

2010 No 781

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

# Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

*Made 15th March 2010*

*Coming into force 1st April 2010*

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

In accordance with section 20(8) of the Act, the Secretary of State has consulted such persons as he 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 approved by resolution of each House of Parliament.

## Part 1 General

### Citation and commencement

#### 1

These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and come into force on 1st April 2010.

### NOTES

#### Initial Commencement

##### *Specified date*

Specified date: 1 April 2010: see above.

#### Interpretation

#### 2

In these Regulations—

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

“the 1983 Act” means the Mental Health Act 1983;

“the 2006 Act” means the National Health Service Act 2006;

“the 2001 Order” means the [Health and Social Work Professions Order 2001];

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

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

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

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

“chiroprapist or podiatrist” means a person registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order;

“employment” means—

- (a) employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract (including under a carer agreement); and
- (b) the grant of practising privileges,

and “employed” and “employer” should be construed accordingly;

“employment agency” and “employment business” have the same meanings as in the Employment Agencies Act 1973;

“health care professional” means, except in paragraph 5 of Schedule 1, a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999 applies;

“hospital”, except in paragraphs 1(3)(d) and 6 of Schedule 1, has the same meaning as in section 275 of the 2006 Act;

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

“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 5(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;

“personal care” means—

- (a) physical assistance given to a person in connection with—
  - (i) eating or drinking (including the administration of 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 chiropodist or podiatrist); or
- (b) the prompting, together with supervision, of a person, in relation to the performance of any of the activities listed in paragraph (a), where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision;

“practising privileges” means the grant, by a person managing a hospital, to a medical practitioner of permission to practise as a medical practitioner in that hospital;

“premises” means—

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

“registered manager” means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a manager in respect of that activity, and “manage” should be construed accordingly;

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

“school” has the same meaning as in the Education Act 1996;

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

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

“treatment”, except in paragraph 6 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 59 of the Safeguarding Vulnerable Groups Act 2006.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Amendment

In definition "the 2001 Order" words "Health and Social Work Professions Order 2001" in square brackets substituted by SI 2012/1479, art 11, Schedule, Pt 1, para 64.

Date in force: 1 August 2012: see SI 2012/1479, art 1(2).

## Part 2 Regulated Activities

### Prescribed activities

#### 3

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

(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) . . .

(4) . . .

(5) An activity is only a regulated activity if it is carried on in England.

(6) . . .

(7) Subject to paragraph (8), the activities specified in Schedule 2 are not regulated activities.

[(8) In Schedule 2, paragraphs 3, 6 and 7 and, in paragraph 4, the words "and except where paragraph 3 applies," shall cease to have effect—

(a) on 1st April 2012 in relation to all activities carried on by providers of out of hours services (whether or not those activities are carried on in the out of hours period); and

(b) on 1st April 2013 for all other purposes.]

[(9) The following definitions shall apply for the purposes of paragraph (8)—

"bank holiday" means any day that is specified or proclaimed as a bank holiday in England

pursuant to section 1 (bank holidays) of the Banking and Financial Dealings Act 1971;

“out of hours period” means—

- (a) in the case of arrangements made pursuant to section 83(2)(b) (primary medical services) of the 2006 Act—
  - (i) except where sub-paragraph (ii) applies, the period which falls outside the period defined as core hours under the terms of the arrangements, or
  - (ii) where the primary medical services under the terms of the arrangements are required to be provided only outside the period beginning at 8am and ending at 6.30pm on any day from Monday to Friday unless that day is Good Friday, Christmas Day or a bank holiday, the period which falls outside the period beginning at 8am and ending at 6.30pm on any day from Monday to Friday unless that day is Good Friday, Christmas Day or a bank holiday;
- (b) in all other cases—
  - (i) the period beginning at 6.30pm on any day from Monday to Thursday and ending at 8am on the following day,
  - (ii) the period between 6.30pm on Friday and 8am the following Monday, and
  - (iii) Good Friday, Christmas Day and bank holidays;

“out of hours services” means primary medical services provided in all or part of the out of hours period;

“provider of out of hours services” means a person that provides out of hours services—

- (a) as a provider of primary medical services under arrangements made pursuant to section 83(2)(b) (primary medical services) of the 2006 Act to patients who are neither registered patients of that provider nor accepted as temporary residents by that provider;
- (b) under arrangements made pursuant to section 92 (arrangements by Strategic Health Authorities for the provision of primary medical services) of the 2006 Act to patients who are neither registered patients of that provider nor accepted as temporary residents by that provider; or
- (c) as an out of hours services sub-contractor of a provider of primary medical services under—
  - (i) arrangements made pursuant to section 83(2)(b) (primary medical services) of the 2006 Act;
  - (ii) a contract entered into pursuant to section 84 (general medical services contracts: introductory) of the 2006 Act; or
  - (iii) arrangements made pursuant to section 92 (arrangements by Strategic Health Authorities for the provision of primary

medical services) of the 2006 Act;

“registered patient” means—

(a) a person who is recorded by the Primary Care Trust as being on the provider’s list of patients; or

(b) a person whom the provider has accepted for inclusion on its list of patients (whether or not notification of that acceptance has been received by the Primary Care Trust) and who has not been the subject of a notification by the Primary Care Trust to the provider as having ceased to be on that list; and

“temporary resident” means a person who is not a registered patient and who is accepted by a provider of primary medical services as a patient under the terms of that provider’s contract.]

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Amendment

Paras (3), (4): revoked by SI 2011/2711, reg 2(1), (2).

Date in force: 30 November 2011: see SI 2011/2711, reg 1.

Para (6): revoked by SI 2011/2711, reg 2(1), (2).

Date in force: 30 November 2011: see SI 2011/2711, reg 1.

Para (8): substituted by SI 2011/2711, reg 2(1), (3).

Date in force: 30 November 2011: see SI 2011/2711, reg 1.

Para (9): inserted by SI 2011/2711, reg 2(1), (4).

Date in force: 30 November 2011: see SI 2011/2711, reg 1.

## Part 3

### 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 paragraph (4); or
  - [(b) a partnership and—
    - (i) each of the partners satisfies the requirements set out in paragraph (5); and
    - (ii) P satisfies the requirement set out in paragraph (6).]
- (4) The requirements referred to [in paragraph 3(a) are that P] is—

- (a) of good character;
- (b) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and
- (c) able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.

[(5) The requirements referred to in paragraph 3(b)(i) are that each of the partners is—

- (a) of good character;
- (b) physically and mentally fit to carry on the regulated activity; and
- (c) able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.

(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.]

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Amendment

Para (3): sub-para (b) substituted by SI 2012/1513, regs 2, 3(a).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para (4): words “in paragraph 3(a) are that P” in square brackets substituted by SI 2012/1513, regs 2, 3(b).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Paras (5), (6): inserted by SI 2012/1513, regs 2, 3(c).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

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

## 5

(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 employed as a director, manager or secretary of the body and who is 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 is—

- (a) of good character;
- (b) physically and mentally fit to supervise the management of the carrying on of the regulated activity and has the necessary qualifications, skills and experience to do so; and
- (c) able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Requirements relating to registered managers

## 6

- (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) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and
  - (c) able to supply to the Commission, or arrange for the availability of, the information relating to themselves specified in Schedule 3.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Registered person: training

## 7

- (1) If the service provider is—
- (a) an individual, the individual must undertake;
  - (b) a partnership, it must ensure that one of the partners undertakes; or
  - (c) a body other than a partnership, it must ensure that the nominated individual undertakes,

from time to time such training as is reasonably practicable and appropriate to ensure that there are the necessary experience and skills available for carrying on the regulated activity.

- (2) The registered manager must undertake from time to time such training as is appropriate to ensure that the manager has the experience and skills necessary for managing the carrying on of the regulated activity.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

## Part 4

### Quality and Safety of Service Provision in Relation to Regulated Activity

#### General



## 8

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

### NOTES

#### Initial Commencement

##### *Specified date*

Specified date: 1 April 2010: see reg 1.

#### Care and welfare of service users

## 9

(1) The registered person must take proper steps to ensure that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe, by means of—

- (a) the carrying out of an assessment of the needs of the service user; and
- (b) the planning and delivery of care and, where appropriate, treatment in such a way as to—
  - (i) meet the service user's individual needs,
  - (ii) ensure the welfare and safety of the service user,
  - (iii) reflect, where appropriate, published research evidence and guidance issued by the appropriate professional and expert bodies as to good practice in relation to such care and treatment, and
  - (iv) avoid unlawful discrimination including, where applicable, by providing for the making of reasonable adjustments in service provision to meet the service user's individual needs.

(2) The registered person must have procedures in place for dealing with emergencies which are reasonably expected to arise from time to time and which would, if they arose, affect, or be likely to affect, the provision of services, in order to mitigate the risks arising from such emergencies to service users.

### NOTES

#### Initial Commencement

##### *Specified date*

Specified date: 1 April 2010: see reg 1.

#### Assessing and monitoring the quality of service provision

## 10

(1) The registered person must protect service users, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to—

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirements set out in this Part of these Regulations; and

- (b) identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.
- (2) For the purposes of paragraph (1), the registered person must—
- (a) where appropriate, obtain relevant professional advice;
  - (b) have regard to—
    - (i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by service users, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 19,
    - (ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the regulated activity,
    - (iii) the information contained in the records referred to in regulation 20,
    - (iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a)),
    - (v) reports prepared by the Commission from time to time relating to the registered person's compliance with the provisions of these Regulations, and
    - (vi) periodic reviews and special reviews and investigations carried out by the Commission in relation to the provision of health or social care, where such reviews or investigations are relevant to the regulated activity carried on by the service provider;
  - (c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—
    - (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a service user, and
    - (ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;
  - (d) establish mechanisms for ensuring that—
    - (i) decisions in relation to the provision of care and treatment for service users are taken at the appropriate level and by the appropriate person (P), and
    - (ii) P is subject to an appropriate obligation to answer for a decision made by P, in relation to the provision of care and treatment for a service user, to the person responsible for supervising or managing P in relation to that decision; and
  - (e) regularly seek the views (including the descriptions of their experiences of care and treatment) of service users, persons acting on their behalf and persons who are employed for the purposes of the carrying on of the regulated activity, to enable the registered person to come to an informed view in relation to the standard of care and

treatment provided to service users.

(3) The registered person must send to the Commission, when requested to do so, a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with, together with any plans that the registered person has for improving the standard of the services provided to service users with a view to ensuring their health and welfare.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Safeguarding service users from abuse

## 11

(1) The registered person must make suitable arrangements to ensure that service users are safeguarded against the risk of abuse by means of—

- (a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
- (b) responding appropriately to any allegation of abuse.

(2) Where any form of control or restraint is used in the carrying on of the regulated activity, the registered person must have suitable arrangements in place to protect service users against the risk of such control or restraint being—

- (a) unlawful; or
- (b) otherwise excessive.

(3) For the purposes of paragraph (1), “abuse”, in relation to a service user, means—

- (a) sexual abuse;
- (b) physical or psychological ill-treatment;
- (c) theft, misuse or misappropriation of money or property; or
- (d) neglect and acts of omission which cause harm or place at risk of harm.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Cleanliness and infection control

## 12

(1) The registered person must, so far as reasonably practicable, ensure that—

- (a) service users;
- (b) persons employed for the purpose of the carrying on of the regulated activity; and

- (c) others who may be at risk of exposure to a health care associated infection arising from the carrying on of the regulated activity,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

- (2) The means referred to in paragraph (1) are—
  - (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;
  - (b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and
  - (c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—
    - (i) premises occupied for the purpose of carrying on the regulated activity,
    - (ii) equipment and reusable medical devices used for the purpose of carrying on the regulated activity, and
    - (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection.

[(3) In this regulation, “medical device” has the same meaning as in regulation 2 (interpretation) of the Medical Devices Regulations 2002.]

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Amendment

Para (3): inserted by SI 2012/1513, regs 2, 4.

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

## Management of medicines

### 13

The registered person must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

## Meeting nutritional needs

### 14

- (1) Where food and hydration are provided to service users as a component of the carrying

on of the regulated activity, the registered person must ensure that service users are protected from the risks of inadequate nutrition and dehydration, by means of the provision of—

- (a) a choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs;
- (b) food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background; and
- (c) support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.

(2) For the purposes of this regulation, "food and hydration" includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.

## **NOTES**

### **Initial Commencement**

#### ***Specified date***

Specified date: 1 April 2010: see reg 1.

### **Safety and suitability of premises**

#### **15**

(1) The registered person must ensure that service users and others having access to premises where a regulated activity is carried on are protected against the risks associated with unsafe or unsuitable premises, by means of—

- (a) suitable design and layout;
- (b) appropriate measures in relation to the security of the premises; and
- (c) adequate maintenance and, where applicable, the proper—
  - (i) operation of the premises, and
  - (ii) use of any surrounding grounds,

which are owned or occupied by the service provider in connection with the carrying on of the regulated activity.

(2) In paragraph (1), the term "premises where a regulated activity is carried on" does not include a service user's own home.

## **NOTES**

### **Initial Commencement**

#### ***Specified date***

Specified date: 1 April 2010: see reg 1.

### **Safety, availability and suitability of equipment**

#### **16**

(1) The registered person must make suitable arrangements to protect service users and others who may be at risk from the use of unsafe equipment by ensuring that equipment provided for the purposes of the carrying on of a regulated activity is—

- (a) properly maintained and suitable for its purpose; and
  - (b) used correctly.
- (2) The registered person must ensure that equipment is available in sufficient quantities in order to ensure the safety of service users and meet their assessed needs.
- (3) Where equipment is provided to support service users in their day to day living, the registered person must ensure that, as far as reasonably practicable, such equipment promotes the independence and comfort of service users.
- (4) For the purposes of this regulation—
- (a) “equipment” includes a medical device; and
  - (b) “medical device” has the same meaning as in the Medical Devices Regulations 2002.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Respecting and involving service users

#### 17

- (1) The registered person must, so far as reasonably practicable, make suitable arrangements to ensure—
- (a) the dignity, privacy and independence of service users; and
  - (b) that service users are enabled to make, or participate in making, decisions relating to their care or treatment.
- (2) For the purposes of paragraph (1), the registered person must—
- (a) treat service users with consideration and respect;
  - (b) provide service users with appropriate information and support in relation to their care or treatment;
  - (c) encourage service users, or those acting on their behalf, to—
    - (i) understand the care or treatment choices available to the service user, and discuss with an appropriate health care professional, or other appropriate person, the balance of risks and benefits involved in any particular course of care or treatment, and
    - (ii) express their views as to what is important to them in relation to the care or treatment;
  - (d) where necessary, assist service users, or those acting on their behalf, to express the views referred to in sub-paragraph (c)(ii) and, so far as appropriate and reasonably practicable, accommodate those views;
  - (e) where appropriate, provide opportunities for service users to manage their own care or treatment;

- (f) where appropriate, involve service users in decisions relating to the way in which the regulated activity is carried on in so far as it relates to their care or treatment;
- (g) provide appropriate opportunities, encouragement and support to service users in relation to promoting their autonomy, independence and community involvement; and
- (h) take care to ensure that care and treatment is provided to service users with due regard to their age, sex, religious persuasion, sexual orientation, racial origin, cultural and linguistic background and any disability they may have.

## **NOTES**

### **Initial Commencement**

#### ***Specified date***

Specified date: 1 April 2010: see reg 1.

### **[Consent to care and treatment]**

## **NOTES**

### **Amendment**

Substituted by SI 2012/1513, regs 2, 5.

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

## **[18]**

[(1) In relation to the care and treatment provided for the service user, the registered person must have suitable arrangements in place for—

- (a) obtaining, and acting in accordance with, the consent of service users, or the consent of another person who is able lawfully to consent to care and treatment on that service user's behalf; or
- (b) where (a) does not apply, establishing, and acting in accordance with, the best interests of the service user.

(2) Section 4 of the Mental Capacity Act 2005 (best interests) applies for the purposes of this regulation as it applies for the purposes of that Act.]

## **NOTES**

### **Amendment**

Substituted by SI 2012/1513, regs 2, 5.

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

### **Complaints**

## **19**

(1) For the purposes of assessing, and preventing or reducing the impact of, unsafe or inappropriate care or treatment, the registered person must have an effective system in place (referred to in this regulation as “the complaints system”) for identifying, receiving, handling and responding appropriately to complaints and comments made by service users, or persons acting on their behalf, in relation to the carrying on of the regulated activity.

(2) In particular, the registered person must—

- (a) bring the complaints system to the attention of service users and persons acting on their behalf in a suitable manner and format;

- (b) provide service users and those acting on their behalf with support to bring a complaint or make a comment, where such assistance is necessary;
  - (c) ensure that any complaint made is fully investigated and, so far as reasonably practicable, resolved to the satisfaction of the service user, or the person acting on the service user's behalf; and
  - (d) take appropriate steps to coordinate a response to a complaint where that complaint relates to care or treatment provided to a service user in circumstances where the provision of such care or treatment has been shared with, or transferred to, others.
- (3) The registered person must send to the Commission, when requested to do so, a summary of the—
- (a) complaints made pursuant to paragraph (1); and
  - (b) responses made by the registered person to such complaints.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Records

## 20

- (1) The registered person must ensure that service users are protected against the risks of unsafe or inappropriate care and treatment arising from a lack of proper information about them by means of the maintenance of—
- (a) an accurate record in respect of each service user which shall include appropriate information and documents in relation to the care and treatment provided to each service user; and
  - (b) such other records as are appropriate in relation to—
    - (i) persons employed for the purposes of carrying on the regulated activity, and
    - (ii) the management of the regulated activity.
- (2) The registered person must ensure that the records referred to in paragraph (1) (which may be in paper or electronic form) are—
- (a) kept securely and can be located promptly when required;
  - (b) retained for an appropriate period of time; and
  - (c) securely destroyed when it is appropriate to do so.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Requirements relating to workers



## 21

The registered person must—

- (a) operate effective recruitment procedures in order to ensure that no person is employed for the purposes of carrying on a regulated activity unless that person—
  - (i) is of good character,
  - (ii) has the qualifications, skills and experience which are necessary for the work to be performed, and
  - (iii) is physically and mentally fit for that work;
- (b) ensure that information specified in Schedule 3 is available in respect of a person employed for the purposes of carrying on a regulated activity, and such other information as is appropriate;
- (c) ensure that a person employed for the purposes of carrying on a regulated activity is registered with the relevant professional body where such registration is required by, or under, any enactment in relation to—
  - (i) the work that the person is to perform, or
  - (ii) the title that the person takes or uses; and
- (d) take appropriate steps in relation to a person who is no longer fit to work for the purposes of carrying on a regulated activity including—
  - (i) where the person is a health care professional, informing the body responsible for regulation of the health care profession in question, or
  - (ii) where the person is a [social worker registered in Part 16 of the register maintained by the Health and Care Professions Council,] informing the Council.

### NOTES

#### Initial Commencement

##### *Specified date*

Specified date: 1 April 2010: see reg 1.

#### Amendment

In para (d)(ii) words from “social worker registered” to “Care Professions Council,” in square brackets substituted by SI 2012/1479, art 11, Schedule, Pt 2, para 88(1), (2).

Date in force: 1 August 2012: see SI 2012/1479, art 1(2).

### Staffing

## 22

In order to safeguard the health, safety and welfare of service users, the registered person must take appropriate steps to ensure that, at all times, there are sufficient numbers of suitably qualified, skilled and experienced persons employed for the purposes of carrying on the regulated activity.

### NOTES

#### Initial Commencement

##### *Specified date*

Specified date: 1 April 2010: see reg 1.

### **Supporting workers**

#### **23**

(1) The registered person must have suitable arrangements in place in order to ensure that persons employed for the purposes of carrying on the regulated activity are appropriately supported in relation to their responsibilities, to enable them to deliver care and treatment to service users safely and to an appropriate standard, including by—

- (a) receiving appropriate training, professional development, supervision and appraisal; and
- (b) being enabled, from time to time, to obtain further qualifications appropriate to the work they perform.

(2) Where the regulated activity carried on involves the provision of health care, the registered person must (as part of a system of clinical governance and audit) ensure that healthcare professionals employed for the purposes of carrying on the regulated activity are enabled to provide evidence to their relevant professional body demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise.

(3) For the purposes of paragraph (2), “system of clinical governance and audit” means a framework through which the registered person endeavours continuously to—

- (a) evaluate and improve the quality of the services provided; and
- (b) safeguard high standards of care by creating an environment in which clinical excellence can flourish.

### **NOTES**

#### **Initial Commencement**

##### ***Specified date***

Specified date: 1 April 2010: see reg 1.

### **Cooperating with other providers**

#### **24**

(1) The registered person must make suitable arrangements to protect the health, welfare and safety of service users in circumstances where responsibility for the care and treatment of service users is shared with, or transferred to, others, by means of—

- (a) so far as reasonably practicable, working in cooperation with others to ensure that appropriate care planning takes place;
- (b) subject to paragraph (2), the sharing of appropriate information in relation to—
  - (i) the admission, discharge and transfer of service users, and
  - (ii) the co-ordination of emergency procedures; and
- (c) supporting service users, or persons acting on their behalf, to obtain appropriate health and social care support.

(2) Nothing in this regulation shall require or permit any disclosure or use of information which is prohibited by or under any enactment, or by court order.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

## Part 5 Compliance and Offences

### Compliance with regulations

#### 25

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

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Guidance and Code

#### 26

- (1) 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 in relation to the requirements set out in Parts 3 and 4 (with the exception of regulation 12 in so far as it applies to health care associated infections); and
  - (b) in relation to regulation 12, any Code of Practice issued by the Secretary of State in relation to the prevention or control of health care associated infections.
- (2) For the purposes of paragraph (1)—
- (a) “guidance” means the guidance referred to in section 23 of the Act; and
  - (b) “Code of Practice” means the code of practice referred to in section 21 of the Act.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Offences

#### 27

- (1) A failure to comply with any of the provisions of regulations 9 to 24 shall be an offence.

(2) The Commission may not bring proceedings in respect of a failure by a registered person to comply with any of those provisions unless—

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

(3) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine not exceeding £50,000.

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

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Amendment

Para (4): words “took all reasonable steps and exercised all due diligence” in square brackets substituted by SI 2012/1513, regs 2, 6.

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

## Part 6 Penalty Notices

### 28

(1) The offences under the provisions listed in the first column of Schedule 4 are prescribed as fixed penalty offences for the purposes of section 86 of the Act.

(2) The monetary amount of the penalty for each fixed penalty offence is prescribed in the third column of Schedule 4.

(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 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 or debit 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) Where 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 pursuant to 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—

“electronic communication” has the same meaning as in the Electronic Communications Act 2000;

“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;

“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.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

## Part 7 Revocation

### Revocation

29

The Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009 are revoked.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

## [Part 8 Review]

## NOTES

### Amendment

Inserted by SI 2012/1513, regs 2, 7.

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

### [Review]

## NOTES

### Amendment

Inserted by SI 2012/1513, regs 2, 7.

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

**[30]**

[(1) Before 1st October 2017, 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.]

**NOTES**

**Amendment**

Inserted by SI 2012/1513, regs 2, 7.

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Signed by authority of the Secretary of State for Health.

*Mike O'Brien*

Minister of State,

Department of Health

15th March 2010

**SCHEDULE 1  
REGULATED ACTIVITIES**

Regulation 3

**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) This paragraph does not apply where paragraph 2 (accommodation for persons who require nursing or personal care) or paragraph 4 (accommodation and nursing or personal care in the further education sector) applies.

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

- (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) 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) and (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 an adult placement carer under the terms of a carer agreement;
  - (b) in a school; or
  - (c) in an institution within the further education sector [or in a 16 to 19 Academy].

### **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.

#### **Accommodation and nursing or personal care in the further education sector**

##### **4**

(1) Subject to sub-paragraph (2), the provision of residential accommodation together with nursing or personal care for persons in an institution within the further education sector.

(2) Sub-paragraph (1) only applies where the number of persons to whom nursing or personal care and accommodation are provided is more than one tenth of the number of students to whom both education and accommodation are provided.

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

##### **5**

(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 multi-disciplinary team which includes a health care professional; or
- (b) a social worker, or a multi-disciplinary 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 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 14 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 or regulation 8 or 12 of the Work in Compressed Air Regulations 1996, 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.
- (4) In this paragraph—
- (a) “health care professional” means a person who is—
    - (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” mean persons registered as such with the Health 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;
  - (d) “dental hygienist”, “dental therapist”, “dental nurse”, “dental technician” and “orthodontic therapist” mean 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;
  - (g) “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 Health and Social Work Professions Order 2001].

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

### **6**

(1) [Subject to sub-paragraph (1A),] 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; 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.

[(1A) 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) of that Act.]

(2) In this paragraph—

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

## **Surgical procedures**

### **7**

(1) Subject to sub-paragraphs (2) to (5), 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;
- [(aa) the purpose of sterilisation or reversal of sterilisation;]
- (b) cosmetic purposes, where the procedure involves the use of instruments or equipment which are inserted into the body; or
- (c) 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)(b)—
- (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**

#### **8**

- (1) Subject to [sub-paragraphs (3), (4A) and (4C)], 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) 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,

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.

(2) Subject to [sub-paragraphs (3), (4A) and (4C)], 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) 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,

where such procedures are part of neither the planning and delivery of care or treatment nor a national screening programme, other than for cancer;

(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; and

[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; and
- (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 for which a licence has been granted to that person under section 16 (grant of licence) of that Act].

[(4A) 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 (4B), and the analysis and reporting of the results of those procedures, are excepted from sub-paragraphs (1) and (2) of this paragraph.

(4B) The procedures referred to in sub-paragraph (4A) 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.

(4C) 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.]

(5) For the purposes of this paragraph—

- [(za) “16 to 19 Academy” has the same meaning as in section 1B of the Academies Act 2010;]
- (a) “chiropractor” means a person registered with the General Chiropractic Council pursuant to section 3, 4, 5 or 5A of the Chiropractors Act 1994;
- [(aa) “hearing aid dispenser” means a person registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order;] and
- (b) “physiotherapist” means a person registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order.

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

#### **9**

[(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—

“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**

#### **10**

(1) [Subject to sub-paragraphs (2A) and (2B),] 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.

[(2A) Transport services which are provided within the confines of the site or venue being used for an activity or event mentioned in paragraph 5(3)(f) or (g) are excepted from sub-paragraph (1).

(2B) 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; and
- (b) the person providing the air ambulance does not provide treatment to a patient.]

(3) For the purposes of this paragraph—

- (a) “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; and
- (b) “vehicle” includes an air or water ambulance.

### **Maternity and midwifery services**

#### **11**

(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**

#### **12**

The termination of pregnancies.

### **Services in slimming clinics**

#### **13**

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**

#### **14**

- (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

15

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

### NOTES

#### Initial Commencement

##### *Specified date*

Specified date: 1 April 2010: see reg 1.

#### Amendment

Para 1: sub-para (3)(c) substituted by SI 2012/1513, regs 2, 8(1), (2)(a).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 1: in sub-para (4) definition “related third party” inserted by SI 2012/1513, regs 2, 8(1), (2)(b).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 2: in sub-para (2)(c) words “or in a 16 to 19 Academy” in square brackets inserted by SI 2012/979, art 2, Schedule, para 27.

Date in force: 1 May 2012: see SI 2012/979, art 1(b).

Para 5: in sub-para (4)(g) words from “in Part 16” to “Health and Social Work Professions Order 2001” in square brackets substituted by SI 2012/1479, art 11, Schedule, Pt 2, para 88(1), (3).

Date in force: 1 August 2012: see SI 2012/1479, art 1(2).

Para 6: in sub-para (1) words “Subject to sub-paragraph (1A),” in square brackets inserted by SI 2012/1513, regs 2, 8(1), (3)(a).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 6: sub-para (1A) inserted by SI 2012/1513, regs 2, 8(1), (3)(b).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 7: sub-para (1)(aa) inserted by SI 2012/1513, regs 2, 8(1), (4).

Date in force: 1 October 2012: see SI 2012/1513, reg 1(2)(b).

Para 8: in sub-para (1) words “sub-paragraphs (3), (4A) and (4C)” in square brackets substituted by SI 2012/1513, regs 2, 8(1), (5)(a).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 8: in sub-para (2) words “sub-paragraphs (3), (4A) and (4C)” in square brackets substituted by SI 2012/1513, regs 2, 8(1), (5)(a).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 8: in sub-para (4)(a)(i) words “or from a vein” in square brackets inserted by SI 2012/1513, regs 2, 8(1), (5)(b).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 8: sub-para (4)(g)–(o) substituted, for sub-para (4)(g) as originally enacted, by SI 2012/1513, regs 2, 8(1), (5)(b).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 8: sub-paras (4A)–(4C) inserted by SI 2012/1513, regs 2, 8(1), (5)(c).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 8: sub-para (5)(za) inserted by SI 2012/1513, regs 2, 8(1), (5)(d)(i).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 8: sub-para (5)(aa) inserted by SI 2012/1513, regs 2, 8(1), (5)(d)(ii).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 9: sub-para (1) numbered as such by SI 2012/1513, regs 2, 8(1), (6)(a).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 9: in sub-para (1) words “Subject to sub-paragraph (2),” in square brackets inserted by SI 2012/1513, regs 2, 8(1), (6)(b).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 9: sub-paras (2), (3) inserted by SI 2012/1513, regs 2, 8(1), (6)(c).

- Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).  
Para 10: in sub-para (1) words “Subject to sub-paragraphs (2A) and (2B),” in square brackets inserted by SI 2012/1513, regs 2, 8(1), (7)(a).  
Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).  
Para 10: in sub-para (1) words omitted revoked by SI 2011/2711, reg 2(1), (5).  
Date in force: 30 November 2011: see SI 2011/2711, reg 1.  
Para 10: sub-paras (2A), (2B) inserted by SI 2012/1513, regs 2, 8(1), (7)(b).  
Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

## **SCHEDULE 2**

### **REGULATED ACTIVITIES: GENERAL EXCEPTIONS**

Regulations 3(7) and (8)

#### **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 involves the carrying on of an establishment or agency within the meaning of the Care Standards Act 2000 for which Her Majesty's Chief Inspector of Education, Children's Services and Skills is the registration authority under that Act.

#### **3**

The provision of all medical services (including medical services provided otherwise than under the 2006 Act) by a provider whose sole or main purpose is the provision of primary medical services—

- (a) under arrangements made pursuant to the following sections of the 2006 Act—
- [(i) section 3A (power of clinical commissioning groups as to commissioning certain health services),]
  - (ii) section 83(2)(b) (primary medical services),
  - (iii) section 92 (arrangements by [the Board] for the provision of primary medical services); or
- (b) under a contract entered into pursuant to section 84 of that Act (general medical services contracts: introductory).

#### 4

Subject to paragraph 5, and except where paragraph 3 applies, the provision of treatment in a surgery or consulting room otherwise than under arrangements made pursuant to the 2006 Act by—

- (a) *an individual medical practitioner who also provides services (whether there or elsewhere) under arrangements made pursuant to the 2006 Act; or*
- (b) *a group of medical practitioners all of whom also provide services (whether there or elsewhere) under arrangements made pursuant to the 2006 Act.*

#### [4

(1) Subject to paragraph 5, and except where paragraph 3 applies, the provision of treatment in a surgery or consulting room by a medical practitioner who is (or group of medical practitioners who are)—

- (a) a service provider in respect of a regulated activity specified in paragraph 5 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.]

#### 5

Paragraph 4 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 7(2) of Schedule 1] or intravenously administered sedation;
- (b) *dental treatment carried out under general anaesthesia;*
- (c) *obstetric services and, in connection with childbirth, medical services;*
- [(c) medical services provided in connection with childbirth;]
- (d) the termination of pregnancies;
- (e) cosmetic surgery, with the exception of the procedures referred to in paragraph 7(4) of Schedule 1;
- (f) haemodialysis or peritoneal dialysis;
- (g) *endoscopy; or*
- [(g) 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;]
- (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 such therapy is carried out

by or under the supervision or direction of a medical practitioner]; or

(i) intravenous, intrathecal or epidural administration of medicines or diagnostic agents;

(j) the therapeutic or diagnostic use of x-rays, radiation, protons or magnetic resonance imaging; or

(k) invasive cardiac physiology tests].

## 6

The provision by a general medical practitioner (other than one who is a provider for the purposes of paragraph 3) of—

- (a) primary medical services under arrangements made pursuant to the sections of the 2006 Act referred to in paragraph 3(a) and (b); or
- (b) any of the services listed in paragraph 5 in premises which are the premises used by that practitioner for the purpose of the provision of primary medical services under the 2006 Act.

## 7

The provision of services (other than in a surgery, consulting room or hospital) involving treatment by medical practitioners working for the purposes of an undertaking which also provides such services in pursuance of the 2006 Act.

## 8

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.

## 9

...

## 10

Forensic medical [or dental] services provided under arrangements made with a police authority as defined in section 101 (interpretation) of the Police Act 1996.

## 11

...

## 12

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.

**13**

Pharmaceutical services and local pharmaceutical services provided under Part 7 of the 2006 Act[, 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, at or from premises that are a registered pharmacy (within the meaning given by section 74 of the Medicines Act 1968)].

**14**

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.

**15**

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.

**16**

Treatment provided in a school to the pupils of that school by a nurse who is engaged and directed by the school.

**17**

In this Schedule—

- (a) “insurance provider” means—
  - (i) a person regulated by the [Financial Conduct Authority or the Prudential Regulation Authority] who sells insurance, or underwrites the risk of such insurance, or
  - (ii) the agent of such a person; and
- (b) “primary dental services” includes the provision of dental implants.

**[Exemption for the Olympics and Paralympics**

**18**

(1) Any activity which is carried on under temporary arrangements in relation to those persons taking part in, or attending, a London Olympic event during the London Olympics period.

(2) In this paragraph, “London Olympic event” and “London Olympics period” have the meanings given by section 1 (interpretation of principal terms) of the London Olympic Games and Paralympic Games Act 2006.]

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Amendment

Para 3: sub-para (a)(i) substituted by SI 2013/235, art 11, Sch 2, Pt 1, para 150(1), (2)(a).

Date in force: 1 April 2013: see SI 2013/235, art 1(2).

Para 3: in sub-para (a)(iii) words “the Board” in square brackets substituted by SI 2013/235, art 11, Sch 2, Pt 1, para 150(1), (2)(b).

Date in force: 1 April 2013: see SI 2013/235, art 1(2).

Para 4: substituted by SI 2012/1513, regs 2, 9(1), (2).

Date in force: 1 October 2013: see SI 2012/1513, reg 1(2)(c).

Para 5: in sub-para (a) words from “(other than local” to “of Schedule 1)” in square brackets inserted by SI 2012/1513, regs 2, 9(1), (3)(a).

Date in force: 1 October 2013: see SI 2012/1513, reg 1(2)(c).

Para 5: sub-para (b) revoked by SI 2012/1513, regs 2, 9(1), (3)(b).

Date in force: 1 October 2013: see SI 2012/1513, reg 1(2)(c).

Para 5: sub-para (c) substituted by SI 2012/1513, regs 2, 9(1), (3)(c).

Date in force: 1 October 2013: see SI 2012/1513, reg 1(2)(c).

Para 5: sub-para (g) substituted by SI 2012/1513, regs 2, 9(1), (3)(d).

Date in force: 1 October 2013: see SI 2012/1513, reg 1(2)(c).

Para 5: sub-paras (i)–(k) inserted by SI 2012/1513, regs 2, 9(1), (3)(e).

Date in force: 1 October 2013: see SI 2012/1513, reg 1(2)(c).

Para 8: words “or dental” in square brackets inserted by SI 2012/1513, regs 2, 9(1), (4)(a).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 8: words “in conjunction with the provision of accommodation” in square brackets inserted by SI 2012/1513, regs 2, 9(1), (4)(b).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 9: revoked by SI 2011/2711, reg 2(1), (6).

Date in force: 30 November 2011: see SI 2011/2711, reg 1.

Para 10: words “or dental” in square brackets inserted by SI 2012/1513, regs 2, 9(1), (5).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

Para 11: revoked by SI 2011/2711, reg 2(1), (6).

Date in force: 30 November 2011: see SI 2011/2711, reg 1.

Para 13: words from “, services of a kind” to “Medicines Act 1968” in square brackets substituted by SI 2013/235, art 11, Sch 2, Pt 1, para 150(1), (3).

Date in force: 1 April 2013: see SI 2013/235, art 1(2).

Para 17: in sub-para (a)(i) words “Financial Conduct Authority or the Prudential Regulation Authority” in square brackets substituted by SI 2013/472, art 3, Sch 2, para 186.

Date in force: 1 April 2013: see SI 2013/472, art 1(1).

Para 18: inserted by SI 2012/1513, regs 2, 9(1), (6).

Date in force: 18 June 2012: see SI 2012/1513, reg 1(2)(a).

## SCHEDULE 3

### INFORMATION REQUIRED IN RESPECT OF PERSONS SEEKING TO CARRY ON, MANAGE OR WORK FOR THE PURPOSES OF CARRYING ON, A REGULATED ACTIVITY

Regulations 4, 5, 6 and 21

**1**

Proof of identity including a recent photograph.

**2**

Where the certificate is required for a purpose referred to in—

- (a) section 113A(2)(b) of the Police Act 1997, a criminal record certificate issued under section 113A of that Act together with, after the appointed day and where applicable, relevant information relating to children or vulnerable adults; or
- (b) section 113B(2)(b) of the Police Act 1997, an enhanced criminal record certificate issued under section 113B of that Act together with, where applicable, suitability information relating to children or vulnerable adults.

**3**

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.

**4**

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.

**5**

Satisfactory documentary evidence of any relevant qualification.

**6**

A full employment history, together with a satisfactory written explanation of any gaps in employment.

**7**

Satisfactory information about any physical or mental health conditions which are relevant to the person's ability to carry on, manage or work for the purposes of, the regulated activity.

**8**

For the purposes of this Schedule—

- (a) "the appointed day" means the day on which section 30 of the Safeguarding Vulnerable Groups Act 2006 comes into force;
- (b) "relevant information relating to children or vulnerable adults" has the same meaning as in section 31(2) and (3) of that Act;
- (c) "satisfactory" means satisfactory in the opinion of the Commission; and

- (d) “suitability information relating to children or vulnerable adults” means the information specified in sections 113BA and 113BB respectively of the Police Act 1997.

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

## SCHEDULE 4 FIXED PENALTY OFFENCES

Regulation 28

[FTB

<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	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	£1250 in the case of an offence committed by a service provider  £625 in the case of an offence committed by a registered manager]
Regulation 27 of these Regulations	Contravention of, or failure to comply with, requirements relating to quality and safety of service provision in relation to a regulated activity	£4,000 in the case of an offence committed by a service provider;  £2,000 in the case of an offence committed by a registered manager
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

## NOTES

### Initial Commencement

#### *Specified date*

Specified date: 1 April 2010: see reg 1.

### Amendment

Entry relating to "Regulation 25" inserted by SI 2012/921, reg 11.

Date in force: 18 June 2012: see SI 2012/921, reg 1(2)(a).

## EXPLANATORY NOTE

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

These Regulations, which are to come into force on 1st April 2010, are made under the Health and Social Care Act 2008 ("the Act") and prescribe the kinds of activities that will be regulated activities for the purposes of Part 1 of the Act, and the requirements that will apply in relation to the way in which those activities are carried on. Part 1 of the Act establishes the Care Quality Commission and provides for the registration of persons carrying on a prescribed regulated activity. It also provides powers to make regulations imposing requirements in relation to the carrying on of those regulated activities.

Part 1 (regulations 1 and 2) are general provisions dealing with citation, commencement and interpretation.

In Part 2, regulation 3 deals with the activities that will be 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. Regulation 3(3) provides that, until 1st October 2010, an activity will only be a regulated activity if it is carried on by an English NHS body. Regulation 3(4) provides that where social care services are provided by an English NHS body which continues to be registered in respect of those services under the Care Standards Act 2000 then, in so far as those services are capable of being a regulated activity for the purposes of these Regulations, they will not be so until 1st October 2010. An activity is only a regulated activity if it is carried on in England (regulation 3(5)). In addition, regulation 3(7) provides that the activities listed in Schedule 2 (general exceptions) are not to be regulated activities for the purposes of the Regulations. Regulation 3(6) and (8) contain provisions relating to the time limiting of certain specified wording and provisions in Schedules 1 and 2.

In Part 3, regulations 4 to 7, and Schedule 3, contain requirements relating to the 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") in respect of whom this information must be available (regulation 5(2)). Regulation 7 imposes general requirements as to the need for appropriate training in the case of a registered person.

Part 4 makes provision about the conduct of the regulated activity and, in particular, about the quality and safety of service provision including in relation to the care and welfare of service users (regulation 9), assessing and monitoring the quality of service provision (regulation 10), safeguarding vulnerable service users (regulation 11), cleanliness and infection control (regulation 12), the management of medicines (regulation 13), the meeting of nutritional needs (regulation 14), the safety and suitability of premises and equipment (regulations 15 and 16), respecting and involving service users (regulation 17) and the obtaining of consent to care and treatment (regulation 18). Provision is also made about complaints (regulation 19), record keeping (regulation 20), the fitness of workers, staffing and co-operation with other service providers (regulations 21 to 24).

Part 5 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 25). Regulation 26 states that, for the purposes of compliance with the Regulations, a registered person must take account of guidance issued by the Commission under section 23 of the Act and the Code of Practice issued by the Secretary of State under section 21 of the Act in relation to the prevention or control of healthcare associated infections. Regulation 27 provides that a breach of regulations 9 to 24 is to be an offence, and also includes a due diligence defence relating to any proceedings under the Regulations. In addition, it provides that no prosecution may be brought unless the breach is one which the registered person has failed to remedy in response to a warning notice given under section 29 of the Act.

In Part 6, regulation 28 (and Schedule 4) 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 penalty notice 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.

In Part 7, regulation 29 revokes the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009.

An impact assessment of the effect that this instrument will have on the costs and benefits to the service providers in question, together with an Equality Screening Assessment is available on the Department of Health website at <http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/index.htm> and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.