

Please note that the following regulations are still subject to Parliamentary approval. We anticipate that they will come into force in a phased approach from 1 April 2010, depending on the type of provider.

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

D R A F T S T A T U T O R Y I N S T R U M E N T S

2009 No. XXXX

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

**The Health and Social Care Act 2008 (Regulated Activities)
Regulations 2009**

Made - - - - *000*

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(a).

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 2009 and come into force on 1st April 2010.

Interpretation

2. In these Regulations—

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

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

(a) 2008 c. 14. “Prescribed” and “regulations” are defined in section 97(1) of the Act.

(b) 1983 c.20.

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

“the 2001 Order” means the Health Professions Order 2001(b);

“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(c);

“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(d);

“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(e) 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(f);

“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(g);

“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) 2006 c.41.
(b) S.I. 2002/254.
(c) See the definition of “relevant professions” in Schedule 3, paragraph 1 of the 2001 Order as amended by S.I. 2004/2033, article 10(5)(b)(i).
(d) 1973 c.35. See section 13(2) and (3). Section 13(2) was amended by the Employment Relations Act 1999 (c.26), Schedule 7, paragraphs 1 and 7.
(e) 1999 c.8. Section 60(2) was amended by the Health and Social Care Act 2008, Schedule 8, paragraph 1(3) and Schedule 15, Part 2 and by S.I. 2002/253 and the 2001 Order.
(f) 1992 c.13.
(g) The definition of “registered medical practitioner” in Schedule 1 to the Interpretation Act 1978 (c.30) has been substituted by S.I. 2002/3135, Schedule 1, paragraph 10 with effect from 16th November 2009.

- (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(a);

“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(b).

(a) 1996 c.56; *see* section 4 for the meaning of “school”. Section 4 has been amended by the Education Act 1997 (c. 44), sections 51, 57(1) and (4) and Schedule 7, paragraphs 10(a) and (b) and Schedule 8, by the Education Act 2002 (c. 32), section 215(2) and Schedule 22, Part 3, and by the Childcare Act 2006 (c. 21), section 95(1), (2) and (3).

(b) 2006 c. 47. Section 59 was amended by S.I. 2008/912, Schedule 1, paragraph 21 and by the Education and Skills Act 2008 (c. 25), section 147(8).

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) Subject to paragraph (4), until 1st October 2010, an activity is only a regulated activity if it is carried on by an English NHS body^(a).

(4) Where services involving, or connected with, the provision of social care are provided by an English NHS body which is registered as an establishment or agency under Part 2 of the Care Standards Act 2000^(b) in relation to the provision of those services then, to the extent that those services are capable of being a regulated activity for the purposes of these Regulations, they are only a regulated activity with effect from 1st October 2010.

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

(6) In Schedule 1, in paragraph 10(1), the words “by an English NHS provider” shall cease to have effect on 1st April 2011.

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

(8) In Schedule 2—

(a) paragraphs 3, 6 and 7 and, in paragraph 4, the words “and except where paragraph 3 applies”, shall cease to have effect on 1st April 2012; and

(b) paragraphs 9 and 11 shall cease to have effect on 1st April 2011.

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 each of the partners satisfies the requirements set out in paragraph (4);

(4) The requirements referred to are that P or, where applicable, each of the partners 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.

(a) See section 97(1) of the Act for the definition of “English NHS body”.

(b) 2000 c. 14.

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.

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.

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.

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.

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.

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.

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) The registered person must have regard to any guidance issued by the Secretary of State or an appropriate expert body, in relation to—

- (a) the protection of children and vulnerable adults generally; and
- (b) in particular, the appropriate use of methods of control or restraint.

(4) 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.

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.

Management of medicines

13.—(1) 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.

(2) In making the arrangements referred to in paragraph (1), the registered person must have regard to any guidance issued by the Secretary of State or an appropriate expert body in relation to the safe handling and use of medicines.

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.

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.

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 in accordance with the technical specifications and guidance issued by the manufacturer, the Secretary of State or appropriate expert bodies.

(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(a).

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.

(a) S.I. 2002/618; the relevant amending instrument is S.I. 2008/2936.

Consent to care and treatment

18. The registered person must—

- (a) have suitable arrangements in place for obtaining, and acting in accordance with, the consent of service users in relation to the care and treatment provided for them; and
- (b) have regard to any guidance issued by the Secretary of State or other appropriate expert body in relation to the matters referred to in paragraph (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.

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.

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 care worker registered with the General Social Care Council, informing the Council^(a).

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.

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.

^(a) The General Social Care Council is established under Part 5 of the Care Standards Act 2000 (c.14). See section 55 of that Act for the definition of “social care worker”, and S.I. 2004/561.

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.

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.

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.

Offences

27.—(1) A contravention of, or failure to comply with, any of the provisions of regulations 9 to 24 shall be an offence.

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

(3) 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 or exercised all due diligence to ensure that the provision in question was complied with.

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(a);

“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(b);

“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(c).

PART 7 REVOCATION

Revocation

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

Signed by authority of the Secretary of State for Health

Date

Name
Parliamentary Under Secretary of State
Department of Health

(a) 2000 c.7; see section 15 as amended by the Communications Act 2003 (c.21), Schedule 17, paragraph 158.
(b) 1971 c. 80.
(c) 1974 c. 39.
(d) S.I. 2009/660.

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) 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, 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 in order to meet that 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).

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.

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^(a) or regulation 8 or 12 of the Work in Compressed Air Regulations 1996^(b), 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^(c).

(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,

(a) S.I. 1997/2776.

(b) S.I. 1996/1656.

(c) 1990 c. 37. Paragraph 1 of Schedule 2 was amended by the Human Fertilisation and Embryology Act 2008 (c. 22), Schedule 2, paragraph 2 and Schedule 8, Part I and by S.I. 2007/1522.

- (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(a);
 - (c) “dental practitioner” means a dentist registered as such with the General Dental Council pursuant to section 14 of the Dentists Act 1984(b);
 - (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(c);
 - (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 with the General Social Care Council pursuant to section 56(1)(a) of the Care Standards Act 2000(d).

Assessment or medical treatment for persons detained under the 1983 Act

6.—(1) 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(e));
- (b) recalled to that hospital under section 17E of that Act(f); 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) In this paragraph—

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

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;

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- (a) “Relevant professions” are set out in Schedule 3, paragraph 1 of the 2001 Order. *See* S.I. 2004/2033, articles 3(4)(c) and 10(5)(b)(ii) and S.I. 2007/3101, Part 21, for relevant amendments.
 - (b) Section 14 of the Dentists Act 1984 (c.24) (“the 1984 Act”) was substituted by the Dentists Act 1984 (Amendment) Order 2005 (S.I. 2005/2011) (“the 2005 Order”), article 2(6) and amended by S.I. 2007/3101, regulation 111.
 - (c) The dental care professionals register was established by section 36B of the 1984 Act as inserted by article 29 of the 2005 Order and amended by S.I. 2001/3101, regulation 122.
 - (d) 2000 c.14. *See* also S.I. 2007/3101, regulations 230 and 232(a) for relevant amendments.
 - (e) Section 135 was amended by the Mental Health (Scotland) Act 1984 (c.36) Schedule 3, paragraph 56, the Police and Criminal Evidence Act 1984 (c.60) Schedule 6, Part 1 and Schedule 7, Part 1, the National Health Service and Community Care Act 1990 (c.19) Schedule 10, the Care Standards Act 2000 (c.14) Schedule 4, paragraph 9, the Mental Health Act 2007 (“the 2007 Act”) (c.12) section 44 and Schedule 2, paragraph 10(a) and S.I. 2005/2078, Schedule 1, paragraph 2(9). Section 136 was amended by the 2007 Act, section 44 and Schedule 2, paragraph 10(b).
 - (f) Section 17E was inserted by section 32 of the 2007 Act.
 - (g) *See* sections 34(2) and 145(1) of the 1983 Act; relevant amendments were made by the Care Standards Act 2000, Schedule 4, paragraph 9.
 - (h) Section 145 was amended by section 7 of the 2007 Act.
 - (i) Section 1 was amended by section 1(2) of the 2007 Act.

- (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-paragraph (3), 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-paragraph (3), 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, 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 use of an auroscope.

(5) For the purposes of this paragraph—

- (a) “chiropractor” means a person registered with the General Chiropractic Council pursuant to section 3, 4, 5 or 5A of the Chiropractors Act 1994^(a); 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. 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.

Transport services, triage and medical advice provided remotely

10.—(1) Transport services provided by an English NHS provider^(b) 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) For the purposes of this paragraph—

^(a) 1994 c. 17. Section 5A was inserted by S.I. 2007/3101, regulation 219.

^(b) See section 97(1) of the Act for the definition of “English NHS provider”. See regulation 3(6) which provides that the words “by an English NHS provider” cease to have effect on 1st April 2011.

- (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.

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 involves the carrying on of an establishment or agency within the meaning of the Care Standards Act 2000^(a) 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 3 (Secretary of State's duty as to provision of certain services),
 - (ii) section 83(2)(b) (primary medical services),
 - (iii) section 92 (arrangements by Strategic Health Authorities 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)^(b).
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.
5. Paragraph 4 does not apply in relation to—
- (a) treatment carried out under anaesthesia or intravenously administered sedation;
 - (b) dental treatment carried out under general anaesthesia;
 - (c) obstetric services and, in connection with childbirth, medical services;
 - (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
 - (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.

(a) 2000 c.14.

(b) This paragraph will cease to have effect on 1st April 2012: see regulation 3(8)(a).

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(a).

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(b).

8. Medical services provided (otherwise than 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. Treatment provided in a vehicle which is operated by an ambulance provider which is not an English NHS body(c).

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

11. Dental services—

- (a) provided as primary dental services in pursuance of Part 5 of the 2006 Act, except where those services are provided—
 - (i) by a Primary Care Trust under section 99(2) (primary dental services) of that Act, or
 - (ii) by an NHS trust or NHS foundation trust; or
- (b) of a kind which, if provided in pursuance of that Act, would be provided as primary dental services under Part 5, except where those services are provided in a hospital(e).

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 and 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.

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;

(a) This paragraph will cease to have effect on 1st April 2012: *see* regulation 3(8)(a).

(b) This paragraph will cease to have effect on 1st April 2012: *see* regulation 3(8)(a).

(c) This paragraph will cease to have effect on 1st April 2011: *see* regulation 3(8)(b).

(d) 1996 c.16. The definition of police authority in section 101 was amended by the Greater London Authority Act 1999 (c. 29), section 312(2).

(e) This paragraph will cease to have effect on 1st April 2011: *see* regulation 3(8)(b).

- (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 Services 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.

SCHEDULE 3

Regulations 4, 5, 6 and 21

Information Required In Respect Of Persons Seeking To Carry On, Manage Or Work For The Purposes Of Carrying On, A Regulated Activity

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), 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.

(a) 1997 c. 50. Sections 113A and 113B were inserted by the Serious Organised Crime and Police Act 2005 (c. 15), section 163(2), and amended by the Safeguarding Vulnerable Groups Act 2006 (c. 47), Schedule 9, Part 2, paragraphs 14(1), (2) and (3).

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^(a) 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^(b).

^(a) 2006 c.47.

^(b) Sections 113BA and 113BB were inserted into the Police Act 1997 by the Safeguarding Vulnerable Groups Act 2006, section 63(1), Schedule 9, Part 2, paragraph 14(1) and (4).

SCHEDULE 4

Regulation 28

Fixed Penalty Offences

<i>Provision creating offence</i>	<i>General nature of offence</i>	<i>Monetary amount of penalty</i>
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

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 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.

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2009 No. XXXX

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

The Care Quality Commission (Registration) Regulations 2009

<i>Made</i>	- - - -	2009
<i>Laid before Parliament</i>		2009
<i>Coming into force</i>		1st April 2010

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 10(2), 13(1), 16(a), 17(1), 20, 30(3), 39(1) and (4), 41(1), 42, 65(1) and (3), 89 and 161(3) and (4) of the Health and Social Care Act 2008(a).

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

PART 1
GENERAL

Citation and commencement

1. These Regulations may be cited as the Care Quality Commission (Registration) Regulations 2009 and shall come into force on 1st April 2010.

Interpretation

2. In these Regulations—

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

“health service body” means an English NHS body(b), NHS Blood and Transplant(c) or the Health Protection Agency(d);

“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;

(a) 2008 c.14. “Prescribed” and “regulations” are defined in section 97(1) of the Act.

(b) “English NHS body” is defined in section 97(1) of the Act.

(c) NHS Blood and Transplant was established as a Special Health Authority in October 2005 (see: S.I. 2005/2529) and is a cross-border Special Health Authority as defined in section 97(1) of the Act.

(d) The Health Protection Agency was established by the Health Protection Agency Act 2004 (c. 17), section 1.

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

“relevant address” means—

- (a) where the service provider is registered to carry on the regulated activity to which the enforcement action relates from one address, that address; or
- (b) where the service provider is registered to carry on the regulated activity from more than one address, any of those addresses to which the enforcement action is relevant;

“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.

PART 2

REGISTRATION

Register of regulated activities

3. The Commission must establish and maintain a register containing such information as appears to the Commission to be necessary to keep the public informed about the identity of registered persons and their carrying on of regulated activities.

Persons to be regarded as the person carrying on a regulated activity

4.—(1) For the purposes of Chapter 2 of Part 1 of the Act (registration in respect of the provision of health or social care), the following provisions apply.

(2) Where a regulated activity is carried on by a person (A) and one or more other persons who are—

- (a) individuals; and
- (b) employees of A for the purpose of carrying on the regulated activity,

A is to be regarded as the person who carries on the regulated activity.

(3) For the purposes of paragraph (2), a person is an employee of A where that person—

- (a) is employed by A under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract (including under a carer agreement); or
- (b) has been granted practising privileges by A.

(4) Where the provision of services under arrangements between a body of trustees established for the purpose of providing services to meet the health or social care needs of a named beneficiary and a provider of such services falls to be regarded as a regulated activity, it is the provider and not the body of trustees which shall be regarded as the person who carries on that regulated activity.

(5) In this regulation—

- (a) “carer agreement” has the same meaning as in the Adult Placement Schemes (England) Regulations 2004(a); and
- (b) “practising privileges” means the grant, by a person managing a hospital (as defined in section 275 of the National Health Service Act 2006(b)), to a registered medical practitioner(c) of permission to practise as a medical practitioner in that hospital.

(a) S.I. 2004/2071 to which there are amendments not relevant to these Regulations.

(b) 2006 c.41.

(c) The definition of “registered medical practitioner” in Schedule 1 to the Interpretation Act 1978 (c.30) has been substituted by S.I. 2002/3135, Schedule 1, paragraph 10 with effect from 16th November 2009.

Registered manager condition

5.—(1) Subject to paragraph (2), for the purposes of section 13(1) of the Act, the registration of a service provider in respect of a regulated activity must be subject to a registered manager condition where the service provider is—

- (a) a body of persons corporate or unincorporate; or
- (b) an individual who—
 - (i) is not a fit person to manage the carrying on of the regulated activity, or
 - (ii) is not, or does not intend to be, in full-time day to day charge of the carrying on of the regulated activity.

(2) Paragraph (1)(a) does not apply where the service provider is a health service body.

(3) A service provider (P) is not a fit person to manage the carrying on of a regulated activity unless P—

- (a) is of good character;
- (b) is physically and mentally fit to manage the carrying on of the regulated activity;
- (c) has the necessary qualifications, skills and experience to do so; and
- (d) is able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 1.

Cancellation of registration

6.—(1) The grounds specified for the purposes of section 17(1)(e) of the Act as grounds on which the Commission may cancel the registration of a registered person in respect of a regulated activity are that the registered person—

- (a) has made a statement which is false or misleading in a material respect, or provided false information, in relation to any application for—
 - (i) registration, or
 - (ii) the variation or removal of a condition in relation to their registration;
- (b) has failed to pay any fees payable under provision under section 85 of the Act; or
- (c) if the registered person is a service provider, is not, and has not been for a continuous period of 12 months ending with the date of the decision to cancel registration, carrying on that regulated activity.

PART 3

PUBLICATION OF INFORMATION AND EXPLANATIONS

Publication of information relating to enforcement action

7.—(1) Except in the circumstances specified in paragraphs 5 to 7 of Part 1 of Schedule 2, the Commission must publish the information prescribed in that Part of that Schedule in the time prescribed in paragraph 8 of that Part.

(2) The Commission may publish the information prescribed in Part 2 of Schedule 2 subject, in the case of the information prescribed in paragraph 13, to the conditions specified in subparagraph (2) of that paragraph.

Exemptions from the requirement to notify bodies of certain matters

8. Section 39(1) of the Act does not apply to—

- (a) a notice to a person who applies for registration as a registered person given under—
 - (i) section 26(2) or (3) of the Act (notice of proposals), or

- (ii) section 28(1) or (3) of the Act (notice of decisions);
- (b) a notice of proposal given under section 26(4)(c) or (d) of the Act, or a notice of decision given under section 28(3) of the Act, which—
 - (i) relates to the variation or removal of any condition for the time being in force in relation to a registration or the imposition of an additional condition in relation to a registration, and
 - (ii) appears to the Commission not to have a material impact on the regulated activity being carried on;
- (c) a notice of proposal given under section 26(5) of the Act or a notice of decision given under section 28(3) of the Act to refuse an application by the registered person under section 19(1) of the Act; and
- (d) a warning notice given under section 29 of the Act which appears to the Commission not to have a material impact on the regulated activity being carried on.

Notification to Primary Care Trust, English local authority and Strategic Health Authority

9.—(1) The Primary Care Trust or English local authority that is required to be given—

- (a) notice of an application for an order for cancellation of the registration of a registered person under section 30 of the Act; or
- (b) a copy of a notice under section 39 of the Act,

is to be determined in accordance with paragraphs (2) to (8).

(2) Where the application under section 30 of the Act, or the notice of which a copy is required to be given under section 39 of the Act, is in respect of a regulated activity that involves, or is connected with, the provision of health care, the Commission must give notice or a copy of the notice to the relevant Primary Care Trust.

(3) Where the application under section 30 of the Act, or the notice of which a copy is required to be given under section 39 of the Act, is in respect of a regulated activity that involves, or is connected with, the provision of social care, the Commission must give notice or a copy of the notice to the relevant local authority.

(4) Subject to paragraph (6), the relevant Primary Care Trust is any Primary Care Trust in whose area the regulated activity is being carried on.

(5) Subject to paragraph (6), the relevant local authority is any local authority in whose area the regulated activity is being carried on.

(6) Where a registered service provider is carrying on a regulated activity from more than one set of premises, and a notice of which a copy is required to be given under section 39 of the Act is in respect of the carrying on of a regulated activity from particular premises—

- (a) the relevant Primary Care Trust is any Primary Care Trust in whose area those particular premises are situated; and
- (b) the relevant local authority is any local authority in whose area those particular premises are situated.

(7) Subject to paragraph (8), the Strategic Health Authority that must be given notice under section 30(3)(b) of the Act or a copy of a notice under section 39(1)(b) of the Act is any Strategic Health Authority in whose area the regulated activity to which the application or notice relates is being carried on.

(8) Where a registered service provider is carrying on a regulated activity from more than one set of premises and a copy of the notice required to be given to a Strategic Health Authority under section 39(1)(b) is in respect of the carrying on of a regulated activity from particular premises, the Strategic Health Authority that must be given a copy of the notice is any Strategic Health Authority in whose area those particular premises are situated.

Power to require an explanation

10.—(1) Where the Commission considers an explanation of a relevant matter^(a) necessary or expedient for the purposes of any of its regulatory functions, the persons specified in paragraph (3) must, if so requested, provide an explanation of that matter to the Commission or to persons authorised by it.

(2) Explanations required under paragraph (1) must be provided at such times and such places as may be specified by the Commission.

(3) The persons referred to in paragraph (1) are—

- (a) a person carrying on a regulated activity;
- (b) a chair, director or employee of a person carrying on a regulated activity;
- (c) an English NHS body;
- (d) a member of an English NHS body other than an NHS foundation trust;
- (e) a member of a committee or sub-committee of an English NHS body other than an NHS foundation trust;
- (f) a member of a committee or sub-committee of the board of directors of an NHS foundation trust;
- (g) an employee of an English NHS body other than one falling within sub-paragraph (b);
- (h) a local authority;
- (i) a member or officer of a local authority;
- (j) a member of a committee or sub-committee of a local authority or a member of a joint committee of two or more local authorities;
- (k) an elected mayor of a local authority within the meaning given in section 39 of the Local Government Act 2000^(b);
- (l) a person (other than a person prescribed in sub-paragraphs (b) to (k)) who is assisting in the carrying on of a regulated activity;
- (m) a person providing equipment or premises to a registered person;
- (n) a chair, director or employee of a person providing equipment or premises to a registered person; and
- (o) a person (other than a person prescribed in sub-paragraph (n)) who is assisting a person providing equipment or premises to a registered person.

PART 4

REGISTRATION REQUIREMENTS

General

11. A registered person must, insofar as they are applicable, comply with the requirements specified in regulations 12 to 20 in relation to any regulated activity in respect of which they are registered.

Statement of purpose

12.—(1) The registered person must give the Commission a statement of purpose containing the information listed in Schedule 3.

(a) See section 65(2) of the Act for the definition of “relevant matter”.

(b) 2000 c. 22; section 39 has been amended by section 66 of the Local Government and Public Involvement in Health Act 2007 (c. 28).

(2) The registered person must keep under review and, where appropriate, revise the statement of purpose.

(3) The registered person must provide written details of any revision to the statement of purpose to the Commission within 28 days of any such revision.

Financial position

13.—(1) Subject to paragraph (2), the service provider must take all reasonable steps to carry on the regulated activity in such a manner as to ensure the financial viability of the carrying on of that activity for the purposes of—

- (a) achieving the aims and objectives set out in the statement of purpose; and
- (b) meeting the registration requirements prescribed pursuant to section 20 of the Act.

(2) This regulation does not apply where the service provider is—

- (a) an English local authority; or
- (b) a health service body.

Notice of absence

14.—(1) Subject to paragraphs (7) and (8), where—

- (a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or
- (b) the registered manager,

proposes to be absent from carrying on or managing the regulated activity for a continuous period of 28 days or more, the registered person must give notice in writing to the Commission of the proposed absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) must be given no later than 28 days before the proposed absence commences or within such shorter period as may be agreed with the Commission and must contain the following information in relation to the proposed absence—

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for the management of the carrying on of the regulated activity during the period of absence;
- (d) the name, address and qualifications of the person who will be responsible for the management of the carrying on of the regulated activity during that absence;
- (e) in the case of the absence of the registered manager, the arrangements that have been, or are proposed to be, made for appointing another person to manage the carrying on of the regulated activity during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence referred to in paragraph (1) arises as the result of an emergency, the registered person must give notice of the absence to the Commission within 5 working days of its occurrence specifying the matters set out in paragraph (2)(a) to (e).

(4) Where—

- (a) the service provider, if the provider is the person in day to day charge of the carrying on of the regulated activity; or
- (b) the registered manager,

has been absent for a continuous period of 28 days or more, and the Commission has not been given notice of the absence, the registered person shall forthwith give notice in writing to the Commission specifying the matters set out in paragraph (2)(a) to (e).

(5) The registered person must notify the Commission of the return to duty of the service provider or (as the case may be) the registered manager not later than 7 working days after the date of that return.

(6) In this regulation “working day” means any day other than a Saturday, a Sunday, Christmas Day, Good Friday or a day which is a bank holiday in England and Wales within the meaning of the Banking and Financial Dealings Act 1971^(a).

(7) Subject to paragraph (8), this regulation does not apply where the service provider is a health service body.

(8) Where the service provider is a health service body and is subject to a registered manager condition pursuant to regulation 5 or section 12(3) or (5) of the Act, this regulation shall have effect in relation any absence, proposed absence or return to duty of that registered manager.

Notice of changes

15.—(1) Subject to paragraph (2), the registered person must give notice in writing to the Commission, as soon as it is reasonably practicable to do so, if any of the following events takes place or is proposed to take place—

- (a) a person other than the registered person carries on or manages the regulated activity;
- (b) a registered person ceases to carry on or manage the regulated activity;
- (c) the name of a registered person (where that person is an individual) changes;
- (d) where the service provider is a partnership, any change in the membership of the partnership;
- (e) where the service provider is a body other than a partnership—
 - (i) a change in the name or address of the body,
 - (ii) a change of director, secretary or other similar officer of the body, or
 - (iii) a change of nominated individual;
- (f) where the service provider is—
 - (i) an individual, the appointment of a trustee in bankruptcy in relation to that individual, or
 - (ii) a company or partnership, the appointment of a receiver, manager, liquidator or provisional liquidator in relation to that company or partnership.

(2) Paragraph (1)(e)(ii) does not apply where the service provider is a health service body.

(3) In this regulation, “nominated individual” means the individual who is employed as a director, manager or secretary of the body and whose name has been notified to the Commission as being the person who is responsible for supervising the management of the carrying on of the regulated activity by that body.

Notification of death of service user

16.—(1) Except where paragraph (2) applies, the registered person must notify the Commission without delay of the death of a service user—

- (a) whilst services were being provided in the carrying on of a regulated activity; or
- (b) as a consequence of the carrying on of a regulated activity.

(2) Subject to paragraph (4), where the service provider is a health service body, the registered person must notify the Commission of the death of a service user where the death—

- (a) occurred—
 - (i) whilst services were being provided in the carrying on of a regulated activity, or
 - (ii) as a consequence of the carrying on of a regulated activity; and

(a) 1971 c.80.

- (b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care or treatment.

(3) Notification of the death of a service user must include a description of the circumstances of the death.

(4) Paragraph (2) does not apply if, and to the extent that, the registered person has reported the death to the National Patient Safety Agency(a).

(5) This regulation does not apply where regulation 17 applies.

Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983

17.—(1) The registered person must notify the Commission without delay of the death or unauthorised absence of a service user who is liable to be detained by the registered person—

- (a) under the Mental Health Act 1983(b) (“the 1983 Act”); or
- (b) pursuant to an order or direction made under another enactment (which applies in relation to England), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

(2) Notification of the death of a service user must include a description of the circumstances of the death.

(3) In this regulation—

- (a) references to persons “liable to be detained” include a community patient who has been recalled to hospital in accordance with section 17E of the 1983 Act(c), but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42(d), 73(e) or 74(f) of the 1983 Act;
- (b) “community patient” has the same meaning as in section 17A of the 1983 Act(g);
- (c) “hospital” means a hospital within the meaning of Part 2 of that Act(h); and
- (d) “unauthorised absence” means an unauthorised absence from a hospital.

Notification of other incidents

18.—(1) Subject to paragraphs (3) and (4), the registered person must notify the Commission without delay of the incidents specified in paragraph (2) which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity.

(2) The incidents referred to in paragraph (1) are—

- (a) any injury to a service user which, in the reasonable opinion of a health care professional, has resulted in—
 - (i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary,
 - (ii) changes to the structure of a service user's body,
 - (iii) the service user experiencing prolonged pain or prolonged psychological harm, or

(a) The National Patient Safety Agency is a Special Health Authority established by the National Patient Safety Agency (Establishment and Constitution) Order 2001 (S.I. 2001/1743), to which there are amendments which are not relevant to these Regulations.

(b) 1983 c.20.

(c) Section 17E was inserted by the Mental Health Act 2007 (c.12) (“the 2007 Act”), section 32(2).

(d) Section 42 was amended by the 2007 Act, sections 40(2) and 55 and Schedule 11, Part 8.

(e) Section 73 was amended by the 2007 Act, section 4(9) and S.I. 2001/3712 and 2008/2833.

(f) Section 74 was amended by the Crime (Sentences) Act 1997 (c. 43), Schedule 4, paragraphs 12(10) to (12), the Criminal Justice Act 2003 (c. 44), section 295 and S.I. 2008/2833.

(g) Section 17A was inserted by section 32(2) of the 2007 Act.

(h) See sections 34(2) and 145(1) of the 1983 Act; relevant amendments were made by the Care Standards Act 2000, Schedule 4, paragraph 9 and by the National Health Service (Consequential Provisions) Act 2006 (c.43), Schedule 1, paragraph 70(c).

- (iv) the shortening of the life expectancy of the service user;
- (b) any injury to a service user which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—
 - (i) the death of the service user, or
 - (ii) an injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a);
- (c) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation, including the result of such a request;
- (d) any application made to a court in relation to depriving a service user of their liberty pursuant to section 16(2)(a) of the 2005 Act;
- (e) any abuse or allegation of abuse in relation to a service user;
- (f) any incident which is reported to, or investigated by, the police;
- (g) any event which prevents, or appears to the service provider to be likely to threaten to prevent, the service provider's ability to continue to carry on the regulated activity safely, or in accordance with the registration requirements, including—
 - (i) an insufficient number of suitably qualified, skilled and experienced persons being employed for the purposes of carrying on the regulated activity,
 - (ii) an interruption in the supply to premises owned or used by the service provider for the purposes of carrying on the regulated activity of electricity, gas, water or sewerage where that interruption has lasted for longer than a continuous period of 24 hours,
 - (iii) physical damage to premises owned or used by the service provider for the purposes of carrying on the regulated activity which has, or is likely to have, a detrimental effect on the treatment or care provided to service users, and
 - (iv) the failure, or malfunctioning, of fire alarms or other safety devices in premises owned or used by the service provider for the purposes of carrying on the regulated activity where that failure or malfunctioning has lasted for longer than a continuous period of 24 hours.

(3) Paragraph (2)(f) does not apply where the service provider is an English NHS body.

(4) Where the service provider is a health service body, paragraph (1) does not apply if, and to the extent that, the registered person has reported the incident to the National Patient Safety Agency.

(5) In this regulation—

- (a) “the 2005 Act” means the Mental Capacity Act 2005(a);
- (b) “abuse”, in relation to a service user, means—
 - (i) sexual abuse,
 - (ii) physical or psychological ill-treatment,
 - (iii) theft, misuse or misappropriation of money or property, or
 - (iv) neglect and acts of omission which cause harm or place at risk of harm;
- (c) “health care professional” means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(b) applies;
- (d) “registration requirements” means any requirements or conditions imposed on the registered person by or under Chapter 2 of Part 1 of the Act;
- (e) “standard authorisation” has the meaning given under Part 4 of Schedule A1 to the 2005 Act;

(a) 2005 c. 9. Schedule A1 was inserted by Schedule 7 to the Mental Health Act 2007 (c. 12).

(b) 1999 c. 8. Section 60(2) was amended by the Health and Social Care Act 2008, Schedule 8, paragraph 1(3) and Schedule 15, Part 2 and by S.I. 2002/253 and 254.

- (f) “supervisory body” has the meaning given in paragraph 180 (in relation to a hospital in England) or paragraph 182 (in relation to a care home) of Schedule A1 to the 2005 Act;
- (g) for the purposes of paragraph (2)(a)—
 - (i) “prolonged pain” and “prolonged psychological harm” means pain or harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days, and
 - (ii) a sensory, motor or intellectual impairment is not temporary if such an impairment has lasted, or is likely to last, for a continuous period of at least 28 days.

Fees etc.

19.—(1) Where a service user will be responsible for paying the costs of their care or treatment (either in full or partially), the registered person must provide a statement to the service user, or to a person acting on the service user’s behalf—

- (a) specifying the terms and conditions in respect of the services to be provided to the service user, including as to the amount and method of payment of fees; and
 - (b) including, where applicable, the form of contract for the provision of services by the service provider.
- (2) The statement referred to in paragraph (1) must be—
- (a) in writing; and
 - (b) as far as reasonably practicable, provided prior to the commencement of the services to which the statement relates.

Requirements relating to termination of pregnancies

20.—(1) This regulation applies to a registered person who—

- (a) carries on or manages the regulated activity consisting of the termination of pregnancies; and
- (b) is not an English NHS body.

(2) The registered person must ensure that, unless two certificates of opinion have been received in respect of the service user—

- (a) no termination of pregnancy is carried out; and
- (b) no fee is demanded or accepted from a service user.

(3) The registered person must ensure that a certificate of opinion in respect of a service user undergoing termination of a pregnancy is completed and included with the service user’s medical record.

(4) The registered person must ensure that no termination of pregnancy is undertaken after the 20th week of gestation, unless—

- (a) the service user is treated by persons who are suitably qualified, skilled and experienced in the late termination of pregnancy; and
- (b) appropriate procedures are in place to deal with any medical emergency which occurs during or as a result of the termination.

(5) The registered person must ensure that no termination of a pregnancy is undertaken after the 24th week of gestation.

(6) The registered person must ensure that a register of service users undergoing a termination of pregnancy is maintained, which is—

- (a) completed in respect of each service user at the time the termination is undertaken; and
- (b) retained for a period of not less than 3 years beginning on the date of the last entry.

(7) The registered person must ensure that a record is maintained of the total numbers of terminations of pregnancies undertaken.

(8) The registered person must ensure that the record referred to in paragraph (7) (which may be in paper or electronic form) is—

- (a) accurate;
- (b) kept securely and can be located promptly when required;
- (c) retained for an appropriate period of time; and
- (d) securely destroyed when it is appropriate to do so.

(9) The registered person must ensure that notice in writing is sent to the Chief Medical Officer of the Department of Health of each termination of pregnancy^(a).

(10) If the registered person—

- (a) receives information concerning the death of a service user who has undergone termination of a pregnancy during the period of 12 months ending on the date on which the information is received; and

(b) has reason to believe that the service user's death may be associated with the termination, the registered person must give notice in writing to the Commission of that information, within the period of 14 days beginning on the day on which the information is received.

(11) The registered person must prepare and implement appropriate procedures to ensure that foetal tissue is treated with respect.

(12) In this regulation, “certificate of opinion” means a certificate required by regulations made under section 2(1) of the Abortion Act 1967^(b).

PART 5

OTHER MISCELLANEOUS REQUIREMENTS

Death of service provider

21.—(1) Where the service provider is a partnership and a partner dies, the surviving partner shall without delay notify the Commission of the death in writing.

(2) Where the service provider is an individual and that individual dies, that individual's personal representative must notify the Commission in writing—

- (a) without delay of the death; and
- (b) within 28 days of the date of death of their intentions regarding the future carrying on of the regulated activity.

(3) The personal representative of the deceased service provider may carry on the regulated activity without being registered in respect of it—

- (a) for a period not exceeding 28 days; and
- (b) for any future period as may be determined in accordance with paragraph (4).

(4) The Commission may extend the period specified in paragraph (3)(a) by such further period, not exceeding one year, as the Commission shall determine, and shall notify any such determination to the personal representative in writing.

(5) The personal representative of the deceased service provider shall appoint a person to take full-time day to day charge of the carrying on of the regulated activity during any period in which, in accordance with paragraph (3), they carry on the regulated activity without being registered in respect of it.

(a) See section 4 of the Abortion Act 1967 (c.87) which requires such notice to be given by the medical practitioner carrying out the termination. For relevant amendments see: S.I. 2002/887.

(b) The Regulations made under section 2 are S.I. 1991/499. Relevant amending instrument is S.I. 2002/887.

Appointment of liquidators

- 22.**—(1) Any person to whom paragraph (2) applies must—
- (a) notify the Commission of their appointment and the reasons for their appointment;
 - (b) appoint a manager to manage the regulated activity in any cases where there is not a registered manager; and
 - (c) before the end of the period of 28 days beginning with the date of their appointment, notify the Commission of their intentions regarding the future carrying on of the regulated activity.
- (2) This paragraph applies to any person appointed as—
- (a) a receiver or manager of the property of the relevant company**(a)**;
 - (b) the liquidator or provisional liquidator of a relevant company; or
 - (c) the trustee in bankruptcy of a relevant individual**(b)**.

PART 6

COMPLIANCE, GUIDANCE AND OFFENCES

Compliance with regulations

23. 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.

Guidance

24.—(1) For the purposes of compliance with the requirements set out in these Regulations, the registered person must have regard to guidance issued by the Commission in relation to the requirements set out in Part 4 of these Regulations.

(2) For the purposes of paragraph (1), “guidance” means the guidance referred to in section 23 of the Act.

Offences

25.—(1) A contravention of, or failure to comply with, any of the provisions of regulations 12 and 14 to 20 shall be an offence.

(2) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale.

Signed by authority of the Secretary of State

Parliamentary Under Secretary of State
Department of Health

Date

(a) See section 41(3) of the Act for the definitions of “company” and “relevant company”.
(b) See section 41(3) of the Act for the definition of “relevant individual”.

**INFORMATION REQUIRED IN RESPECT OF A SERVICE
PROVIDER WHO PROPOSES TO MANAGE THE CARRYING ON
OF A REGULATED ACTIVITY**

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), 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 manage the carrying on 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(b) 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(c).

(a) 1997 c. 50. Sections 113A and 113B were inserted by the Serious Organised Crime and Police Act 2005 (c. 15), section 163(2), and amended by the Safeguarding Vulnerable Groups Act 2006 (c. 47), Schedule 9, Part 2, paragraphs 14(1), (2) and (3).

(b) 2006 c. 47.

(c) Sections 113BA and 113BB were inserted into the Police Act 1997 by the Safeguarding Vulnerable Groups Act 2006, section 63(1), Schedule 9, Part 2, paragraph 14(1) and (4).

**PUBLICATION OF INFORMATION RELATING TO
ENFORCEMENT ACTION**

PART 1

**INFORMATION RELATING TO ENFORCEMENT ACTION WHICH MUST BE
PUBLISHED**

1. In relation to the cancellation or suspension of a registered person's registration under section 17, 18, 30 or 31 of the Act, the prescribed information, subject to paragraph 5, is—

- (a) a description of the regulated activity to which the cancellation or suspension relates;
- (b) the name of the service provider in respect of that regulated activity;
- (c) where the cancellation or suspension relates to a registered manager, the name of the registered manager;
- (d) an explanation of why the registration has been cancelled or suspended and, where applicable, the period of suspension; and
- (e) the relevant address.

2. In relation to the conviction of any person in respect of an offence under Part 1 of the Act, except an offence under section 76 (disclosure of confidential personal information: offence), the prescribed information, subject to paragraph 6, is—

- (a) a description of the offence;
- (b) a description of the regulated activity that the person so convicted is carrying on, or involved in carrying on;
- (c) the name of the service provider in respect of that regulated activity;
- (d) where the person convicted is the registered manager, the name of the registered manager; and
- (e) the relevant address.

3.—(1) This paragraph applies to a decision under section 12(5) of the Act to vary or remove a condition for the time being in force in relation to a person's registration, or to impose an additional condition, which—

- (a) takes effect from the time when the notice is given in accordance with section 31 of the Act; or
- (b) appears to the Commission to have a material impact on the regulated activity being carried on.

(2) The prescribed information, subject to paragraph 5, in cases to which this paragraph applies is—

- (a) a description of the regulated activity that the variation or removal of a condition, or the imposition of an additional condition, relates to;
- (b) the name of the service provider in respect of that regulated activity;
- (c) where the decision relates to a condition in respect of a registered manager, the name of the registered manager;
- (d) a description of the condition being varied, removed or imposed and, where applicable, the variation or removal;
- (e) an explanation of why the decision was taken; and
- (f) the relevant address.

4. In relation to the payment by any person of a penalty in accordance with a penalty notice issued under section 86 of the Act other than in respect of an offence under section 63(7), 64(4) or 65(4) of that Act, the prescribed information, subject to paragraph 7, is—

- (a) a description of the fixed penalty offence;
- (b) a description of the regulated activity that the person given the penalty notice was carrying on or involved in carrying on;
- (c) the name of the service provider in respect of that regulated activity;
- (d) where the penalty notice is given to a registered manager, the name of the registered manager; and
- (e) the relevant address.

5. Paragraphs 1 and 3 do not apply, and the information prescribed in that paragraph must not be published, where an appeal is brought under section 32 of the Act and the First-tier Tribunal has directed that the Commission's decision is not, or is to cease, to have effect, or the order made by a justice of peace is to cease to have effect.

6. Paragraph 2 does not apply, and the information prescribed in that paragraph must not be published, where an appeal is brought against a conviction for an offence under Part 1 of the Act and the conviction is quashed.

7. Paragraph 4 does not apply, and the information prescribed in that paragraph must not be published, where a penalty notice is withdrawn in accordance with regulations made under section 87(1)(e) of the Act after the penalty has been paid but before publication of the information prescribed in paragraph 4.

8.—(1) The time prescribed for information required to be published under paragraphs 1 and 3 where no appeal is brought under section 32 of the Act is within the period starting immediately after the end of the period of 28 days referred to in section 32(2) of the Act and ending 4 months after service on the person of the notice of the Commission's decision or the date of the order under section 30 of the Act.

(2) The time prescribed for information required to be published under paragraphs 1 and 3 where an appeal is brought under section 32 of the Act is within 3 months of the determination or abandonment of the appeal.

(3) The time prescribed for information required to be published under paragraph 2 where no appeal is brought against a conviction is within the period starting immediately after the end of the period of 28 days after the date of the conviction and ending 4 months after the date of the conviction.

(4) The time prescribed for information required to be published under paragraph 2 where an appeal is brought against a conviction is within 3 months of the determination or abandonment of the appeal.

(5) The time prescribed for information to be published under paragraph 4 is within 3 months of the date of payment of the penalty.

PART 2

INFORMATION RELATING TO ENFORCEMENT ACTION WHICH MAY BE PUBLISHED

9. In relation to a conviction in respect of an offence under Part 1 of the Act, except an offence under section 76, the prescribed information is the penalty imposed.

10. In relation to decisions under section 12(5) of the Act which do not fall within paragraph 3(1), the prescribed information is the information listed in paragraph 3(2)(a) to (f).

11. Where a person who is not a registered person is convicted of an offence under Part 1 of the Act, except an offence under section 76, the prescribed information is the name of, and such other details as the Commission considers relevant about, the individual convicted of the offence.

12. In relation to the payment by any person of a penalty in accordance with a penalty notice issued under section 86 of the Act in respect of an offence under section 63(7), 64(4) or 65(4) of that Act, which is committed in connection with the carrying on of a regulated activity, the prescribed information is the information listed in paragraph 4(a) to (e).

13.—(1) In relation to a warning notice given under section 29 of the Act, the prescribed information is—

- (a) a description of the regulated activity to which the warning notice relates;
- (b) the name of the service provider in respect of that regulated activity;
- (c) where the warning notice is given to a registered manager, the name of the registered manager;
- (d) a description of the conduct which appears to the Commission to constitute a failure to comply with the relevant requirements and a description of the requirements concerned; and
- (e) the relevant address.

(2) Before publishing the information prescribed under sub-paragraph (1), the Commission must—

- (a) provide the person to whom the notice was given an opportunity to make representations to the Commission relating to the matters dealt with in the notice; and
- (b) take any such representations into account when determining whether to publish the prescribed information.

SCHEDULE 3

Regulation 12

INFORMATION TO BE INCLUDED IN THE STATEMENT OF PURPOSE

- 1.** The aims and objectives of the service provider in carrying on the regulated activity.
- 2.** The kinds of services provided for the purposes of the carrying on of the regulated activity and the range of service users' needs which those services are intended to meet.
- 3.** The full name of the service provider and of any registered manager, together with their business address, telephone number and, where available, electronic mail addresses.
- 4.** The legal status of the service provider.
- 5.** Details of the locations at which the services provided for the purposes of the regulated activity are carried on.

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 apply in relation to regulated activities carried on in England. Part 1 of the Act establishes the Care Quality Commission (“the Commission”) and provides for the registration of persons carrying on a regulated activity.

Part 1 of the Regulations contains provisions relating to citation, commencement and interpretation (regulations 1 and 2).

Part 2 of the Regulations contains provisions relating to registration. Regulation 3 requires the Commission to keep a register of persons registered with the Commission under Chapter 2 of Part 1 of the Act as a service provider or a manager in respect of a regulated activity and regulation 4 contains details of the persons to be regarded as carrying on the regulated activity for the purposes of Chapter 2 of Part 1 of the Act (registration in respect of the provision of health or social care). Regulation 5 (and Schedule 1) sets out the circumstances in which the registration of a service provider is to be subject to a registered manager condition. Regulation 6 specifies the grounds on which the Commission may cancel a service provider's registration pursuant to section 17(1)(e) of the Act.

Part 3 contains provisions relating to the publication of information and explanations. Regulation 7 (and Schedule 2) prescribe information relating to enforcement action that the Commission must publish and the time by which it must be published, and information that the Commission may publish. Regulation 8 prescribes cases in which copies of notices of proposals given under section 26 of the Act, notices of decisions given under section 28 of the Act and warning notices given under section 29 of the Act do not need to be given to persons listed in section 39 of the Act. Regulation 9 defines which Primary Care Trust, local authority and Strategic Health Authority is required to be notified by the Commission of an application for an order for cancellation of the registration of a service provider under section 30 of the Act or given a copy of a notice referred to in section 39(2) of the Act. Regulation 10 enables the Commission to require the persons prescribed to provide an explanation of a relevant matter to the Commission, or to persons authorised by it, in circumstances where the Commission considers the explanation necessary or expedient for the purposes of its regulatory functions. It also gives the Commission power to require the explanation to be given at such times and such places as it specifies.

Part 4 contains registration requirements. Regulation 11 provides that a registered person must comply with the requirements contained in regulations 12 to 20 in so far as they apply to an activity in respect of which they are registered. Regulation 12 provides that the registered person must give to the Commission a statement of purpose containing the information set out in Schedule 3 and regulation 13 contains provision as to the financial viability of a service provider (excluding English local authorities or a health service body). Regulations 14 and 15 require the giving of notices to the Commission in relation to the absence of a registered person and in relation to certain changes affecting the carrying on of the regulated activity. Regulations 16 and 17 prescribe the circumstances in which notification of the death of a service user must be given to the Commission (and regulation 17 also requires notification of the unauthorised absence of a service user who is liable to be detained under the Mental Health Act 1983) and regulation 18 prescribes the incidents, occurring whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity, which must be notified to the Commission. Regulation 19 deals with information to be given to service users in relation to fees for care or treatment. Regulation 20 contains requirements relating to a registered person who carries on the regulated activity of termination of pregnancies.

Part 5 contains other miscellaneous requirements. Regulation 21 deals with the notification to be given to the Commission where a service provider dies. Regulation 22 contains provisions which apply where a liquidator or similar person has been appointed in relation to the carrying on of a regulated activity.

Part 6 contains provisions relating to compliance, guidance and offences. Regulation 23 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 24 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. Regulation 25 provides that a breach of certain of the requirements in the Regulations is to be an offence punishable, on summary conviction, with a fine not exceeding level 4 on the standard scale.

An impact assessment of the effect that this instrument will have on the costs and benefits to the service provider in question, together with an Equality Screening Assessment was published alongside a draft Statutory Instrument entitled the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009 and is available on the Department of Health website at <http://dh.gov.uk/en/Publicationsandstatistics/Legislation/index.htm>.