
STATUTORY INSTRUMENTS

2014 No. 000

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

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

Made - - - - - ***

Coming into force - - - - - *1st October 2014*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 20 and 161(3) and (4) of the Health and Social Care Act 2008(a).

In accordance with section 20(8) of that Act, the Secretary of State has consulted such persons as the Secretary of State considers appropriate.

A draft of these Regulations was laid before Parliament in accordance with section 162(3) of the Health and Social Care Act 2008, and was approved by a resolution of each House of Parliament.

PART 1

General

Citation and commencement

1. These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and come into force on 1st October 2014.

Interpretation

2.—(1) In these Regulations—

“the Act” means the Health and Social Care Act 2008;

“the 2005 Act” means the Mental Capacity Act 2005(a);

“the 2006 Act” means the National Health Service Act 2006(b);

“the 2010 Regulations” means Health and Social Care Act 2008 (Regulated Activities) Regulations 2010(c);

“adult placement carer” means an individual who, under the terms of a carer agreement, provides, or intends to provide, personal care for service users together with, where necessary, accommodation in the individual’s home;

“adult placement scheme” means a scheme carried on (whether or not for profit) by a local authority or other person for the purposes of—

- (a) recruiting and training adult placement carers,
- (b) making arrangements for the placing of service users with adult placement carers, and
- (c) supporting and monitoring placements;

“agency worker” and “temporary work agency” have the same meaning as in the Agency Workers Regulations 2010(d);

“carer agreement” means an agreement entered into between a person carrying on an adult placement scheme and an individual for the provision, by that individual, of personal care to a service user together with, where necessary, accommodation in the individual’s home;

“chiropodist or podiatrist” means a person registered as such with the Health and Care Professions Council(e) pursuant to article 5 of the Health Professions Order 2001(f);

“employment” means—

- (d) employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract, and
 - (e) the grant of practising privileges,
- and “employed” is to be construed accordingly;

“equipment” includes a medical device and materials used in, or used by persons employed in, the carrying on of a regulated activity;

“healthcare professional” means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(g) (regulation of health professions, social workers, other care workers, etc) applies;

“hospital” has the same meaning as in section 275 of the 2006 Act;

“medical device” has the same meaning as in regulation 2 (interpretation) of the Medical Devices Regulations 2002(h);

“medical practitioner” means a registered medical practitioner;

“personal care” means—

- (a) physical assistance given to a person in connection with—
 - (i) eating or drinking (including the maintenance of established parenteral nutrition),
 - (ii) toileting (including in relation to the process of menstruation),
 - (iii) washing or bathing,
 - (iv) dressing,

(a) 2005 c. 9.

(b) 2006 c. 41.

(c) S.I. 2010/781, as amended by S.I. 2011/2711, 2012/921, 2012/979, 2012/1479, 2012/1513, 2013/235 and 2013/472.

(d) S.I. 2010/93. Relevant amendments were made by S.I. 2011/1941.

(e) The Health and Care Professions Council is the body corporate, formally known as the Health Professions Council, continued under section 214(1) of the Health and Social Care Act 2012 (c. 7).

(f) S.I. 2002/254. See the definition of “relevant professions” in Schedule 3, paragraph 1 of the Order as amended by S.I. 2004/2033, article 10(5)(b)(i).

(g) 1999 c. 21.

(h) S.I. 2002/618. Relevant amendments were made by S.I. 2008/2986.

- (v) oral care, or
- (vi) the skin, hair and nails (with the exception of nail care provided by a chiropodist or podiatrist); or
- (b) the prompting, together with supervision, of a person, in relation to the performance of any of the activities listed in paragraph (a), where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision;

“practising privileges” means the grant by a service provider to a registered medical practitioner of permission to practice as a medical practitioner in a hospital managed by the service provider;

“premises” means—

- (c) any building or other structure, including any machinery, engineering systems or other objects which are physically affixed and integral to such building or structure, and any surrounding grounds; or
- (a) a vehicle;

“registered manager” means, in respect of a regulated activity, a person registered with the Commission^(a) under Chapter 2 of Part 1 of the Act as a manager in respect of that activity;

“registered person” means, in respect of a regulated activity, a person who is the service provider or registered manager in respect of that activity;

“relevant person” means the service user or, where the service user is not competent to make a decision in relation to their care or treatment, a person lawfully acting on their behalf;

“service provider” means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a service provider in respect of that activity;

“service user” means a person who receives services provided in the carrying on of a regulated activity;

“treatment” includes—

- (a) a diagnostic or screening procedure carried out for medical purposes;
- (b) the ongoing assessment of a service user’s mental or physical state;
- (c) nursing, personal and palliative care; and
- (d) the giving of vaccinations and immunisations; and

“vulnerable adult” has the same meaning as in section 60(1) of the Safeguarding Vulnerable Groups Act 2006^(b).

(2) In the definition of “employment” in paragraph (1), the reference to otherwise than under a contract includes—

- (a) under a carer agreement;
- (b) under an agreement between the service provider and a temporary work agency for the supply of an agency worker to the service provider; and
- (c) under arrangements for persons to provide their services voluntarily.

(a) By section 1(1) of the Health and Social Care Act 2008, “the Commission” means the Care Quality Commission.

(b) 2006 c. 47.

PART 2

Quality and Safety of Service Provision in Relation to Regulated Activity

SECTION 1

General

General

3. A registered person must, in so far as they are applicable to each regulated activity, comply with regulations 4 to 14 in carrying on the regulated activities in respect of which they are registered.

SECTION 2

Fundamental standards

Person-centred care

- 4.—(1) The care and treatment of service users must reflect their needs and preferences.
- (2) Paragraph (1) applies—
- (a) subject to paragraph (4), and
 - (b) in so far as it is in accordance with generally accepted professional standards, practices and principles for the care and treatment to reflect such needs and preferences.
- (3) The things which a registered person is required to do to comply with paragraph (1) include—
- (a) carrying out an assessment of the needs and preferences for care and treatment of the service user;
 - (b) designing care or treatment with a view to ensuring service users' welfare;
 - (c) so far as is reasonably practicable, permitting and encouraging service users to make, or participate in making, decisions relating to their care or treatment to the maximum extent possible;
 - (d) where the service user is unable to express their preferences because they lack capacity, determining and acting in accordance with the best interests of the service user;
 - (e) where applicable, providing for the making of reasonable adjustments to meet the service user's individual needs; and
 - (f) have sufficient quantities of suitably accessible equipment and medicines to ensure the safety of service users and to meet their assessed needs.
- (4) Where Part 4 or 4A of the Mental Health Act 1983^(a) applies to a service user, care and treatment must be provided in accordance with the provisions of that Act.
- (5) For the purposes of paragraph (3)(d)—
- (a) section 2 of the 2005 Act (people who lack capacity) applies for the purposes of determining whether a service user lacks capacity, and
 - (b) section 4 of the 2005 Act (best interests) applies as it applies for the purposes of that Act.

Dignity and respect

- 5.—(1) Service users must be treated with dignity and respect.
- (2) The things which a registered person is required to do to comply with paragraph (1) include—

(a) 1983 c. 20.

- (a) promoting the privacy, autonomy, independence and involvement in the community of the service user; and
- (b) having due regard to any protected characteristics (as laid down in section 4 of the Equality Act 2010^(a)) of the service user.

Need for consent

6.—(1) Care and treatment must only be provided with, and in accordance with, the consent of the relevant person.

(2) Where the relevant person is unable to give such consent because they lack capacity, the registered person must determine and act in accordance with the best interests of the service user.

(3) Where Part 4 or 4A of the Mental Health Act 1983 applies to a service user, paragraph (1) is subject to the provisions of that Act.

(4) For the purposes of paragraph (2)—

- (a) section 2 of the 2005 Act applies for the purposes of determining whether a service user lacks capacity, and
- (b) section 4 of the 2005 Act (best interests) applies as it applies for the purposes of that Act.

Safe and appropriate care and treatment

7.—(1) All care and treatment provided to service users must be appropriate and safe.

(2) The things which a registered person is required to do to comply with paragraph (1) include—

- (a) taking appropriate steps to mitigate the risks to service users of receiving care or treatment that is inappropriate or unsafe;
- (b) taking appropriate steps for the proper and safe management of medicines;
- (c) establishing and operating effectively systems designed to assess the risk of, and to prevent, detect and control the spread of, infections, including those that are health care associated; and
- (d) where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working in cooperation with such other persons to ensure that appropriate care planning takes place to ensure the health, safety and welfare of the service users.

(3) For the purposes of paragraph (1), care or treatment will not be appropriate if it is not provided in accordance with generally accepted professional standards, practices and principles or if it includes—

- (a) unlawful discrimination against service users, or
- (b) control or restraint which is—
 - (i) unlawful, or
 - (ii) not necessary to prevent, or not proportionate to, the risk posed if the service user was not subject to control or restraint.

Safeguarding service users from abuse

8.—(1) Service users must not be subject to abuse.

(2) Appropriate steps must be taken—

- (i) to prevent abuse before it occurs, and
- (ii) to respond to any allegation of abuse.

(a) 2010 c. 15.

- (3) For the purposes of this regulation, “abuse”, in relation to a service user, includes—
- (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 to a service user or place the service user at risk of harm.

Meeting nutritional needs

9.—(1) The nutritional needs of service users must be met.

(2) In this regulation, “nutritional needs” means adequate nutrition to sustain life and good health and includes—

- (a) those needs which can be met wholly or in part by the provision of food or drink,
- (b) parenteral nutrition and dietary supplements when prescribed by a healthcare professional,
- (c) any reasonable requirements arising from a service user’s religious or cultural background, and
- (d) where necessary, support to eat and drink.

Cleanliness, safety and suitability of premises and equipment

10.—(1) All premises and equipment used by the registered provider must, in accordance with generally accepted professional standards, practices and principles, be—

- (a) safe, clean and secure,
- (b) suitable for the purpose for which they are being used, and
- (c) properly used and maintained.

(2) The registered provider must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purpose for which they are being used.

(3) For the purposes of this regulation “premises” does not include a service user’s own home

Receiving and acting on complaints

11.—(1) Any complaint received must be appropriately investigated and appropriate action must be taken in response to the complaint.

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

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

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

(2) Such systems or processes must enable the registered person, in particular, to—

- (a) assess, monitor and improve the quality of the services provided (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 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;
- (d) maintain such other records as are appropriate in relation to—
 - (i) persons employed, and
 - (ii) the management of the regulated activity;
- (e) seek and act on feedback from service users 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; and
- (f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).

Staffing

13.—(1) The registered person must deploy sufficient numbers of suitably qualified, skilled and experienced persons in order to meet the requirements of this Part.

(2) The registered person must ensure that persons employed by the registered provider in the provision of a regulated activity—

- (a) receive appropriate support, training, professional development, supervision and appraisal;
- (b) are enabled where appropriate, from time to time, to obtain further qualifications appropriate to the work they perform; and
- (c) where such persons are healthcare professionals, or social workers or other professionals registered with the Health and Care Professions Council, 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 practice.

Fit and proper persons employed

14.—(1) Persons employed by the registered person must—

- (a) be of good character,
- (b) have the qualifications, skills and experience which are necessary for the work to be performed, and
- (c) be physically and mentally capable, 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 paragraph (1).

(3) The information specified in the Schedule and such other information as is appropriate must be available in relation to each such person 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) Appropriate steps must be taken in relation to a person employed by the registered person who no longer meets the criteria in paragraph (1), including—

- (a) where the person is a healthcare professional, informing the body responsible for regulation of the health care profession in question, or
- (b) where the person is a social worker or other professional registered with the Health and Care Professions Council, informing the Council.

PART 3

Compliance and Offences

Compliance with regulations

15. Where there is more than one registered person in respect of a regulated activity, or in respect of that activity as carried on at or from particular premises, anything which is required under these Regulations to be done by the registered person is not, if done by one of the registered persons, to be required to be done by any of the other registered persons.

Guidance and Code

16. For the purposes of compliance with the requirements set out in these Regulations, the registered person must have regard to—

- (a) guidance issued by the Commission under section 23 of the Act in relation to the requirements set out in Part 2 (with the exception of regulation 7 in so far as it applies to health care associated infections); and
- (b) in relation to regulation 7, any code of practice issued by the Secretary of State under section 21 of the Act in relation to the prevention or control of health care associated infections.

Offences

17.—(1) A breach of any of regulations 4 to 14 is an offence.

(2) The Commission may not bring proceedings in respect of a failure to comply with any of those regulations where such breach is a result only of a failure to comply with any of regulations 4(3)(c) or (f), 7(2), 11(2), 11(3) or 12 to 14 unless the conditions in paragraph (3) or (4) (as the case may be) have been met.

(3) In the case of an NHS trust established under section 25 of the National Health Service Act 2006 or an NHS foundation trust—

- (a) the Commission has given the registered person a notice in respect of the alleged failure, setting out what the alleged failure is, and
- (b) the registered person did not secure compliance with the relevant requirement within the period specified in the notice.

(4) In the case of any other registered person—

- (a) the alleged failure is one in respect of which the Commission has given a warning notice to the registered person under section 29 of the Act;
- (b) that warning notice specified a time within which the registered person must take action to secure compliance pursuant to section 29(2)(c)(ii) of the Act; and
- (c) the registered person did not secure compliance within the specified time.

(5) No proceedings may be brought against an NHS trust or an NHS foundation trust for an offence that arises out of a failure to which a notice under paragraph (3)(a) relates, so far as occurring before the time specified in that notice for securing compliance with the relevant requirement.

(6) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine.

(7) In any proceedings for an offence under this regulation, it is a defence for the registered person to prove that they took all appropriate steps and exercised all due diligence to ensure that the provision in question was complied with.

Onus of proving limits of what is practicable etc

18. In any proceedings for an offence under regulation 4 or 14 consisting of a failure to comply with a requirement to do something so far as is reasonably practicable, it is for the accused to prove that it was not reasonably practicable to do more than was in fact done to satisfy the requirement, or that there was no better practicable means than was in fact used to satisfy the requirement.

PART 4

Revocations, Amendments and Review

Revocations

19. Regulations 8 to 24, 27 and 30 of the 2010 Regulations are revoked.

Amendments

20.—(1) The 2010 Regulations are amended in accordance with this regulation.

(2) In regulation 1, omit the entries for “employment” and “practising privileges”.

(3) In regulation 26—

- (a) in paragraph (1)(a), for the words “set out in Part 3 and 4” to the end substitute “Part 3”; and
- (b) omit paragraphs (1)(b) and (2)(b).

(4) For the entry relating to regulation 27 of the 2010 Regulations in Schedule 4 (fixed penalty offences) substitute—

“Regulation 17 of the Health and Social Care Act 2008 (Regulation of Regulated Activities) Regulations 2014	Contravention of, or failure to comply with, requirements relating to quality and safety of service provision in relation to a regulated activity	£4,000 in the case of an offence committed by a service provider; £2,000 in the case of an offence committed by a registered manager”
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Review

21.—(1) Before 1st October 2017, the Secretary of State must—

- (a) carry out a review of these Regulations and the 2010 Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations and the 2010 Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

Signed by the authority of the Secretary of State for Health

Name

SCHEDULE

Regulation 14

**Information Required in Respect of Persons Employed for the Purposes
of a Regulated Activity**

1. Proof of identity including a recent photograph.
2. Where required for a purpose referred to in section 113A(2)(b) of the Police Act 1997^(a), a copy of a criminal record certificate issued under section 113A of that Act together with, after the appointed day and where applicable, the information mentioned in section 30A(3) of the Safeguarding Vulnerable Groups Act 2006 (provision of barring information on request)^(b).
3. Where required for a purpose referred to in section 113B(2)(b) of the Police Act 1997, a copy of an enhanced criminal record certificate issued under section 113B of that Act together with, where applicable, suitability information relating to children or vulnerable adults.
4. Satisfactory evidence of conduct in previous employment concerned with the provision of services relating to—
 - (a) health or social care, or
 - (b) children or vulnerable adults.
5. Where a person (P) has been previously employed in a position whose duties involved work with children or vulnerable adults, satisfactory verification, so far as reasonably practicable, of the reason why P's employment in that position ended.
6. Satisfactory documentary evidence of any relevant qualification.
7. A full employment history, together with a satisfactory written explanation of any gaps in employment.
8. Satisfactory information about any physical or mental health conditions which are relevant to the person's capability to properly perform tasks which are intrinsic to their employment for the purposes of the regulated activity.
9. For the purposes of this Schedule—
 - (a) "the appointed day" means the day on which section 30A of the Safeguarding Vulnerable Groups Act 2006 comes into force;
 - (b) "satisfactory" means satisfactory in the opinion of the Commission; and
 - (c) "suitability information relating to children or vulnerable adults" means the information specified in sections 113BA and 113BB respectively of the Police Act 1997.

EXPLANATORY NOTE*(This note is not part of the Regulations)*

These Regulations make provision for the requirements that will apply in relation to the way in which regulated activities for the purposes of Part 1 of the Health and Social Care Act 2008 ("the Act") are carried on. Regulations 4 to 14 lay down fundamental standards to be met by registered persons.

The fundamental standards provide that, in so far as they are applicable to the carrying on of a regulated activity:

(a) 1997 c. 50.
(b) 2006 c. 47.

- (a) care and treatment must reflect service users needs and preferences (regulation 4);
- (b) service users must be treated with dignity and respect (regulation 5);
- (c) care and treatment must only be provided with consent (regulation 6)
- (d) all care and treatment provided must be appropriate and safe (regulation 7);
- (e) service users must not be subject to abuse (regulation 8);
- (f) service users' nutritional needs must be met (regulation 9);
- (g) all premises and equipment used must be safe, clean, secure, suitable for the purpose for which they are being used, and properly used and maintained (regulation 10);
- (h) complaints must be appropriately investigated and appropriate action taken in response (regulation 11);
- (i) systems and processes must be established to ensure compliance with the fundamental standards (regulation 12);
- (j) sufficient numbers of suitably qualified, skilled and experienced staff must be deployed (regulation 13); and
- (k) persons employed must be of good character, have the necessary qualifications, skills and experience, and be capable of performing the work for which they are employed (regulation 14).

Regulation 15 deals with who is responsible for complying with the Regulations in circumstances where there is more than one registered person in respect of a regulated activity. Regulation 16 states that, for the purposes of compliance with the Regulations, a registered person must take account of guidance issued by the Care Quality Commission under section 23 of the Act and the code of practice issued by the Secretary of State under section 21 of the Act in relation to the prevention or control of healthcare associated infections.

Regulation 17 provides that a breach of regulations 4 to 14 is to be an offence, and also includes a due diligence defence relating to any proceedings under the Regulations. In addition, it provides that no prosecution may be brought for a breach of any of the requirements listed in paragraph (2) of regulation 17 unless the breach is one which the registered person has failed to remedy in response to a notice from the Care Quality Commission.

Regulation 19 revokes regulations 8 to 24, 27 and 30 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 ("the 2010 Regulations"), which are replaced by regulations 3 to 14, 17 and 21 of these Regulations. Regulation 20 makes amendments to the 2010 Regulations which are needed as a consequence of these Regulations.

A full impact assessment of the costs and benefits of this instrument is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS (www.gov.uk/government/organisations/department-of-health) and is published alongside this instrument and its Explanatory Memorandum at www.legislation.gov.uk.