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.

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⁽²⁾.

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.

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.

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—

(2) The General Social Care Council is established under Part 5 of the Care Standards Act 2000 (c.14). See section 55 of that Act for the definition of “social care worker”, and S.I. 2004/561.

- (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.