

*Draft Regulations laid before Parliament under section 162(3)(b) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**2014 No. 000**

**NATIONAL HEALTH SERVICE, ENGLAND  
SOCIAL CARE, ENGLAND  
PUBLIC HEALTH, ENGLAND**

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

*Made* - - - - *\*\*\**

*Coming into force in accordance with regulation 1*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 8, 20(1) to (5A), 35, 86(2) and (4), 87(1) and (2) and 161(3) and (4) of the Health and Social Care Act 2008<sup>(1)</sup>.

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.—(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.

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(1) 2008 c. 14. Section 20 of the Health and Social Care Act 2008 (“the 2008 Act”) was amended by section 81 of the Care Act 2014 (c. 23). Section 161(3) of the 2008 Act was amended by section 294(4) of the Health and Social Care Act 2012 (c. 7).

(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(2);

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

“the 1983 Act” means the Mental Health Act 1983(3);

“the 2005 Act” means the Mental Capacity Act 2005(4);

“the 2006 Act” means the National Health Service Act 2006(5);

“the 2001 Order” means the Health and Social Work Professions Order 2001(6);

“the 2010 Regulations” means the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010(7);

“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(8);

“equipment” includes—

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(2) 2010 c. 32. Section 1B was inserted by section 53(7) of the Education Act 2011 (c. 21).

(3) 1983 c. 20.

(4) 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.

(5) 2006 c. 41.

(6) 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.

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

(8) 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.

(a) a medical device (as defined in regulation 2(1) (interpretation) of the Medical Devices Regulations 2002)(9), 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(10) (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(11);

“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;

“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

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

(10) 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.

(11) 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.

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(12);

“registered manager” means, in respect of a regulated activity, a person registered with the Commission(13) 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(14);

“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;

“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

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(12) 2010 c. 15.

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

(14) 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.

(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<sup>(15)</sup>.

(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<sup>(16)</sup>.

## 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.

(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

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<sup>(15)</sup> 2006 c. 47. Relevant amendments were made by section 65(2) of the Protection of Freedoms Act 2012 (c. 9).

<sup>(16)</sup> S.I. 2010/93. Relevant amendments were made by S.I. 2011/1941.

- (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(17),
  - (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.

### **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,

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(17) 2003 c. 42.

- (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(18) 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<sup>(19)</sup>;

“electronic communication” has the same meaning as in the Electronic Communications Act 2000<sup>(20)</sup>;

“working day” means any day other than—

- (a) a Saturday or Sunday,
- (b) Christmas Day or Good Friday, or
- (c) a day which is a bank holiday in England and Wales under the Banking and Financial Dealings Act 1971<sup>(21)</sup>.

## 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<sup>(22)</sup>,

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<sup>(19)</sup> 1974 c. 39.

<sup>(20)</sup> 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.

<sup>(21)</sup> 1971 c. 80. See section 1 and paragraph 1 of Schedule 1.

<sup>(22)</sup> S.I. 2011/2711.

- (c) regulation 11 of the Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012(23), and
- (d) the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012(24).

### **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—

- (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.

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(23) S.I. 2012/921.

(24) S.I. 2012/1513.

Signed by the authority of the Secretary of State for Health

Date

*Name*  
Minister of State  
Department of Health

## SCHEDULE 1

Regulation 3(1)

### Regulated Activities

#### Personal care

1.—(1) Subject to sub-paragraphs (2) and (3), the provision of personal care for persons who, by reason of old age, illness or disability are unable to provide it for themselves, and which is provided in a place where those persons are living at the time the care is provided.

(2) Sub-paragraph (1) does not apply where paragraph 2 (accommodation for persons who require nursing or personal care) applies.

(3) Sub-paragraph (1) does not apply to—

- (a) the supply of carers to a service provider by an undertaking acting as an employment agency or employment business for the purposes of that provider carrying on a regulated activity,
- (b) the introduction of carers to an individual (other than a service provider) by a person (including an employment agency or an employment business) having no ongoing role in the direction or control of the service provided to that individual,
- (c) the services of a carer employed by an individual or related third party, without the involvement of an undertaking acting as an employment agency or employment business, and working wholly under the direction and control of that individual or related third party in order to meet the individual's own care requirements, and
- (d) the provision of personal care by a person managing a prison or other similar custodial establishment (other than a hospital within the meaning of Part 2 of the 1983 Act).

(4) In sub-paragraph (3)—

“carer” means an individual who provides personal care to a person referred to in sub-paragraph (1);

“related third party” means—

- (a) an individual with parental responsibility (within the meaning of section 3 of the Children Act 1989<sup>(25)</sup>) for a child to whom personal care services are to be provided;
- (b) an individual with power of attorney or other lawful authority to make arrangements on behalf of the person to whom personal care services are to be provided;
- (c) a group of individuals mentioned in either of paragraphs (a) or (b) making arrangements on behalf of one or more persons to whom personal care services are to be provided;
- (d) a trust established for the purpose of providing services to meet the health or social care needs of a named individual.

#### Accommodation for persons who require nursing or personal care

2.—(1) The provision of residential accommodation together with nursing or personal care.

(2) Sub-paragraph (1) does not apply to the provision of accommodation—

- (a) to an individual by a shared lives carer under the terms of a shared lives agreement,
- (b) in a school,
- (c) in an institution within the further education sector or in a 16 to 19 Academy, or

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(25) 1989 c. 41.

- (d) in an institution within the further education sector where the number of persons to whom nursing or personal care and accommodation are provided is not more than one-tenth of the number of students to whom both education and accommodation are provided

### **Accommodation for persons who require treatment for substance misuse**

3. The provision of residential accommodation for a person together with treatment for drug or alcohol misuse, where acceptance by the person of such treatment is a condition of the provision of the accommodation.

### **Treatment of disease, disorder or injury**

4.—(1) Subject to sub-paragraph (2), the provision of treatment for a disease, disorder or injury by or under the supervision of—

- (a) a health care professional, or a team which includes a health care professional, or
  - (b) a social worker, or a team which includes a social worker, where the treatment is for a mental disorder.
- (2) The activities set out in sub-paragraph (3) are excepted from sub-paragraph (1).
- (3) The activities referred to in sub-paragraph (2) are—
- (a) assessment or medical treatment for persons detained under the 1983 Act,
  - (b) the provision of treatment by means of surgical procedures,
  - (c) diagnostic and screening procedures,
  - (d) services in slimming clinics,
  - (e) the practice of alternative and complementary medicine, with the exception of the practice of osteopathy or chiropractic,
  - (f) the provision of treatment in a sports ground or gymnasium (including associated premises) where it is provided for the sole benefit of persons taking part in, or attending, sporting activities and events,
  - (g) the provision of treatment (not being first aid for the purposes of paragraph 9 of Schedule 2) under temporary arrangements to deliver health care to those taking part in, or attending, sporting or cultural events,
  - (h) the provision of hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber which is gradually pressurised with compressed air, where the primary use of that chamber is—
    - (i) pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997<sup>(26)</sup> or regulation 8 or 12 of the Work in Compressed Air Regulations 1996<sup>(27)</sup>, or
    - (ii) otherwise for the treatment of workers in connection with the work which they perform, and
  - (i) the carrying on of any of the activities authorised by a licence granted by the Human Fertilisation and Embryology Authority under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990<sup>(28)</sup>.
- (4) In this paragraph—
- (a) “health care professional” means a person who is—

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<sup>(26)</sup> S.I. 1997/2776.

<sup>(27)</sup> S.I. 1996/1656.

<sup>(28)</sup> 1990 c. 37. Relevant amendments were made by: the Human Fertilisation and Embryology Act 2008 (c. 22), sections 11 and 66, Paragraphs 1 and 2 of Schedule 2, and Schedule 8, Part 1; and S.I. 2007/1522.

- (i) a medical practitioner,
- (ii) a dental practitioner,
- (iii) a dental hygienist,
- (iv) a dental therapist,
- (v) a dental nurse,
- (vi) a dental technician,
- (vii) an orthodontic therapist,
- (viii) a nurse,
- (ix) a midwife,
- (x) a biomedical scientist,
- (xi) a clinical scientist,
- (xii) an operating department practitioner,
- (xiii) a paramedic, or
- (xiv) a radiographer;
- (b) “biomedical scientist”, “clinical scientist”, “operating department practitioner”, “paramedic” and “radiographer” means persons registered as such with the Health and Care Professions Council pursuant to article 5 of the 2001 Order;
- (c) “dental practitioner” means a dentist registered as such with the General Dental Council pursuant to section 14 of the Dentists Act 1984<sup>(29)</sup>;
- (d) “dental hygienist”, “dental therapist”, “dental nurse”, “dental technician” and “orthodontic therapist” means persons registered as such with the General Dental Council in the dental care professionals register;
- (e) “mental disorder” means any disorder or disability of the mind, including dependence on alcohol or drugs;
- (f) “midwife” means a registered midwife.

#### **Assessment or medical treatment for persons detained under the 1983 Act**

**5.—(1)** Subject to sub-paragraph (2), the assessment of, or medical treatment (other than surgical procedures) for, a mental disorder affecting a person in a hospital where that person is—

- (a) detained in that hospital pursuant to the provisions of the 1983 Act (with the exception of section 135 or 136),
- (b) recalled to that hospital under section 17E of that Act<sup>(30)</sup>, or
- (c) detained in that hospital pursuant to an order or direction made under another enactment, where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

(2) Sub-paragraph (1) does not apply to the assessment or treatment by a registered medical practitioner appointed for the purposes of Part 4 of the 1983 Act in giving a certificate under sections 57 (treatment requiring consent and a second opinion), 58 (treatment requiring consent or a second opinion) or 58A (electro-convulsive therapy, etc) of that Act.

(3) In this paragraph—

<sup>(29)</sup> 1984 c. 24. Section 14 was substituted by S.I. 2005/2011 and amended by S.I. 2007/3101.

<sup>(30)</sup> Section 17E was inserted into the Mental Health Act 1983 (c. 20) by section 32(1) and (2) of the Mental Health Act 2007 (c. 12).

- “hospital” means a hospital within the meaning of Part 2 of the 1983 Act;  
“medical treatment” has the same meaning as in section 145 (interpretation) of that Act;  
“mental disorder” has the same meaning as in section 1 of that Act.

### **Surgical procedures**

- 6.—(1) Subject to sub-paragraphs (2) to (4), surgical procedures (including all pre-operative and post-operative care associated with such procedures) carried on by a health care professional for—
- (a) the purpose of treating disease, disorder or injury,
  - (b) the purpose of sterilisation or reversal of sterilisation,
  - (c) cosmetic purposes, where the procedure involves the use of instruments or equipment which are inserted into the body, or
  - (d) the purpose of religious observance.
- (2) Subject to sub-paragraph (3), the following procedures are excepted from sub-paragraph (1)—
- (a) nail surgery and nail bed procedures carried out by a health care professional on any area of the foot, and
  - (b) surgical procedures involving the curettage, cautery or cryocautery of warts, verrucae or other skin lesions carried out by—
    - (i) a medical practitioner, or
    - (ii) another health care professional on any area of the foot.
- (3) Sub-paragraph (2) only applies where the procedures are carried out—
- (a) without anaesthesia, or
  - (b) using local anaesthesia.
- (4) The following cosmetic procedures are excepted from sub-paragraph (1)(c)—
- (a) the piercing of any part of the human body,
  - (b) tattooing,
  - (c) the subcutaneous injection of a substance or substances for the purpose of enhancing a person’s appearance, and
  - (d) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.

### **Diagnostic and screening procedures**

- 7.—(1) Subject to sub-paragraphs (3), (5) and (7), diagnostic and screening procedures involving—
- (a) the use of X-rays and other methods in order to examine the body by the use of radiation, ultrasound or magnetic resonance imaging,
  - (b) the use of instruments or equipment which are inserted into the body to—
    - (i) view its internal parts, or
    - (ii) gather physiological data,
  - (c) the removal of tissues, cells or fluids from the body for the purposes of discovering the presence, cause or extent of disease, disorder or injury,
  - (d) the use of equipment in order to examine cells, tissues and other bodily fluids for the purposes of obtaining information on the causes and extent of a disease, disorder or injury, and

- (e) for the purposes of obtaining information on the causes and extent of a disease, disorder or injury, or the response to a therapeutic intervention, where such information is needed for the purposes of the planning and delivery of care or treatment, the use of equipment to measure or monitor physiological data in relation to the—
  - (i) audio-vestibular system,
  - (ii) vision system,
  - (iii) neurological system,
  - (iv) cardiovascular system,
  - (v) respiratory system,
  - (vi) gastro-intestinal system, or
  - (vii) urinary system.

(2) Subject to sub-paragraphs (3), (5) and (7), the analysis and reporting of the results of the procedures referred to in sub-paragraph (1).

(3) The procedures specified in sub-paragraph (4), and the analysis and reporting of the results of those procedures, are excepted from sub-paragraphs (1) and (2).

(4) The procedures referred to in sub-paragraph (3) are—

- (a) the taking of blood samples where—
  - (i) the procedure is carried out by means of a pin prick or from a vein, and
  - (ii) it is not necessary to send such samples for analysis to a place which is established for the purposes of carrying out tests or research in relation to samples of bodily cells, tissues or fluids;
- (b) where part of neither the planning and delivery of care or treatment nor a national screening programme, other than for cancer, the taking and analysis of samples of bodily tissues, cells or fluids in order to ascertain—
  - (i) the existence of a genetically inherited disease or disorder, or
  - (ii) the influence of an individual's genetic variation on drug response;
- (c) the carrying out of procedures as part of a national cancer screening programme by a body established solely for the purpose of such a programme;
- (d) fitness screening procedures carried out in a gymnasium in order to ascertain that a person is sufficiently healthy to use fitness equipment or take part in fitness routines safely;
- (e) the taking of X-rays by chiropractors;
- (f) the use of ultrasound equipment by physiotherapists;
- (g) the carrying out of a hearing needs assessment or the supply and fitting of a hearing aid carried out by a hearing aid dispenser or a person acting under the direction or supervision of a hearing aid dispenser where—
  - (i) the patient is aged 19 or over, or
  - (ii) the patient is under 19 years old and the procedure is carried out in, or arranged by, a school or 16 to 19 Academy;
- (h) the taking of urine samples where it is not necessary to send such samples for analysis to a place which is established for the purposes of carrying out tests or research in relation to samples of bodily cells, tissues or fluids;
- (i) the taking and analysing of wound swabs, hair samples or nail clippings;
- (j) the non-ambulatory recording of blood pressure;
- (k) the use of 12-lead electrocardiography;



- (l) the use of a peak flow meter to measure peak expiratory flow;
  - (m) pulse oximetry when used for the purpose of spot recording;
  - (n) spirometry when carried out for screening, non-diagnostic or monitoring purposes;
  - (o) diagnostic and screening procedures carried out by a person in connection with any of the activities listed in Schedule 2 (activities for which licences may be granted) to the Human Fertilisation and Embryology Act 1990<sup>(31)</sup> for which a licence has been granted to that person under section 16 (grant of licence) of that Act.
- (5) Where a service provider is registered in respect of an activity listed in any other paragraph of this Schedule, the procedures specified in sub-paragraph (6), and the analysis and reporting of the results of those procedures, are excepted from sub-paragraphs (1) and (2) of this paragraph.
- (6) The procedures referred to in sub-paragraph (5) are—
- (a) the taking of blood or urine samples,
  - (b) the analysis of urine or stool samples by means of dip stick or other reagent, and
  - (c) the taking of tissue samples by means of—
    - (i) a swab specimen from any external part of the body or from the mouth, ear, nose or throat, or
    - (ii) skin scrapings.
- (7) The carrying out of diagnostic and screening procedures mentioned in sub-paragraph (1) or analysis and reporting of such procedures for research is excepted from sub-paragraphs (1) and (2) where those procedures, or that analysis and reporting, do not form any part of an individual's care or treatment.
- (8) For the purposes of this paragraph—
- “chiropractor” means a person registered with the General Chiropractic Council under section 3, 4, 5 or 5A of the Chiropractors Act 1994<sup>(32)</sup>;
- “hearing aid dispenser” means a person registered as such with the Health and Care Professions Council pursuant to article 5 of the 2001 Order;
- “physiotherapist” means a person registered as such with the Health and Care Professions Council pursuant to article 5 of the 2001 Order.

### **Management of supply of blood and blood derived products etc**

- 8.—(1) Subject to sub-paragraph (2), the management of—
- (a) the supply of blood, blood components and blood derived products intended for transfusion,
  - (b) the supply of tissues and tissue derived products intended for transplant, grafting or use in a surgical procedure, and
  - (c) the matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion.
- (2) Sub-paragraph (1) does not apply to the management of the supply of blood, blood components, tissues and products mentioned in sub-paragraph (1)(a) and (b) where that management does not involve direct physical contact with patients or donors.
- (3) For the purposes of this paragraph—

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<sup>(31)</sup> Relevant amendments were made by: the Human Fertilisation and Embryology Act 2008 (c. 22), sections 11 and 66, Schedule 2, and Schedule 8, Part 1; and S.I. 2007/1522 and 2009/2232.

<sup>(32)</sup> 1994 c.17. Relevant amendments were made by S.I. 2007/3101 and 2008/1774.

“donor” means a person from whom anything mentioned in sub-paragraph (1)(a) or (b) is derived;

“patient” means a person to whom anything mentioned in sub-paragraph (1)(a) or (b) is administered.

### **Transport services, triage and medical advice provided remotely**

**9.**—(1) Subject to sub-paragraphs (3) and (4), transport services provided by means of a vehicle which is designed for the primary purpose of carrying a person who requires treatment.

(2) Medical advice in cases where immediate action or attention is needed, or triage provided, over the telephone or by electronic mail by a body established for that purpose.

(3) Transport services which are provided within the confines of the site or venue being used for an activity or event mentioned in paragraph 4(3)(f) or (g) are excepted from sub-paragraph (1).

(4) The provision of an air ambulance is excepted from sub-paragraph (1) where—

(a) the aircraft is registered with the Civil Aviation Authority pursuant to article 6 (aircraft to be registered) of the Air Navigation Order 2009<sup>(33)</sup>, and

(b) the person providing the air ambulance does not provide treatment to a patient.

(5) For the purposes of this paragraph—

“triage” means the assignment of degrees of urgency to diseases, disorders or injuries in order to decide the order and place of treatment of service users;

“vehicle” includes an air or water ambulance.

### **Maternity and midwifery services**

**10.**—(1) Subject to sub-paragraph (2), maternity and midwifery services carried on by, or under the supervision of, a health care professional.

(2) The following services are excepted from sub-paragraph (1)—

(a) midwifery services, where the provision of those services is carried on by an individual—

(i) acting on their own behalf,

(ii) otherwise than in pursuance of the 2006 Act, and

(iii) who provides such services only to service users in their own homes;

(b) the provision of advice, information and support in relation to pregnancy, childbirth or the acquisition of parenting skills, where provided by a body whose primary purpose or function is not the provision of health care (other than that advice, information and support);

(c) services provided under arrangements relating to the care of pregnant women and women who are breast feeding made pursuant to section 254 of, and Schedule 20 to, the 2006 Act (local social services authorities).

### **Termination of pregnancies**

**11.** The termination of pregnancies.

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(33) S.I. 2009/3015. There are no relevant amendments to article 6 of the Air Navigation Order 2009.

### Services in slimming clinics

12. Services provided in a slimming clinic consisting of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of weight reduction.

### Nursing care

13.—(1) Subject to sub-paragraph (2), the provision of nursing care, including nursing care provided in a person's own home which is not—

- (a) provided as part of any other regulated activity, and
- (b) exempted from being a regulated activity under any other paragraph in this Schedule.

(2) The following types of provision are excepted from sub-paragraph (1)—

- (a) the supply of nurses to a service provider by an undertaking acting as an employment agency or employment business for the purposes of that provider carrying on a regulated activity,
- (b) the introduction of nurses to an individual (other than a service provider) by a person (including an employment agency or an employment business) having no ongoing role in the direction or control of the service provided to that individual, and
- (c) the services of a nurse employed by an individual, without the involvement of an undertaking acting as an employment agency or an employment business, and working wholly under the direction and control of that individual in order to meet that individual's own nursing requirements.

### Family planning services

14. The insertion or removal of an intrauterine contraceptive device carried out by, or under the supervision of, a health care professional.

## SCHEDULE 2

Regulation 3(4)

### Regulated Activities: General Exceptions

1.—(1) Any activity which is carried on—

- (a) in the course of a family or personal relationship, and
- (b) for no commercial consideration.

(2) A family relationship includes a relationship between two persons who—

- (a) live in the same household, and
- (b) treat each other as though they were members of the same family.

(3) A personal relationship is a relationship between or among friends.

(4) A friend of a person (A) includes a person who is a friend of a member of A's family.

2. Any activity which involved the carrying on of an establishment or agency within the meaning of the Care Standards Act 2000<sup>(34)</sup> for which Her Majesty's Chief Inspector of Education, Children's Services and Skills is the registration authority under that Act.

3.—(1) Subject to paragraph 4, the provision of treatment in a surgery or consulting room by a medical practitioner who is (or a group of medical practitioners who are)—

- (a) a service provider in respect of a regulated activity specified in paragraph 4 of Schedule 1 (treatment of disease, disorder or injury) or employed by such a service provider, and
- (b) either on the medical performers list for a designated body or employed by a service provider that is a designated body.

(2) In this paragraph, “designated body” means a body prescribed by regulation 4 of the Medical Profession (Responsible Officers) Regulations 2010<sup>(35)</sup>.

4. Paragraph 3 does not apply in relation to—

- (a) treatment carried out under anaesthesia (other than local anaesthesia for the purposes of a procedure mentioned in paragraph 6(2) of Schedule 1) or intravenously administered sedation,
- (b) medical services provided in connection with childbirth,
- (c) the termination of pregnancies,
- (d) cosmetic surgery, with the exception of the procedures referred to in paragraph 6(4) of Schedule 1,
- (e) haemodialysis or peritoneal dialysis,
- (f) endoscopy other than using a device which does not have a lumen or other channel for the purpose or design of passing fluid or instruments through, or removing body tissue or fluid or any other item from, a person's body,
- (g) the provision of hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber which is gradually pressurised with compressed air, where such therapy is carried out by or under the supervision or direction of a medical practitioner,
- (h) intravenous, intrathecal or epidural administration of medicines or diagnostic agents,
- (i) the therapeutic or diagnostic use of x-rays, radiation, protons or magnetic resonance imaging, or
- (j) invasive cardiac physiology tests.

5.—(1) Medical or dental services provided (otherwise than in conjunction with the provision of accommodation in a hospital) only under arrangements made on behalf of service users by—

- (a) their employer,
- (b) a government department, or
- (c) an insurance provider with whom the service users hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity.

(2) In this paragraph, “insurance provider” means—

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<sup>(34)</sup> 2000 c. 14. See section 5 (registration authorities), as amended by the Adoption and Children Act 2002 (c. 38), section 139(1) and paragraphs 103 and 105 of Schedule 3, the Health and Social Care Act 2008, section 95 and paragraphs 1 and 6 of Schedule 5, and section 4(2)(b) of the Children and Young Persons Act 2008 (c. 23).

<sup>(35)</sup> S.I. 2010/2841. Relevant amendments were made by S.I. 2011/2581 and 2013/391.

- (a) a person regulated by the Financial Conduct Authority or the Prudential Regulation Authority who sells insurance, or underwrites the risk of such insurance, or
  - (b) the agent of such a person.
6. Forensic medicine or dental services provided under arrangements made with a local policing body as defined in section 101 of the Police Act 1996<sup>(36)</sup> (interpretation).
7. Primary ophthalmic services provided under Part 6 of the 2006 Act and services of a kind which, if provided in pursuance of that Act, would be provided as primary ophthalmic services under that Part.
8. Services which are provided at or from premises that are a registered pharmacy (within the meaning given by section 74 of the Medicines Act 1968<sup>(37)</sup>) and which are—
- (a) pharmaceutical services and local pharmaceutical services provided under Part 7 of the 2006 Act, or
  - (b) services of a kind which, if provided in pursuance of that Act, would be provided as pharmaceutical services or local pharmaceutical services under that Part or services provided in pursuance of that Act.
9. The provision of first aid by—
- (a) health care professionals where it is provided in unexpected or potentially dangerous situations requiring immediate action,
  - (b) organisations established for that purpose, or
  - (c) non-health care professionals trained to deliver such treatment.
- 10.—(1) Defence medical and dental services being—
- (a) health or dental care provided by the armed services,
  - (b) education and training provided by the armed services to service and other personnel in connection with the provision of health or dental care, including the maintenance of the clinical skills of such personnel, and
  - (c) any service or facility falling within sub-paragraph (a) or (b) provided on behalf of the armed services under any agreement or arrangement made with the armed services.
- (2) In sub-paragraph (1), “armed services” means the naval, military and air forces of the Crown and includes the reserve forces.
11. Treatment provided in a school to the pupils of that school by a nurse who is engaged and directed by the school.

### SCHEDULE 3

Regulations 4 to 7 and 19(3)

#### Information Required in Respect of Persons Employed or Appointed for the Purposes of a Regulated Activity

1. Proof of identity including a recent photograph.

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<sup>(36)</sup> 1996 c. 16. Relevant amendments were made by section 96(2)(a) of the Police Reform and Social Responsibility Act 2011 (c. 13).

<sup>(37)</sup> 1968 c. 67. Section 74 was amended by the Statute Law (Repeals) Act 1993 (c. 50) and S.I. 2010/231.

2. Where required for the purposes of an exempted question in accordance with section 113A(2)(b) of the Police Act 1997<sup>(38)</sup>, 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)<sup>(39)</sup>.

3. Where required for the purposes of an exempted question asked for a prescribed purpose under 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. In so far as it is reasonably practicable to obtain, satisfactory documentary evidence of any qualification relevant to the duties for which the person is employed or appointed to perform.

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, after reasonable adjustments are made, to properly perform tasks which are intrinsic to their employment or appointment 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;
- (c) "suitability information relating to children or vulnerable adults" means the information specified in sections 113BA and 113BB respectively of the Police Act 1997.

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<sup>(38)</sup> 1997 c. 50. Sections 113A and 113B were inserted by section 163(2) of the Serious Crime and Police Act 2005 (c. 15) and amended by: the Safeguarding Vulnerable Groups Act 2006, section 63(1) and Schedule 9, Part 2, paragraph 14; the Armed Forces Act 2006 (c. 52), section 378(1) and paragraph 149 of Schedule 16; the Criminal Justice and Immigration Act 2008 (c. 4), section 50; the Policing and Crime Act 2009 (c. 26), sections 97(2) and 112(2) and Part 8 of Schedule 8; the Protection of Freedoms Act 2012, sections 79(2), 80(1), 82 and 115, paragraphs 35 to 37 and 135 of Schedule 9, and Parts 5 and 6 of Schedule 10; the Crime and Courts Act 2013 (c. 22), section 15(3) and Schedule 8, Part 2, paragraphs 55 and 60; and S.I. 2009/203, 2010/1146, 2012/3006 and 2013/1200.

<sup>(39)</sup> Section 30A was inserted by section 72(1) of the Protection of Freedoms Act 2012 and amended by S.I. 2012/3006.

## SCHEDULE 4

Regulation 5

### Good character and unfit person tests

#### PART 1

##### Unfit person test

1. The person is an undischarged bankrupt or a person whose estate has had sequestration awarded in respect of it and who has not been discharged.
2. The person is the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order or an order to like effect made in Scotland or Northern Ireland.
3. The person is a person to whom a moratorium period under a debt relief order applies under Part VIIA (debt relief orders) of the Insolvency Act 1986<sup>(40)</sup>.
4. The person has made a composition or arrangement with, or granted a trust deed for, creditors and not been discharged in respect of it.
5. The person is included in the children’s barred list or the adults’ barred list maintained under section 2 of the Safeguarding Vulnerable Groups Act 2006, or in any corresponding list maintained under an equivalent enactment in force in Scotland or Northern Ireland.
6. The person is prohibited from holding the relevant office or position, or in the case of an individual from carrying on the regulated activity, by or under any enactment.

#### PART 2

##### Good character

7. Whether the person has been convicted in the United Kingdom of any offence or been convicted elsewhere of any offence which, if committed in any part of the United Kingdom, would constitute an offence.
8. Whether the person has been erased, removed or struck-off a register of professionals maintained by a regulator of health care or social work professionals.

## SCHEDULE 5

Regulation 24

### Fixed Penalty Offences

<i>Provision creating offence</i>	<i>General nature of offence</i>	<i>Monetary amount of penalty</i>
Regulation 25 of the Care Quality Commission (Registration) Regulations 2009 <sup>(41)</sup>	Contravention of, or failure to comply with, any of the provisions of regulations 12 and 14 to 20 of the Care Quality Commission (Registration) Regulations 2009	£1,250 in the case of an offence committed by a service provider;

<sup>(40)</sup> 1986 c. 45. Part VIIA was inserted by section 108 of, and Schedule 17 to, the Tribunals, Courts and Enforcement Act 2007 (c. 15).

<sup>(41)</sup> S.I. 2009/3112, as amended by S.I. 2010/49, 2012/921, 2012/1641 and 2013/235.

**Draft Legislation:** This is a draft item of legislation. This draft has since been made as a UK Statutory Instrument: The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 No. 2936

<i>Provision creating offence</i>	<i>General nature of offence</i>	<i>Monetary amount of penalty</i>
		£625 in the case of an offence committed by a registered manager
Regulation 22(1)(a) or (2) of these Regulations	Contravention of, or failure to comply with, requirements in regulations 11, 12, 13(1) to (4) and 14	£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
Regulation 22(1)(b) or (c) of these Regulations	Contravention of, or failure to comply with, requirements in regulations 16(3) and 17(3)	£300
Regulation 22(3) of these Regulations	Contravention of, or failure to comply with, requirements in regulation 20(2)(a) and (3)	£1,250
Section 10(1) of the Act	Carrying on a regulated activity without being registered	£4,000
Section 33 of the Act	Failure to comply with conditions	£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
Section 34(1) of the Act	Carrying on a regulated activity whilst registration is suspended	£4,000
Section 34(2), (3) or (4) of the Act	Managing a regulated activity whilst registration is cancelled or suspended	£2,000
Section 63(7) of the Act	Obstructing entry and inspection	£300
Section 64(4) of the Act	Failure to provide documents and information	£300
Section 65(4) of the Act	Failure to provide an explanation	£300



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## EXPLANATORY NOTE

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

These Regulations prescribe the kinds of activities that are regulated activities for the purposes of Part 1 of the Health and Social Care Act 2008 (“the Act”) and requirements that apply in relation to the way in which those activities are carried on.

Regulation 3 deals with the activities that are regulated activities for the purposes of section 8(1) of the Act. The activities are set out in Schedule 1 to the Regulations together with certain activity specific exemptions. An activity is only a regulated activity if it is carried on in England (regulation 3(3)). Regulation 3(4) provides that the activities listed in Schedule 2 (general exceptions) are not to be regulated activities for the purposes of section 8(1) of the Act and these Regulations.

In Part 3, regulations 4 to 7, and Schedules 3 and 4, contain requirements in relation to persons registered in respect of the carrying on or management of a regulated activity (“registered persons”), and require certain information to be available in relation to those persons. Where a regulated activity is carried on by a body other than a partnership, that body must nominate an individual (“the nominated individual”) who must meet certain requirements (regulation 6). Regulation 7 lays down requirements in relation to registered managers.

Regulation 5 lays down a new fit and proper person requirement that must be met by directors of an NHS trust, an NHS foundation trust or a Special Health Authority that carries on a regulated activity. The requirement lays down criteria to be met by such directors, including that they are of good character and that none of the grounds of unfitness specified in Part 1 of Schedule 4 apply. A person must not perform the relevant role if they fail the fit and proper person requirement. A health service body that fails to comply with this requirement could have a condition imposed on its registration with the Care Quality Commission, requiring it to comply with the requirement, under section 12(5)(b) of the Act.

Regulations 8 to 19 lay down fundamental standards to be met by registered persons. Regulation 20 lays down a further fundamental standard to be met by health service bodies. The fundamental standards provide that:

- (a) care and treatment must be appropriate and reflect service users needs and preferences (regulation 9);
- (b) service users must be treated with dignity and respect (regulation 10);
- (c) care and treatment must only be provided with consent (regulation 11)
- (d) care and treatment must be provided in a safe way (regulation 12);
- (e) service users must be protected from abuse and improper treatment (regulation 13);
- (f) service users’ nutritional and hydration needs must be met (regulation 14);
- (g) all premises and equipment used must be clean, secure, suitable and used properly (regulation 15);
- (h) complaints must be appropriately investigated and appropriate action taken in response (regulation 16);
- (i) systems and processes must be established to ensure compliance with the fundamental standards (regulation 17);

- (j) sufficient numbers of suitably qualified, competent, skilled and experienced staff must be deployed (regulation 18);
- (k) persons employed must be of good character, have the necessary qualifications, skills and experience, and be able to perform the work for which they are employed (regulation 19);
- (l) health service bodies must be open and transparent with service users about their care and treatment (regulation 20).

Regulation 8(2) 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 21 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 health care associated infections. The guidance issued by the Care Quality Commission is available from the Care Quality Commission, Citygate, Gallowgate, Newcastle upon Tyne, NE1 4PA ([www.cqc.org.uk](http://www.cqc.org.uk)). The code of practice issued by the Secretary of State is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS ([www.gov.uk/government/organisations/department-of-health](http://www.gov.uk/government/organisations/department-of-health)).

Regulation 22 creates offences in relation to breaches of requirements in regulation 11, 12, 13(1) to (4), 14, 16(3), 17(3) or 20(2)(a) and (3) and also includes a due diligence defence relating to any proceedings for such a breach. Regulation 23 imposes penalties for those who commit such offences.

Regulation 24 and Schedule 5 prescribe fixed penalty offences for the purposes of section 86 of the Act and the amount of the penalty, and make provision about the time by which a fixed penalty must be paid and the method by which the payment may be made, the period during which proceedings cannot be instituted for the offence to which the penalty notice relates, the content of the penalty notice and when a penalty notice can be withdrawn.

Regulation 25 revokes the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (“the 2010 Regulations”), together with other enactments which amended those Regulations.

Regulation 26 makes transitional and transitory provision in consequence of these Regulations coming into force. It provides that where enforcement action has been taken in relation to a continuing breach of the 2010 Regulations, and the person or body concerned has been given a specified time by which it must secure compliance with the 2010 Regulations, no criminal proceedings may be taken under these Regulations in relation to the breach in so far as it occurred before that specified time.

Regulation 27 requires the Secretary of State to review the operation and effect of these Regulations and lay a report before Parliament within five years after 1st April 2015 and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

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](http://www.gov.uk/government/organisations/department-of-health)) and is published alongside this instrument and its Explanatory Memorandum at [www.legislation.gov.uk](http://www.legislation.gov.uk).