
DRAFT STATUTORY INSTRUMENTS

2014 No.

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

PART 3

Requirements in relation to Regulated Activities

SECTION 1

Requirements relating to persons carrying on or managing a regulated activity

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—
 - (i) paragraph (4), and
 - (ii) paragraph (5), or
 - (b) a partnership and—
 - (i) each of the partners satisfies the requirements set out in paragraph (4), and
 - (ii) P satisfies the requirement set out in paragraph (6).
- (4) The requirements referred to in paragraph (3)(a)(i) and (b)(i) are that, if P is an individual, that individual or, if P is a partnership, each of the partners—
- (a) is of good character,
 - (b) is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are—
 - (i) where P is an individual, intrinsic to the carrying on of the regulated activity, or
 - (ii) where P is a partnership, intrinsic to their role in the carrying on of the regulated activity, and
 - (c) is able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.
- (5) The requirement referred to in paragraph (3)(a)(ii) is that P has the necessary qualifications, skills and experience to carry on the regulated activity.
- (6) The requirement referred to in paragraph (3)(b)(ii) is that, through the combination of the qualifications, skills and experience of the partners, P has the necessary qualifications, skills and experience to carry on the regulated activity.

Fit and proper persons: directors

5.—(1) This regulation applies where a service provider is a health service body.

(2) Unless the individual satisfies all the requirements set out in paragraph (3), the service provider must not appoint or have in place an individual—

- (a) as a director of the service provider, or
- (b) performing the functions of, or functions equivalent or similar to the functions of, such a director.

(3) The requirements referred to in paragraph (2) are that—

- (a) the individual is of good character,
- (b) the individual has the qualifications, competence, skills and experience which are necessary for the relevant office or position or the work for which they are employed,
- (c) the individual is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the office or position for which they are appointed or to the work for which they are employed,
- (d) the individual has not been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England, would be a regulated activity, and
- (e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual.

(4) In assessing an individual's character for the purposes of paragraph (3)(a), the matters considered must include those listed in Part 2 of Schedule 4.

(5) The following information must be available to be supplied to the Commission in relation to each individual who holds an office or position referred to in paragraph (2)(a) or (b)—

- (a) the information specified in Schedule 3, and
- (b) such other information as is required to be kept by the service provider under any enactment which is relevant to that individual.

(6) Where an individual who holds an office or position referred to in paragraph (2)(a) or (b) no longer meets the requirements in paragraph (3), the service provider must—

- (a) take such action as is necessary and proportionate to ensure that the office or position in question is held by an individual who meets such requirements, and
- (b) if the individual is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question.

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

6.—(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—

- (a) employed as a director, manager or secretary of the body, and
- (b) 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—

- (a) is of good character,
- (b) has the necessary qualifications, skills and experience to properly supervise the management of the carrying on of the regulated activity,

- (c) is able by reason of their health, after reasonable adjustments are made, of properly doing so, and
- (d) is able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

Requirements relating to registered managers

7.—(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) has the necessary qualifications, skills and experience to manage the carrying on of the regulated activity,
 - (c) able by reason of M's health, after reasonable adjustments are made, of doing so, and
 - (d) able to supply to the Commission, or arrange for the availability of, the information specified in Schedule 3.

SECTION 2

Fundamental Standards

General

8.—(1) A registered person must comply with regulations 9 to 19 in carrying on a regulated activity.

(2) But paragraph (1) does not require a person to do something to the extent that what is required to be done to comply with regulations 9 to 19 has already been done by another person who is a registered person in relation to the regulated activity concerned.

(3) For the purposes of determining under regulations 9 to 19 whether a service user who is 16 or over lacks capacity, sections 2 and 3 of the 2005 Act (people who lack capacity) apply as they apply for the purposes of that Act.

Person-centred care

9.—(1) The care and treatment of service users must—

- (a) be appropriate,
- (b) meet their needs, and
- (c) reflect their preferences.

(2) But paragraph (1) does not apply to the extent that the provision of care or treatment would result in a breach of regulation 11.

(3) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—

- (a) carrying out, collaboratively with the relevant person, an assessment of the needs and preferences for care and treatment of the service user;
- (b) designing care or treatment with a view to achieving service users' preferences and ensuring their needs are met;
- (c) enabling and supporting relevant persons to understand the care or treatment choices available to the service user and to discuss, with a competent health care professional or

other competent person, the balance of risks and benefits involved in any particular course of treatment;

- (d) enabling and supporting relevant persons to make, or participate in making, decisions relating to the service user's care or treatment to the maximum extent possible;
- (e) providing opportunities for relevant persons to manage the service user's care or treatment;
- (f) involving relevant persons in decisions relating to the way in which the regulated activity is carried on in so far as it relates to the service user's care or treatment;
- (g) providing relevant persons with the information they would reasonably need for the purposes of sub-paragraphs (c) to (f);
- (h) making reasonable adjustments to enable the service user to receive their care or treatment;
- (i) where meeting a service user's nutritional and hydration needs, having regard to the service user's well-being.

(4) Paragraphs (1) and (3) apply subject to paragraphs (5) and (6).

(5) If the service user is 16 or over and lacks capacity in relation to a matter to which this regulation applies, paragraphs (1) to (3) are subject to any duty on the registered person under the 2005 Act in relation to that matter.

(6) But if Part 4 or 4A of the 1983 Act applies to a service user, care and treatment must be provided in accordance with the provisions of that Act.

Dignity and respect

10.—(1) Service users must be treated with dignity and respect.

(2) Without limiting paragraph (1), the things which a registered person is required to do to comply with paragraph (1) include in particular—

- (a) ensuring the privacy of the service user;
- (b) supporting the autonomy, independence and involvement in the community of the service user;
- (c) having due regard to any relevant protected characteristics (as defined in section 149(7) of the Equality Act 2010) of the service user.

Need for consent

11.—(1) Care and treatment of service users must only be provided with the consent of the relevant person.

(2) Paragraph (1) is subject to paragraphs (3) and (4).

(3) If the service user is 16 or over and is unable to give such consent because they lack capacity to do so, the registered person must act in accordance with the 2005 Act.

(4) But if Part 4 or 4A of the 1983 Act applies to a service user, the registered person must act in accordance with the provisions of that Act.

(5) Nothing in this regulation affects the operation of section 5 of the 2005 Act, as read with section 6 of that Act (acts in connection with care or treatment).

Safe care and treatment

12.—(1) Care and treatment must be provided in a safe way for service users.

(2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—

- (a) assessing the risks to the health and safety of service users of receiving the care or treatment;
- (b) doing all that is reasonably practicable to mitigate any such risks;
- (c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely;
- (d) ensuring that the premises used by the service provider are safe to use for their intended purpose and are used in a safe way;
- (e) ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way;
- (f) where equipment or medicines are supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and to meet their needs;
- (g) the proper and safe management of medicines;
- (h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated;
- (i) where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users.

Safeguarding service users from abuse and improper treatment

13.—(1) Service users must be protected from abuse and improper treatment in accordance with this regulation.

(2) Systems and processes must be established and operated effectively to prevent abuse of service users.

(3) Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse.

(4) Care or treatment for service users must not be provided in a way that—

- (a) includes discrimination against a service user on grounds of any protected characteristic (as defined in section 4 of the Equality Act 2010) of the service user,
- (b) includes acts intended to control or restrain a service user that are not necessary to prevent, or not a proportionate response to, a risk of harm posed to the service user or another individual if the service user was not subject to control or restraint,
- (c) is degrading for the service user, or
- (d) significantly disregards the needs of the service user for care or treatment.

(5) A service user must not be deprived of their liberty for the purpose of receiving care or treatment without lawful authority.

(6) For the purposes of this regulation—

“abuse” means—

- (a) any behaviour towards a service user that is an offence under the Sexual Offences Act 2003⁽¹⁾,
- (b) ill-treatment (whether of a physical or psychological nature) of a service user,
- (c) theft, misuse or misappropriation of money or property belonging to a service user, or
- (d) neglect of a service user.

(1) 2003 c. 42.

- (7) For the purposes of this regulation, a person controls or restrains a service user if that person—
- (a) uses, or threatens to use, force to secure the doing of an act which the service user resists, or
 - (b) restricts the service user's liberty of movement, whether or not the service user resists,
- including by use of physical, mechanical or chemical means.

Meeting nutritional and hydration needs

- 14.—**(1) The nutritional and hydration needs of service users must be met.
- (2) Paragraph (1) applies where—
- (a) care or treatment involves—
 - (i) the provision of accommodation by the service provider, or
 - (ii) an overnight stay for the service user on premises used by the service for the purposes of carrying on a regulated activity, or
 - (b) the meeting of the nutritional or hydration needs of service users is part of the arrangements made for the provision of care or treatment by the service provider.
- (3) But paragraph (1) does not apply to the extent that the meeting of such nutritional or hydration needs would—
- (a) result in a breach of regulation 11, or
 - (b) not be in the service user's best interests.
- (4) For the purposes of paragraph (1), “nutritional and hydration needs” means—
- (a) receipt by a service user of suitable and nutritious food and hydration which is adequate to sustain life and good health,
 - (b) receipt by a service user of parenteral nutrition and dietary supplements when prescribed by a health care professional,
 - (c) the meeting of any reasonable requirements of a service user for food and hydration arising from the service user's preferences or their religious or cultural background, and
 - (d) if necessary, support for a service user to eat or drink.
- (5) Section 4 of the 2005 Act (best interests) applies for the purposes of determining the best interests of a service user who is 16 or over under this regulation as it applies for the purposes of that Act.

Premises and equipment

- 15.—**(1) All premises and equipment used by the service provider must be—
- (a) clean,
 - (b) secure,
 - (c) suitable for the purpose for which they are being used,
 - (d) properly used
 - (e) properly maintained, and
 - (f) appropriately located for the purpose for which they are being used.
- (2) The registered person must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used.
- (3) For the purposes of paragraph (1)(b), (c), (e) and (f), “equipment” does not include equipment at the service user's accommodation if—

- (a) such accommodation is not provided as part of the service user's care or treatment, and
- (b) such equipment is not supplied by the service provider.

Receiving and acting on complaints

16.—(1) Any complaint received must be investigated and necessary and proportionate action must be taken in response to any failure identified by the complaint or investigation.

(2) The registered person must establish and operate effectively an accessible system for identifying, receiving, recording, handling and responding to complaints by service users and other persons in relation to the carrying on of the regulated activity.

(3) The registered person must provide to the Commission, when requested to do so and by no later than 28 days beginning on the day after receipt of the request, a summary of—

- (a) complaints made under such complaints system,
- (b) responses made by the registered person to such complaints and any further correspondence with the complainants in relation to such complaints, and
- (c) any other relevant information in relation to such complaints as the Commission may request.

Good governance

17.—(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.

(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—

- (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);
- (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;
- (c) maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided;
- (d) maintain securely such other records as are necessary to be kept in relation to—
 - (i) persons employed in the carrying on of the regulated activity, and
 - (ii) the management of the regulated activity;
- (e) seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services;
- (f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).

(3) The registered person must send to the Commission, when requested to do so and by no later than 28 days beginning on the day after receipt of the request—

- (a) a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (2)(a) and (b) are being complied with, and
- (b) 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.

Staffing

18.—(1) Sufficient numbers of suitably qualified, competent, skilled and experienced persons must be deployed in order to meet the requirements of this Part.

- (2) Persons employed by the service provider in the provision of a regulated activity must—
- (a) receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform,
 - (b) be enabled where appropriate to obtain further qualifications appropriate to the work they perform, and
 - (c) where such persons are health care professionals, social workers or other professionals registered with a health care or social care regulator, be enabled to provide evidence to the regulator in question 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 or a requirement of their role.

Fit and proper persons employed

19.—(1) Persons employed for the purposes of carrying on a regulated activity must—

- (a) be of good character,
- (b) have the qualifications, competence, skills and experience which are necessary for the work to be performed by them, and
- (c) be able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the work for which they are employed.

(2) Recruitment procedures must be established and operated effectively to ensure that persons employed meet the conditions in—

- (a) paragraph (1), or
- (b) in a case to which regulation 5 applies, paragraph (3) of that regulation.

(3) The following information must be available in relation to each such person employed—

- (a) the information specified in Schedule 3, and
- (b) such other information as is required under any enactment to be kept by the registered person in relation to such persons employed.

(4) Persons employed must be registered with the relevant professional body where such registration is required by, or under, any enactment in relation to—

- (a) the work that the person is to perform, or
- (b) the title that the person takes or uses.

(5) Where a person employed by the registered person no longer meets the criteria in paragraph (1), the registered person must—

- (a) take such action as is necessary and proportionate to ensure that the requirement in that paragraph is complied with, and
- (b) if the person is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question.

(6) Paragraphs (1) and (3) of this regulation do not apply in a case to which regulation 5 applies.

Duty of candour

20.—(1) A health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must—

- (a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and
- (b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

(3) The notification to be given under paragraph (2)(a) must—

- (a) be given in person by one or more representatives of the health service body,
- (b) provide an account, which to the best of the health service body's knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification,
- (c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate,
- (d) include an apology, and
- (e) be recorded in a written record which is kept securely by the health service body.

(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—

- (a) the information provided under paragraph (3)(b),
- (b) details of any enquiries to be undertaken in accordance with paragraph (3)(c),
- (c) the results of any further enquiries into the incident, and
- (d) an apology.

(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body—

- (a) paragraphs (2) to (4) are not to apply, and
- (b) a written record is to be kept of attempts to contact or to speak to the relevant person.

(6) The health service body must keep a copy of all correspondence with the relevant person under paragraph (4).

(7) In this regulation—

“apology” means an expression of sorrow or regret in respect of a notifiable safety incident;

“moderate harm” means—

- (a) harm that requires a moderate increase in treatment, and
- (b) significant, but not permanent, harm;

“moderate increase in treatment” means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

“notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

- (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
- (b) severe harm, moderate harm or prolonged psychological harm to the service user;

“prolonged psychological harm” means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

“relevant person” means the service user or, in the following circumstances, a person lawfully acting on their behalf—

- (a) on the death of the service user,
- (b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
- (c) where the service user is 16 or over and lacks capacity (as determined in accordance with sections 2 and 3 of the 2005 Act) in relation to the matter;

“severe harm” means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user’s illness or underlying condition.