
DRAFT STATUTORY INSTRUMENTS

2014 No.

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

PART 1

General

Citation and commencement

1.—(1) These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

(2) This regulation and regulation 2 come into force on the day after the day on which these Regulations are made.

(3) The provisions to which this paragraph applies come into force at the end of the period of 21 days beginning with the day on which these Regulations are made.

(4) Paragraph (3) applies to—

- (a) regulation 5, and Schedule 3 insofar as it relates to regulation 5;
- (b) regulation 20;
- (c) regulation 21, only insofar as it relates to regulations 5 and 20;
- (d) regulation 22(3);
- (e) regulation 22(4), only insofar as it relates to a breach of regulation 20(2)(a) and (3);
- (f) regulation 23(6);
- (g) regulation 24 and Schedule 5, only insofar as they relate to a contravention of, or a failure to comply with, requirements in regulation 20(2)(a) and (3);
- (h) regulation 26(2);
- (i) Schedule 4.

(5) All other provisions of these Regulations come into force on 1st April 2015.

Interpretation

2.—(1) In these Regulations—

- “16 to 19 Academy” has the same meaning as in section 1B of the Academies Act 2010(1);
- “the Act” means the Health and Social Care Act 2008;
- “the 1983 Act” means the Mental Health Act 1983(2);

(1) 2010 c. 32. Section 1B was inserted by section 53(7) of the Education Act 2011 (c. 21).

(2) 1983 c. 20.

“the 2005 Act” means the Mental Capacity Act 2005(3);

“the 2006 Act” means the National Health Service Act 2006(4);

“the 2001 Order” means the Health and Social Work Professions Order 2001(5);

“the 2010 Regulations” means the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010(6);

“employment” means—

- (a) employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract, and
- (b) the grant of practising privileges by a service provider to a medical practitioner, giving permission to practice as a medical practitioner in a hospital managed by the service provider,

and “employed” and “employer” is to be construed accordingly;

“employment agency” and “employment business” have the same meaning as in section 13 (interpretation) of the Employment Agencies Act 1973(7);

“equipment” includes—

- (a) a medical device (as defined in regulation 2(1) (interpretation) of the Medical Devices Regulations 2002)(8), and
- (b) materials used in, or used by persons employed in, the carrying on of a regulated activity;

“health care professional”, except in paragraph 4 of Schedule 1, means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(9) (regulation of health professions, social workers, other care workers, etc) applies;

“health service body” means—

- (a) an NHS trust established under section 25 of the 2006 Act,
- (b) an NHS foundation trust, or
- (c) a Special Health Authority;

“hospital”, except in paragraphs 1(3)(d) and 5 of Schedule 1, has the same meaning as in section 275 (interpretation) of the 2006 Act;

“institution within the further education sector” has the same meaning as in section 91 (interpretation of Education Acts) of the Further and Higher Education Act 1992(10);

“local anaesthesia” means any anaesthesia other than general, spinal or epidural anaesthesia, and also excludes the administration of a regional nerve block;

“medical practitioner” means a registered medical practitioner;

“nominated individual” must be construed in accordance with regulation 6(2);

“nurse” means a registered nurse;

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- (3) 2005 c. 9. Relevant amendments were made by the Mental Health Act 2007 (c. 12), sections 50 and 55 and Part 10 of Schedule 11.
 - (4) 2006 c. 41.
 - (5) S.I. 2002/254. Relevant amendments were made by sections 213 and 214 of the Health and Social Care Act 2012 (c. 7) and S.I. 2004/2033, 2009/1182 and 2009/1357.
 - (6) S.I. 2010/781, as amended by S.I. 2011/2711, 2012/921, 2012/979, 2012/1479, 2012/1513, 2013/235 and 2013/472.
 - (7) 1973 c. 35. Relevant amendments were made by the Employment Relations Act 1999 (c. 26), section 31 and paragraphs 1 and 7 of Schedule 7.
 - (8) S.I. 2002/618. Relevant amendments were made by S.I. 2008/2986.
 - (9) 1999 c. 21. Relevant amendments were made by the Health and Social Care Act 2008, sections 111 and 116, paragraph 1 of Schedule 8 and Part 2 of Schedule 15, the Health and Social Care Act 2012, sections 209 and 213, and S.I. 2002/253 and 2010/231.
 - (10) 1992 c. 13. Relevant amendments were made by the Apprenticeships, Skills, Children and Learning Act 2009 (c. 22), section 125 and paragraphs 1 and 13(1) and (2) of Schedule 8.

“nursing care” means any services provided by a nurse and involving—

- (a) the provision of care, or
- (b) the planning, supervision or delegation of the provision of care,

other than any services which, having regard to their nature and the circumstances in which they are provided, do not need to be provided by a nurse;

“partnership” does not include a limited liability partnership;

“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,
 - (v) oral care, or
 - (vi) the care of skin, hair and nails (with the exception of nail care provided by a person registered with the Health and Care Professions Council as a chiropodist or podiatrist pursuant to article 5 of the 2001 Order), 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;

“premises” means—

- (a) 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
- (b) a vehicle,

but in regulations 12, 14 and 15 does not include the service user’s accommodation where such accommodation is not provided as part of the service user’s care or treatment;

“reasonable adjustments” means such reasonable adjustments as would be required under the Equality Act 2010⁽¹¹⁾;

“registered manager” means, in respect of a regulated activity, a person registered with the Commission⁽¹²⁾ 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”, except in regulation 20, means the service user or, where the service user is under 16 and not competent to make a decision in relation to their care or treatment, a person lawfully acting on their behalf;

“school” has the same meaning as in section 4 of the Education Act 1996⁽¹³⁾;

“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;

(11) 2010 c. 15.

(12) By section 1(1) of the 2008 Act, “the Commission” means the Care Quality Commission.

(13) 1996 c. 56. Relevant amendments were made by the Education Act 1997 (c. 44), sections 51 and 57, paragraph 10 of Schedule 7 and Schedule 8, the Education Act 2002 (c. 32), section 215 and Part 3 of Schedule 22, the Childcare Act 2006 (c. 21), section 95, and the Education Act 2011 (c. 21), section 54 and paragraph 9 of Schedule 13, and S.I. 2010/1080.

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

“shared lives agreement” means an agreement entered into between a person carrying on a shared lives 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;

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

“shared lives 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 shared lives carers,
- (b) making arrangements for the placing of service users with shared lives carers, and
- (c) supporting and monitoring placements;

“social worker” means a person who is registered as such in Part 16 of the register maintained by the Health and Care Professions Council under article 5 of the 2001 Order;

“treatment”, except in paragraph 5 of Schedule 1, 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;

“vulnerable adult” has the same meaning as in section 60(1) (interpretation) of the Safeguarding Vulnerable Groups Act 2006⁽¹⁴⁾.

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

- (a) under a shared lives 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;
- (c) under arrangements for persons to provide their services voluntarily.

(3) In paragraph (2)—

“agency worker” and “temporary work agency” have the same meaning as in the Agency Workers Regulations 2010⁽¹⁵⁾.

PART 2

Regulated Activities

Prescribed activities

3.—(1) Subject to paragraphs (3) and (4), the activities specified in Schedule 1 are prescribed as regulated activities for the purposes of section 8(1) of the Act.

(2) An activity which is ancillary to, or is carried on wholly or mainly in relation to, a regulated activity shall be treated as part of that activity.

⁽¹⁴⁾ 2006 c. 47. Relevant amendments were made by section 65(2) of the Protection of Freedoms Act 2012 (c. 9).

⁽¹⁵⁾ S.I. 2010/93. Relevant amendments were made by S.I. 2011/1941.

- (3) An activity is only a regulated activity if it is carried on in England.
- (4) The activities specified in Schedule 2 are not regulated activities.

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⁽¹⁶⁾,
- (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.

(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.

(16) 2003 c. 42.

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.

PART 4

Compliance and Offences

Guidance and Code

21. 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 3 (with the exception of regulation 12 in so far as it applies to health care associated infections); and
- (b) in relation to regulation 12, in so far as it applies to health care associated infections, 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

22.—(1) It is an offence for a registered person to fail to comply with any of the requirements in the following regulations, as read with regulation 8—

- (a) regulation 11,
- (b) regulation 16(3), or
- (c) regulation 17(3).

(2) A registered person commits an offence if the registered person fails to comply with a requirement of regulation 12, 13(1) to (4) or 14, as read with regulation 8, and such failure results in—

- (a) avoidable harm (whether of a physical or psychological nature) to a service user,
- (b) a service user being exposed to a significant risk of such harm occurring, or
- (c) in a case of theft, misuse or misappropriation of money or property, any loss by a service user of the money or property concerned.

(3) It is an offence for a health service body to fail to comply with regulation 20(2)(a) and (3).

(4) But it is a defence for a registered person, or (in the case of regulation 20(2)(a) and (3)) a health service body, to prove that they took all reasonable steps and exercised all due diligence to prevent the breach of any of those regulations that has occurred.

Offences: penalties

23.—(1) Paragraph (2) applies if section 85(2) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012(17) is in force on the day these Regulations are made.

(2) A person guilty of an offence under regulation 22(1) for breach of regulation 11 or an offence under regulation 22(2) is liable on summary conviction to a fine.

(3) Paragraph (4) applies if section 85(2) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 is not in force on the day these Regulations are made.

(4) A person guilty of an offence under regulation 22(1) for breach of regulation 11 or an offence under regulation 22(2) is liable on summary conviction to a fine not exceeding £50,000.

(5) A person guilty of an offence under regulation 22(1) for breach of regulation 16(3) or 17(3) is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale.

(6) A health service body guilty of an offence under regulation 22(3) is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale.

PART 5

Penalty Notices

Penalty notices

24.—(1) The offences under the provisions listed in the first column of Schedule 5 are prescribed as fixed penalty offences for the purposes of section 86 of the Act.

(2) The monetary amount of a penalty for each fixed penalty offence is prescribed in the third column of Schedule 5.

(3) The time by which the penalty specified in a penalty notice is to be paid is the end of the period of 28 days beginning with the date of receipt of the notice.

(4) Subject to paragraph (5), the methods by which a penalty notice may be paid are by cash, cheque, credit or debit card, postal order or electronic transfer of funds to the Commission's bank account.

(5) A penalty may only be paid by credit card from the date on which the Commission has in place arrangements to accept such payments.

(6) Where a person is given a penalty notice, proceedings for the offence to which the notice relates may not be instituted before the end of the period of 28 days beginning with the date of receipt of the notice.

(7) Section 93 of the Act applies to a penalty notice as it applies to a notice required to be given under Part 1 of the Act.

(8) If a penalty notice is given by being sent by an electronic communication, in accordance with section 94 of the Act, the notice is, unless the contrary is proved, to be taken to have been received on the next working day after the day on which it is sent.

(9) A penalty notice must give such particulars of the circumstances alleged to constitute the offence as seem to the Commission to be reasonably required to provide the person to whom the notice is given with information about it.

(10) A penalty notice must state—

(a) the name and address of the person to whom the notice is given,

- (b) the amount of the penalty,
 - (c) the period during which proceedings will not be taken for the offence,
 - (d) that payment within that period will discharge any liability for the offence,
 - (e) the consequences of the penalty not being paid before the expiration of the period for paying it,
 - (f) the person to whom and the address at which the penalty may be paid and to which any correspondence about the penalty may be sent, and
 - (g) the means by which payment of the penalty may be made.
- (11) The Commission may withdraw a penalty notice by giving written notice of the withdrawal to the person to whom the notice was given if—
- (a) the Commission determines that it ought not to have been given or it ought not to have been given to the person to whom it was addressed, or
 - (b) it appears to the Commission that the notice contains material errors.
- (12) A penalty notice may be withdrawn in accordance with paragraph (11) whether or not the period for payment referred to in paragraph (3) has expired, and whether or not the penalty has been paid.
- (13) Where a penalty notice has been withdrawn in accordance with paragraph (11), the Commission must—
- (a) repay any amount paid by way of penalty in pursuance of that notice to the person who paid it, within 14 days beginning with the day on which written notice of the withdrawal was given, and
 - (b) remove from publication any information about the payment of the penalty which has been published in accordance with regulations made under section 89 of the Act, within 7 days beginning with the day on which written notice of the withdrawal was given.
- (14) Except as provided in paragraph (15), no proceedings may be instituted or continued against the person to whom a penalty notice was given for the offence to which the penalty notice relates where that notice has been withdrawn in accordance with paragraph (11).
- (15) Where a penalty notice has been withdrawn under paragraph (11)(b), proceedings may be instituted or continued for the offence in connection with which that penalty notice was issued if a further penalty notice in respect of the offence has been given and the penalty has not been paid before the expiration of the period for payment referred to in paragraph (3).
- (16) In this regulation—
- “debit card” means a card the use of which by its holder to make a payment results in a current account of the holder at a bank, or at any other institution providing banking services, being debited with the payment;
- “credit card” means a card which is a credit-token within the meaning of section 14 of the Consumer Credit Act 1974⁽¹⁸⁾;
- “electronic communication” has the same meaning as in the Electronic Communications Act 2000⁽¹⁹⁾;
- “working day” means any day other than—
- (a) a Saturday or Sunday,
 - (b) Christmas Day or Good Friday, or

⁽¹⁸⁾ 1974 c. 39.

⁽¹⁹⁾ 2000 c. 7. See section 15(1) (general interpretation), as amended by the Communications Act 2003 (c. 21), section 406(1) and paragraph 158 of Schedule 17.

- (c) a day which is a bank holiday in England and Wales under the Banking and Financial Dealings Act 1971(20).

PART 6

Miscellaneous

Revocations

25. The following are revoked—

- (a) the 2010 Regulations,
- (b) the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2011(21),
- (c) regulation 11 of the Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012(22), and
- (d) the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012(23).

Transitional and transitory provision

26.—(1) No proceedings for an offence under regulation 22 may be brought against a person for a failure to comply with any of regulations 11, 12, 13(1) to (4), 14, 16(3), 17(3) or 20(2)(a) and (3) in so far as such failure was a continuing failure which—

- (a) was the subject of a warning notice given by the Commission in accordance with regulation 27(2)(a) of the 2010 Regulations (offences), and
- (b) occurred during the period ending with the time specified in that notice within which the registered person must take action to secure compliance in accordance with section 29(2)(c)(ii) of the Act.

(2) Until such time as these Regulations come fully into force, regulation 21 (requirements relating to workers) of the 2010 Regulations is to be read as though there were inserted at the end of that regulation—

“This regulation, except sub-paragraph (c), does not apply in a case to which regulation 5 (fit and proper persons: directors) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 applies.”

Review

27.—(1) Before the end of each review period, the Secretary of State must—

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

(2) The report must in particular—

(20) 1971 c. 80. See section 1 and paragraph 1 of Schedule 1.

(21) S.I. 2011/2711.

(22) S.I. 2012/921.

(23) S.I. 2012/1513.

- (a) set out the objectives intended to be achieved by the regulatory system established by these 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.
- (3) In this regulation, “review period” means—
- (a) the period of five years beginning on 1st April 2015, and
 - (b) subject to paragraph (4), each successive period of five years.
- (4) If a report under this regulation is laid before Parliament before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is laid.

Signed by the authority of the Secretary of State for Health

Date

Name
Minister of State
Department of Health