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STATUTORY INSTRUMENTS

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**2009 No. 3112**

**The Care Quality Commission (Registration) Regulations 2009**

**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.

(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(1).

(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
- (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(2).

(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—

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(2) 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.

- (a) under the Mental Health Act 1983(3) (“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(4), but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42(5), 73(6) or 74(7) of the 1983 Act;
  - (b) “community patient” has the same meaning as in section 17A of the 1983 Act(8);
  - (c) “hospital” means a hospital within the meaning of Part 2 of that Act(9); 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
    - (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;

(3) 1983 c.20.

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

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

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

(7) 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.

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

(9) 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).

- (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<sup>(10)</sup>;
  - (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<sup>(11)</sup> 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;
  - (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.

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<sup>(10)</sup> 2005 c. 9. Schedule A1 was inserted by Schedule 7 to the Mental Health Act 2007 (c. 12).

<sup>(11)</sup> 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.

**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<sup>(12)</sup>.
- (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<sup>(13)</sup>.

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<sup>(12)</sup> 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](#).

<sup>(13)</sup> The Regulations made under section 2 are [S.I. 1991/499](#). Relevant amending instrument is [S.I. 2002/887](#).