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## STATUTORY INSTRUMENTS

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# 2014 No. 2936

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

### PART 1

#### General

##### Citation and commencement

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

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

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

(4) Paragraph (3) applies to—

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

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

[<sup>F1</sup>(6) These Regulations cease to have effect after [<sup>F2</sup>31st March 2025].]

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##### Textual Amendments

**F1** Reg. 1(6) inserted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, 3

**F2** Words in reg. 1(6) substituted (30.3.2022) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2022 \(S.I. 2022/179\)](#), regs. 1, 3

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## Interpretation

### 2.—(1) In these Regulations—

“16 to 19 Academy” has the same meaning as in section 1B of the Academies Act 2010 <sup>M1</sup>;

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

“the 1983 Act” means the Mental Health Act 1983 <sup>M2</sup>;

“the 2005 Act” means the Mental Capacity Act 2005 <sup>M3</sup>;

“the 2006 Act” means the National Health Service Act 2006 <sup>M4</sup>;

“the 2001 Order” means the [<sup>F3</sup>Health Professions Order 2001];

“the 2010 Regulations” means the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 <sup>M5</sup>;

“employment” means—

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

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

“employment agency” and “employment business” have the same meaning as in section 13 (interpretation) of the Employment Agencies Act 1973 <sup>M6</sup>;

“equipment” includes—

- (a) a medical device (as defined in regulation 2(1) (interpretation) of the Medical Devices Regulations 2002) <sup>M7</sup>, and
  - (b) materials used in, or used by persons employed in, the carrying on of a regulated activity;
- “health care professional”, except in paragraph 4 of Schedule 1, means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999 <sup>M8</sup> (regulation of health professions, social workers, other care workers, etc) applies;

“health service body” means—

- (a) an NHS trust established under section 25 of the 2006 Act,
- (b) an NHS foundation trust, <sup>F4</sup> ...
- (c) a Special Health Authority [<sup>F5</sup>, or
- (d) NHS England;]

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

“institution within the further education sector” has the same meaning as in section 91 (interpretation of Education Acts) of the Further and Higher Education Act 1992 <sup>M9</sup>;

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

“medical practitioner” means a registered medical practitioner;

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

“nurse” means a registered nurse;

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

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

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

“partnership” does not include a limited liability partnership;

“personal care” means—

- (a) physical assistance given to a person in connection with—
  - (i) eating or drinking (including the maintenance of established parenteral nutrition),
  - (ii) toileting (including in relation to the process of menstruation),
  - (iii) washing or bathing,
  - (iv) dressing,
  - (v) oral care, or
  - (vi) the care of skin, hair and nails (with the exception of nail care provided by a person registered with the Health and Care Professions Council as a chiropodist or podiatrist pursuant to article 5 of the 2001 Order), or
- (b) the prompting, together with supervision, of a person, in relation to the performance of any of the activities listed in paragraph (a), where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision;

“premises” means—

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

but in regulations 12, 14 and 15 does not include the service user's accommodation where such accommodation is not provided as part of the service user's care or treatment <sup>F6</sup>...;

<sup>F7</sup> ...

“reasonable adjustments” means such reasonable adjustments as would be required under the Equality Act 2010 <sup>M10</sup>;

“registered manager” means, in respect of a regulated activity, a person registered with the Commission <sup>M11</sup> under Chapter 2 of Part 1 of the Act as a manager in respect of that activity;

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

“relevant person”, except in regulation 20, means the service user or, where the service user is under 16 and not competent to make a decision in relation to their care or treatment, a person lawfully acting on their behalf;

“school” has the same meaning as in section 4 of the Education Act 1996 <sup>M12</sup>;

“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;

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

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

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

- (a) recruiting and training shared lives carers,
- (b) making arrangements for the placing of service users with shared lives carers, and
- (c) supporting and monitoring placements [<sup>F8</sup>, and for the purposes of section 20A of the Act (functions relating to processing of information by registered persons) “adult placement scheme” has the same meaning as “shared lives scheme”]

“social worker” means a person who is registered as such in [<sup>F9</sup>the register of social workers in England maintained under section 39(1) of the Children and Social Work Act 2017];

“treatment”, except in paragraph 5 of Schedule 1, includes—

- (a) a diagnostic or screening procedure carried out for medical purposes,
- (b) the ongoing assessment of a service user's mental or physical state,
- (c) nursing, personal and palliative care, and
- (d) the giving of vaccinations and immunisations;

“vulnerable adult” has the same meaning as in section 60(1) (interpretation) of the Safeguarding Vulnerable Groups Act 2006 <sup>M13</sup>.

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

- (a) under a shared lives agreement;
- (b) under an agreement between the service provider and a temporary work agency for the supply of an agency worker to the service provider;
- (c) under arrangements for persons to provide their services voluntarily.

(3) In paragraph (2)—

“agency worker” and “temporary work agency” have the same meaning as in the Agency Workers Regulations 2010 <sup>M14</sup>.

#### Textual Amendments

- F3** Words in reg. 2(1) substituted (2.12.2019) by [The Children and Social Work Act 2017 \(Consequential Amendments\) \(Social Workers\) Regulations 2019 \(S.I. 2019/1094\)](#), reg. 1, **Sch. 3 para. 34(a)**; [S.I. 2019/1436](#), reg. 2(b)
- F4** Word in reg. 2(1) omitted (1.7.2022) by virtue of [The Health and Care Act 2022 \(Consequential and Related Amendments and Transitional Provisions\) Regulations 2022 \(S.I. 2022/634\)](#), regs. 1(2), **124(2)(a)**
- F5** Words in reg. 2(1) inserted (1.7.2022) by [The Health and Care Act 2022 \(Consequential and Related Amendments and Transitional Provisions\) Regulations 2022 \(S.I. 2022/634\)](#), regs. 1(2), **124(2)(b)**
- F6** Words in reg. 2 omitted (15.3.2022) by virtue of [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(Coronavirus\) \(No. 3\) Regulations 2022 \(S.I. 2022/206\)](#), regs. 1(2), **2(2)(a)**

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- F7** Words in [reg. 2](#) omitted (15.3.2022) by virtue of [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(Coronavirus\) \(No. 3\) Regulations 2022 \(S.I. 2022/206\)](#), regs. 1(2), **2(2)(b)**
- F8** Words in [reg. 2\(1\)](#) inserted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **4**
- F9** Words in [reg. 2\(1\)](#) substituted (2.12.2019) by [The Children and Social Work Act 2017 \(Consequential Amendments\) \(Social Workers\) Regulations 2019 \(S.I. 2019/1094\)](#), reg. 1, **Sch. 3 para. 34(b)**; S.I. 2019/1436, reg. 2(b)

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### Marginal Citations

- M1** [2010 c. 32](#). Section 1B was inserted by section 53(7) of the [Education Act 2011 \(c. 21\)](#).
- M2** [1983 c. 20](#).
- M3** [2005 c. 9](#). Relevant amendments were made by the [Mental Health Act 2007 \(c. 12\)](#), **sections 50** and 55 and Part 10 of Schedule 11.
- M4** [2006 c. 41](#).
- M5** [S.I. 2010/781](#), as amended by [S.I. 2011/2711](#), 2012/921, 2012/979, 2012/1479, 2012/1513, 2013/235 and 2013/472.
- M6** [1973 c. 35](#). Relevant amendments were made by the [Employment Relations Act 1999 \(c. 26\)](#), **section 31** and paragraphs 1 and 7 of Schedule 7.
- M7** [S.I. 2002/618](#). Relevant amendments were made by [S.I. 2008/2986](#).
- M8** [1999 c. 21](#). Relevant amendments were made by the [Health and Social Care Act 2008](#), sections 111 and 116, paragraph 1 of Schedule 8 and Part 2 of Schedule 15, the [Health and Social Care Act 2012](#), sections 209 and 213, and [S.I. 2002/253](#) and 2010/231.
- M9** [1992 c. 13](#). Relevant amendments were made by the [Apprenticeships, Skills, Children and Learning Act 2009 \(c. 22\)](#), **section 125** and paragraphs 1 and 13(1) and (2) of Schedule 8.
- M10** [2010 c. 15](#).
- M11** By section 1(1) of the 2008 Act, “the Commission” means the Care Quality Commission.
- M12** [1996 c. 56](#). Relevant amendments were made by the [Education Act 1997 \(c. 44\)](#), **sections 51** and 57, paragraph 10 of Schedule 7 and Schedule 8, the [Education Act 2002 \(c. 32\)](#), **section 215** and Part 3 of Schedule 22, the [Childcare Act 2006 \(c. 21\)](#), **section 95**, and the [Education Act 2011 \(c. 21\)](#), **section 54** and paragraph 9 of Schedule 13, and [S.I. 2010/1080](#).
- M13** [2006 c. 47](#). Relevant amendments were made by section 65(2) of the [Protection of Freedoms Act 2012 \(c. 9\)](#).
- M14** [S.I. 2010/93](#). Relevant amendments were made by [S.I. 2011/1941](#).

## PART 2

### Regulated Activities

#### Prescribed activities

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

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

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

(4) The activities specified in Schedule 2 are not regulated activities.

## PART 3

### Requirements in relation to Regulated Activities

#### SECTION 1

##### *Requirements relating to persons carrying on or managing a regulated activity*

#### **Requirements where the service provider is an individual or partnership**

- 4.—(1) This regulation applies where a service provider (P) is an individual or a partnership.
- (2) P must not carry on a regulated activity unless P is fit to do so.
- (3) P is not fit to carry on a regulated activity unless P is—
- (a) an individual who carries on the regulated activity, otherwise than in partnership with others, and satisfies the requirements set out in—
    - (i) paragraph (4), and
    - (ii) paragraph (5), or
  - (b) a partnership and—
    - (i) each of the partners satisfies the requirements set out in paragraph (4), and
    - (ii) P satisfies the requirement set out in paragraph (6).
- (4) The requirements referred to in paragraph (3)(a)(i) and (b)(i) are that, if P is an individual, that individual or, if P is a partnership, each of the partners—
- (a) is of good character,
  - (b) is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are—
    - (i) where P is an individual, intrinsic to the carrying on of the regulated activity, or
    - (ii) where P is a partnership, intrinsic to their role in the carrying on of the regulated activity, and
  - (c) is able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.
- (5) The requirement referred to in paragraph (3)(a)(ii) is that P has the necessary qualifications [<sup>F10</sup>, competence], skills and experience to carry on the regulated activity.
- (6) The requirement referred to in paragraph (3)(b)(ii) is that, through the combination of the qualifications [<sup>F11</sup>, competence], skills and experience of the partners, P has the necessary qualifications, skills and experience to carry on the regulated activity.
- [<sup>F12</sup>(7) In assessing an individual's character for the purposes of paragraph (4)(a), the matters considered must include those listed in Part 2 of Schedule 4.]

#### **Textual Amendments**

- F10** Word in reg. 4(5) inserted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **5(a)**
- F11** Word in reg. 4(6) inserted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **5(a)**
- F12** Reg. 4(7) inserted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **5(b)**

## Fit and proper persons: directors

- 5.—<sup>F13</sup>(1) This regulation applies where the service provider is a body other than a partnership.]
- (2) Unless the individual satisfies all the requirements set out in paragraph (3), [<sup>F14</sup>a service provider] must not appoint or have in place an individual—
- (a) as a director of the service provider, or
  - (b) performing the functions of, or functions equivalent or similar to the functions of, <sup>F15</sup>... a director.
- (3) The requirements referred to in paragraph (2) are that—
- (a) the individual is of good character,
  - (b) the individual has the qualifications, competence, skills and experience which are necessary for the relevant office or position or the work for which they are employed,
  - (c) the individual is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the office or position for which they are appointed or to the work for which they are employed,
  - (d) the individual has not been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity or providing a service elsewhere which, if provided in England, would be a regulated activity, and
  - (e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual.
- (4) In assessing an individual's character for the purposes of paragraph (3)(a), the matters considered must include those listed in Part 2 of Schedule 4.
- (5) The following information must be available to be supplied to the Commission in relation to each individual who holds an office or position referred to in paragraph (2)(a) or (b)—
- (a) the information specified in Schedule 3, and
  - (b) such other information as is required to be kept by the service provider under any enactment which is relevant to that individual.
- (6) Where an individual who holds an office or position referred to in paragraph (2)(a) or (b) no longer meets the requirements in paragraph (3), the service provider must—
- (a) take such action as is necessary and proportionate to ensure that the office or position in question is held by an individual who meets such requirements, and
  - (b) if the individual is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question.

### Textual Amendments

- F13** Reg. 5(1) substituted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **6(2)**
- F14** Words in reg. 5(2) substituted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **6(3)(a)**
- F15** Word in reg. 5(2)(b) omitted (1.4.2015) by virtue of [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **6(3)(b)**

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

- 6.—(1) This regulation applies where the service provider is a body other than a partnership.

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(2) The body must give notice to the Commission of the name, address and position in the body of an individual (in these Regulations referred to as “the nominated individual”) who is—

- (a) employed as a director, manager or secretary of the body, and
- (b) responsible for supervising the management of the carrying on of the regulated activity by the body.

(3) The registered person must take all reasonable steps to ensure that the nominated individual—

- (a) is of good character,
- (b) has the necessary qualifications [<sup>F16</sup>, competence], skills and experience to properly supervise the management of the carrying on of the regulated activity,
- (c) is able by reason of their health, after reasonable adjustments are made, of properly doing so, and
- (d) is able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

[<sup>F17</sup>(4) In assessing an individual’s character for the purposes of paragraph (3)(a), the matters considered must include those listed in Part 2 of Schedule 4.]

#### Textual Amendments

**F16** Word in reg. 6(3)(b) inserted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **7(a)**

**F17** Reg. 6(4) inserted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **7(b)**

#### Requirements relating to registered managers

7.—(1) A person (M) shall not manage the carrying on of a regulated activity as a registered manager unless M is fit to do so.

(2) M is not fit to be a registered manager in respect of a regulated activity unless M is—

- (a) of good character,
- (b) has the necessary qualifications [<sup>F18</sup>, competence], skills and experience to manage the carrying on of the regulated activity,
- (c) able by reason of M's health, after reasonable adjustments are made, of doing so, and
- (d) able to supply to the Commission, or arrange for the availability of, the information specified in Schedule 3.

[<sup>F19</sup>(3) In assessing an individual’s character for the purposes of paragraph (2)(a), the matters considered must include those listed in Part 2 of Schedule 4.]

#### Textual Amendments

**F18** Word in reg. 7(2)(b) inserted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **8(a)**

**F19** Reg. 7(3) inserted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **8(b)**



## SECTION 2

### Fundamental Standards

#### General

**8.—**(1) A registered person must comply with regulations [F209 to 20A] in carrying on a regulated activity.

(2) But paragraph (1) does not require a person to do something to the extent that what is required to be done to comply with regulations [F209 to 20A] has already been done by another person who is a registered person in relation to the regulated activity concerned.

(3) For the purposes of determining under regulations [F209 to 20A] whether a service user who is 16 or over lacks capacity, sections 2 and 3 of the 2005 Act (people who lack capacity) apply as they apply for the purposes of that Act.

#### Textual Amendments

**F20** Words in [reg. 8](#) substituted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), [regs. 1, 9](#)

#### Person-centred care

**9.—**(1) The care and treatment of service users must—

- (a) be appropriate,
- (b) meet their needs, and
- (c) reflect their preferences.

(2) But paragraph (1) does not apply to the extent that the provision of care or treatment would result in a breach of regulation 11.

(3) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—

- (a) carrying out, collaboratively with the relevant person, an assessment of the needs and preferences for care and treatment of the service user;
- (b) designing care or treatment with a view to achieving service users' preferences and ensuring their needs are met;
- (c) enabling and supporting relevant persons to understand the care or treatment choices available to the service user and to discuss, with a competent health care professional or other competent person, the balance of risks and benefits involved in any particular course of treatment;
- (d) enabling and supporting relevant persons to make, or participate in making, decisions relating to the service user's care or treatment to the maximum extent possible;
- (e) providing opportunities for relevant persons to manage the service user's care or treatment;
- (f) involving relevant persons in decisions relating to the way in which the regulated activity is carried on in so far as it relates to the service user's care or treatment;
- (g) providing relevant persons with the information they would reasonably need for the purposes of sub-paragraphs (c) to (f);
- (h) making reasonable adjustments to enable the service user to receive their care or treatment;

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- (i) where meeting a service user's nutritional and hydration needs, having regard to the service user's well-being.
- (4) Paragraphs (1) and (3) apply subject to paragraphs (5) and (6).
- (5) If the service user is 16 or over and lacks capacity in relation to a matter to which this regulation applies, paragraphs (1) to (3) are subject to any duty on the registered person under the 2005 Act in relation to that matter.
- (6) But if Part 4 or 4A of the 1983 Act applies to a service user, care and treatment must be provided in accordance with the provisions of that Act.

### **[F21] Visiting and accompanying in care homes, hospitals and hospices**

**9A.**—(1) This regulation applies to a registered person in respect of a relevant regulated activity carried on in a care home, hospital or hospice.

- (2) Unless there are exceptional circumstances, service users—
  - (a) whose care or treatment involves an overnight stay or the provision of accommodation in a care home, hospital or hospice, must be facilitated to receive visits at those premises;
  - (b) who are provided with accommodation in a care home, must not be discouraged from taking visits out of that care home;
  - (c) who attend a hospital or hospice for the provision of care or treatment which does not involve an overnight stay, must be enabled to be accompanied at those premises by a family member, friend or a person who is otherwise providing support to the service user.
- (3) Without limiting paragraph (2), the things which a registered person must do to comply with that paragraph include—
  - (a) in relation to paragraph (2)(a), securing that service users are facilitated to receive visits in a way that is appropriate, meets the service user's needs and, so far as reasonably practicable, reflects their preferences;
  - (b) in relation to paragraph (2)(a) and (c), taking such action, or putting in place such precautions, as is necessary and proportionate to ensure that service users may receive visits or be accompanied safely;
  - (c) securing that, when making arrangements or decisions in respect of a service user for the purposes of paragraph (2), regard is given to any care or treatment plan for the service user;
  - (d) involving relevant persons when making any arrangements or decisions in respect of a service user for the purposes of paragraph (2).
- (4) Nothing in this regulation—
  - (a) requires a service user to receive a visit, take a visit out of a care home or be accompanied—
    - (i) without the relevant person's consent, or
    - (ii) where the service user lacks the capacity to give consent, where it would not be in the service user's best interests;
  - (b) requires or enables a registered person to do anything which would not be in accordance with any court or tribunal order or with any provision (including any direction, power or authorisation) contained in, or made by virtue of, any of the legislation listed in paragraph (5) (including by virtue of any instrument made under that legislation).
- (5) The legislation referred to in paragraph (4)(b) is—
  - (a) the 1983 Act;
  - (b) the 2005 Act;
  - (c) so far as relating to high security psychiatric services, the 2006 Act.

- (a) (6) (a) In this regulation—
- “care home” has the meaning given in section 3 (care homes in England) of the Care Standards Act 2000;
- “hospice” means an establishment other than a hospital whose primary function is the provision of palliative care to persons who attend or are resident there who are suffering from a progressive disease in its final stages;
- “relevant regulated activity” means an activity prescribed in regulation 3 as a regulated activity for the purposes of section 8(1) of the Act, except it does not include—
- (i) the regulated activities in paragraphs 1, 3, 8 and 9 of Schedule 1,
  - (ii) any detoxification services for substance misuse provided in the course of carrying on a regulated activity,
  - (iii) any services provided to a service user (other than a service user who is in receipt of services provided in the carrying on of the regulated activity in paragraph 5 of Schedule 1) who—
    - (aa) is, or is required to be, detained in a prison or other institution to which the Prison Act 1952 applies,
    - (bb) is detained under the Immigration Acts,
    - (cc) is required to be detained in a prison or other institution to which equivalent legislation to that referred to in sub-paragraph (aa) applies in Scotland and Northern Ireland;
- “visit” (except in the context of the taking of a visit out of a care home), means a visit from—
- (i) a family member of the service user,
  - (ii) a friend of the service user,
  - (iii) a person visiting to provide support or companionship to the service user;
- (b) in the definition of ‘relevant regulated activity’ in sub-paragraph (a), “prison” has the same meaning as in section 53(1) of the Prison Act 1952;
- (c) a reference to having or lacking capacity, or to a person’s best interests, in this regulation is to be interpreted in accordance with the 2005 Act.]

#### **Textual Amendments**

**F21** [Reg. 9A](#) inserted (6.4.2024) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2023 \(S.I. 2023/1402\)](#), regs. 1(1), **2(2)**

### **Dignity and respect**

- 10.**—(1) Service users must be treated with dignity and respect.
- (2) Without limiting paragraph (1), the things which a registered person is required to do to comply with paragraph (1) include in particular—
- (a) ensuring the privacy of the service user;
  - (b) supporting the autonomy, independence and involvement in the community of the service user;
  - (c) having due regard to any relevant protected characteristics (as defined in section 149(7) of the Equality Act 2010) of the service user.

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**Need for consent**

11.—(1) Care and treatment of service users must only be provided with the consent of the relevant person.

(2) Paragraph (1) is subject to paragraphs (3) and (4).

(3) If the service user is 16 or over and is unable to give such consent because they lack capacity to do so, the registered person must act in accordance with the 2005 Act.

(4) But if Part 4 or 4A of the 1983 Act applies to a service user, the registered person must act in accordance with the provisions of that Act.

(5) Nothing in this regulation affects the operation of section 5 of the 2005 Act, as read with section 6 of that Act (acts in connection with care or treatment).

**Safe care and treatment**

12.—(1) Care and treatment must be provided in a safe way for service users.

(2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include—

- (a) assessing the risks to the health and safety of service users of receiving the care or treatment;
- (b) doing all that is reasonably practicable to mitigate any such risks;
- (c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely;
- (d) ensuring that the premises used by the service provider are safe to use for their intended purpose and are used in a safe way;
- (e) ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way;
- (f) where equipment or medicines are supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and to meet their needs;
- (g) the proper and safe management of medicines;
- (h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated;
- (i) where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning takes place to ensure the health, safety and welfare of the service users.

F22(3) .....

F22(3A) .....

F22(3B) .....

F22(3C) .....

F22(3D) .....

F22(4) .....

F22(5) .....

F22(5A) .....

F22(6) .....

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**Changes to legislation:** The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is up to date with all changes known to be in force on or before 19 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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### Textual Amendments

**F22** Reg. 12(3)-(6) omitted (15.3.2022) by virtue of The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 3) Regulations 2022 (S.I. 2022/206), regs. 1(2), **2(3)**

## Safeguarding service users from abuse and improper treatment

**13.**—(1) Service users must be protected from abuse and improper treatment in accordance with this regulation.

(2) Systems and processes must be established and operated effectively to prevent abuse of service users.

(3) Systems and processes must be established and operated effectively to investigate, immediately upon becoming aware of, any allegation or evidence of such abuse.

(4) Care or treatment for service users must not be provided in a way that—

(a) includes discrimination against a service user on grounds of any protected characteristic (as defined in section 4 of the Equality Act 2010) of the service user,

(b) includes acts intended to control or restrain a service user that are not necessary to prevent, or not a proportionate response to, a risk of harm posed to the service user or another individual if the service user was not subject to control or restraint,

(c) is degrading for the service user, or

(d) significantly disregards the needs of the service user for care or treatment.

(5) A service user must not be deprived of their liberty for the purpose of receiving care or treatment without lawful authority.

(6) For the purposes of this regulation—  
“abuse” means—

(a) any behaviour towards a service user that is an offence under the Sexual Offences Act 2003 <sup>M15</sup>,

(b) ill-treatment (whether of a physical or psychological nature) of a service user,

(c) theft, misuse or misappropriation of money or property belonging to a service user, or

(d) neglect of a service user.

(7) For the purposes of this regulation, a person controls or restrains a service user if that person—

(a) uses, or threatens to use, force to secure the doing of an act which the service user resists, or

(b) restricts the service user's liberty of movement, whether or not the service user resists,

including by use of physical, mechanical or chemical means.

### Marginal Citations

**M15** 2003 c. 42.

## Meeting nutritional and hydration needs

**14.**—(1) The nutritional and hydration needs of service users must be met.

(2) Paragraph (1) applies where—

(a) care or treatment involves—

(i) the provision of accommodation by the service provider, or

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- (ii) an overnight stay for the service user on premises used by the service for the purposes of carrying on a regulated activity, or
  - (b) the meeting of the nutritional or hydration needs of service users is part of the arrangements made for the provision of care or treatment by the service provider.
- (3) But paragraph (1) does not apply to the extent that the meeting of such nutritional or hydration needs would—
- (a) result in a breach of regulation 11, or
  - (b) not be in the service user's best interests.
- (4) For the purposes of paragraph (1), “nutritional and hydration needs” means—
- (a) receipt by a service user of suitable and nutritious food and hydration which is adequate to sustain life and good health,
  - (b) receipt by a service user of parenteral nutrition and dietary supplements when prescribed by a health care professional,
  - (c) the meeting of any reasonable requirements of a service user for food and hydration arising from the service user's preferences or their religious or cultural background, and
  - (d) if necessary, support for a service user to eat or drink.
- (5) Section 4 of the 2005 Act (best interests) applies for the purposes of determining the best interests of a service user who is 16 or over under this regulation as it applies for the purposes of that Act.

### **Premises and equipment**

- 15.**—(1) All premises and equipment used by the service provider must be—
- (a) clean,
  - (b) secure,
  - (c) suitable for the purpose for which they are being used,
  - (d) properly used
  - (e) properly maintained, and
  - (f) appropriately located for the purpose for which they are being used.
- (2) The registered person must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used.
- (3) For the purposes of paragraph (1)(b), (c), (e) and (f), “equipment” does not include equipment at the service user's accommodation if—
- (a) such accommodation is not provided as part of the service user's care or treatment, and
  - (b) such equipment is not supplied by the service provider.

### **Receiving and acting on complaints**

- 16.**—(1) Any complaint received must be investigated and necessary and proportionate action must be taken in response to any failure identified by the complaint or investigation.
- (2) The registered person must establish and operate effectively an accessible system for identifying, receiving, recording, handling and responding to complaints by service users and other persons in relation to the carrying on of the regulated activity.
- (3) The registered person must provide to the Commission, when requested to do so and by no later than 28 days beginning on the day after receipt of the request, a summary of—

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- (a) complaints made under such complaints system,
- (b) responses made by the registered person to such complaints and any further correspondence with the complainants in relation to such complaints, and
- (c) any other relevant information in relation to such complaints as the Commission may request.

### Good governance

17.—(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.

(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—

- (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);
- (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;
- (c) maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided;
- (d) maintain securely such other records as are necessary to be kept in relation to—
  - (i) persons employed in the carrying on of the regulated [<sup>F23</sup>activity,][<sup>F24</sup>and]
  - (ii) the management of the regulated [<sup>F25</sup>activity, <sup>F26</sup>...]
  - <sup>F27</sup>(iii) .....
- (e) seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services;
- (f) evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).

(3) The registered person must send to the Commission, when requested to do so and by no later than 28 days beginning on the day after receipt of the request—

- (a) a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (2)(a) and (b) are being complied with, and
- (b) any plans that the registered person has for improving the standard of the services provided to service users with a view to ensuring their health and welfare.

#### Textual Amendments

**F23** Word in reg. 17(2)(d)(i) substituted (11.11.2021) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(Coronavirus\) Regulations 2021 \(S.I. 2021/891\)](#), regs. 1, **6(a)**

**F24** Word in reg. 17(2)(d)(i) inserted (15.3.2022) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(Coronavirus\) \(No. 3\) Regulations 2022 \(S.I. 2022/206\)](#), regs. 1(2), **2(4)(a)**

**F25** Words in reg. 17(2)(d)(ii) substituted (11.11.2021) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(Coronavirus\) Regulations 2021 \(S.I. 2021/891\)](#), regs. 1, **6(b)**

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- F26** Word in reg. 17(2)(d)(ii) omitted (15.3.2022) by virtue of [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(Coronavirus\) \(No. 3\) Regulations 2022 \(S.I. 2022/206\)](#), regs. 1(2), **2(4)(b)**
- F27** Reg. 17(2)(d)(iii) omitted (15.3.2022) by virtue of [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(Coronavirus\) \(No. 3\) Regulations 2022 \(S.I. 2022/206\)](#), regs. 1(2), **2(4)(c)**

## Staffing

**18.**—(1) Sufficient numbers of suitably qualified, competent, skilled and experienced persons must be deployed in order to meet the requirements of this Part.

- (2) Persons employed by the service provider in the provision of a regulated activity must—
- (a) receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform,
  - (b) be enabled where appropriate to obtain further qualifications appropriate to the work they perform, and
  - (c) where such persons are health care professionals, social workers or other professionals registered with a health care or social care regulator, be enabled to provide evidence to the regulator in question demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise or a requirement of their role.

## Fit and proper persons employed

- 19.**—(1) Persons employed for the purposes of carrying on a regulated activity must—
- (a) be of good character,
  - (b) have the qualifications, competence, skills and experience which are necessary for the work to be performed by them, and
  - (c) be able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the work for which they are employed.
- (2) Recruitment procedures must be established and operated effectively to ensure that persons employed meet the conditions in—
- (a) paragraph (1), or
  - (b) in a case to which regulation 5 applies, paragraph (3) of that regulation.
- (3) [<sup>F28</sup>Subject to paragraph (3A), the] following information must be available in relation to each such person employed—
- (a) the information specified in Schedule 3, and
  - (b) such other information as is required under any enactment to be kept by the registered person in relation to such persons employed.
- [<sup>F29</sup>(3A) Unless regulation 4, 6 or 7 applies, where the person so employed is a volunteer, paragraph (3) does not require the information specified in paragraph 7 of Schedule 3 to be made available.]
- (4) Persons employed must be registered with the relevant professional body where such registration is required by, or under, any enactment in relation to—
- (a) the work that the person is to perform, or
  - (b) the title that the person takes or uses.



(5) Where a person employed by the registered person no longer meets the criteria in paragraph (1), the registered person must—

- (a) take such action as is necessary and proportionate to ensure that the requirement in that paragraph is complied with, and
- (b) if the person is a health care professional, social worker or other professional registered with a health care or social care regulator, inform the regulator in question.

(6) Paragraphs (1) and (3) of this regulation do not apply in a case to which regulation 5 applies.

[<sup>F30</sup>(7) For the purposes of this regulation, a “volunteer” is a person employed under arrangements to provide their services voluntarily as referred to in regulation 2(2)(c).]

#### Textual Amendments

- F28** Words in [reg. 19\(3\)](#) substituted (15.1.2024) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(No. 2\) Regulations 2023 \(S.I. 2023/1404\)](#), regs. 1(1), **2(2)(a)**
- F29** [Reg. 19\(3A\)](#) inserted (15.1.2024) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(No. 2\) Regulations 2023 \(S.I. 2023/1404\)](#), regs. 1(1), **2(2)(b)**
- F30** [Reg. 19\(7\)](#) inserted (15.1.2024) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) \(No. 2\) Regulations 2023 \(S.I. 2023/1404\)](#), regs. 1(1), **2(2)(c)**

#### Duty of candour

**20.**—(1) [<sup>F31</sup>Registered persons] must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a [<sup>F32</sup>registered person] must—

- (a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and
- (b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

(3) The notification to be given under paragraph (2)(a) must—

- (a) be given in person by one or more representatives of the [<sup>F33</sup>registered person],
- (b) provide an account, which to the best of the [<sup>F34</sup>registered person’s] knowledge is true, of all the facts the [<sup>F34</sup>registered person] knows about the incident as at the date of the notification,
- (c) advise the relevant person what further enquiries into the incident the [<sup>F35</sup>registered person] believes are appropriate,
- (d) include an apology, and
- (e) be recorded in a written record which is kept securely by the [<sup>F36</sup>registered person].

(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—

- (a) the information provided under paragraph (3)(b),
- (b) details of any enquiries to be undertaken in accordance with paragraph (3)(c),
- (c) the results of any further enquiries into the incident, and
- (d) an apology.

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(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the [<sup>F37</sup>registered person]—

- (a) paragraphs (2) to (4) are not to apply, and
- (b) a written record is to be kept of attempts to contact or to speak to the relevant person.

(6) The [<sup>F38</sup>registered person] must keep a copy of all correspondence with the relevant person under paragraph (4).

(7) In this regulation—

“apology” means an expression of sorrow or regret in respect of a notifiable safety incident;

“moderate harm” means—

- (a) harm that requires a moderate increase in treatment, and
- (b) significant, but not permanent, harm;

“moderate increase in treatment” means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

[<sup>F39</sup>“notifiable safety incident” has the meaning given in paragraphs (8) and (9);]

[<sup>F40</sup>“prolonged pain” means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;]

“prolonged psychological harm” means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

“relevant person” means the service user or, in the following circumstances, a person lawfully acting on their behalf—

- (a) on the death of the service user,
- (b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
- (c) where the service user is 16 or over and lacks capacity<sup>F41</sup> ... in relation to the matter;

“severe harm” means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

[<sup>F42</sup>(8) In relation to a health service body, “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

- (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
- (b) severe harm, moderate harm or prolonged psychological harm to the service user.

(9) In relation to any other registered person, “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional—

- (a) appears to have resulted in—
  - (i) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition,
  - (ii) an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,

- (iii) changes to the structure of the service user’s body,
  - (iv) the service user experiencing prolonged pain or prolonged psychological harm, or
  - (v) the shortening of the life expectancy of the service user; or
- (b) requires treatment by a health care professional in order to prevent—
- (i) the death of the service user, or
  - (ii) any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).]

#### Textual Amendments

- F31** Words in reg. 20(1) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(2)**
- F32** Words in reg. 20(2) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(3)(a)**
- F33** Words in reg. 20(3)(a) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(3)(b)**
- F34** Words in reg. 20(3)(b) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(3)(b)**
- F35** Words in reg. 20(3)(c) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(3)(b)**
- F36** Words in reg. 20(3)(e) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(3)(b)**
- F37** Words in reg. 20(5) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(3)(c)**
- F38** Words in reg. 20(6) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(3)(d)**
- F39** Words in reg. 20(7) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(4)(a)**
- F40** Words in reg. 20(7) inserted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(4)(b)**
- F41** Words in reg. 20(7) omitted (1.4.2015) by virtue of The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(4)(c)**
- F42** Reg. 20(8)(9) inserted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **10(5)**

#### [<sup>F43</sup>Requirement as to display of performance assessments

**20A.—**(1) This regulation applies where, and to the extent that, a service provider has received a rating of its performance by the Commission following an assessment of its performance under section 46(1) of the Act (reviews and performance assessments).

- (2) There must be shown on every website maintained by or on behalf of any service provider—
- (a) the Commission’s website address,
  - (b) the place on the Commission’s website where the most recent assessment of the service provider’s overall performance and of its performance in relation to particular premises or activities may be accessed, and
  - (c) the most recent rating by the Commission of the service provider’s overall performance and of its performance in relation to particular premises or activities, in a way which makes it clear to which activities or premises a particular rating relates.

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(3) There must be displayed at each premises from which the service provider provides regulated activities at least one sign showing the most recent rating by the Commission that relates to the service provider's performance at those premises.

(4) For the purposes of paragraph (3), where the service provider has not received a rating of its performance at those premises, the rating to be shown is the rating of the service provider's overall performance.

(5) There must be displayed at the service provider's principal place of business at least one sign showing the most recent rating of—

- (a) the service provider's overall performance, and
- (b) its performance in relation to particular premises or activities, in a way which makes it clear to which activities or premises a particular rating relates.

(6) But paragraph (5) does not apply where the service provider's performance at its principal place of business, or at the premises of which it is part, is itself subject to a separate performance rating given by the Commission (in which case paragraphs (3) and (4) apply).

(7) Any sign displayed, or anything shown on a website, under this regulation must—

- (a) be legible,
- (b) be displayed conspicuously in a place which is accessible to service users, and
- (c) for each rating shown, show the date on which it was given by the Commission.

(8) This regulation does not apply to any premises that are—

- (a) the service provider's own home, except where service users have access to it for the purposes of receiving services provided in the carrying on of a regulated activity, or
- (b) a service user's accommodation where such accommodation is not provided as part of the service user's care or treatment.]

#### **Textual Amendments**

**F43** Reg. 20A inserted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **11**

## **PART 4**

### **Compliance and Offences**

#### **Guidance and Code**

**21.** For the purposes of compliance with the requirements set out in these Regulations, the registered person must have regard to—

- (a) guidance issued by the Commission under section 23 of the Act in relation to the requirements set out in Part 3 (with the exception of regulation 12 in so far as it applies to health care associated infections); and
- (b) in relation to regulation 12, in so far as it applies to health care associated infections, any code of practice issued by the Secretary of State under section 21 of the Act in relation to the prevention or control of health care associated infections.

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**Offences**

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

- (a) regulation 11,
- (b) regulation 16(3), <sup>F44</sup>...
- (c) regulation 17(3).
- <sup>F45</sup>(d) regulation 20(2)(a) and (3), or
- (e) regulation 20A.]

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

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

<sup>F46</sup>(3) .....

(4) But it is a defence for a registered person <sup>F47</sup>... to prove that they took all reasonable steps and exercised all due diligence to prevent the breach of any of those regulations that has occurred.

**Textual Amendments**

**F44** Word in reg. 22(1)(b) omitted (1.4.2015) by virtue of The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **12(2)(a)**

**F45** Reg. 22(1)(d)(e) inserted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **12(2)(b)**

**F46** Reg. 22(3) omitted (1.4.2015) by virtue of The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **12(3)**

**F47** Words in reg. 22(4) omitted (1.4.2015) by virtue of The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **12(4)**

**Offences: penalties**

23.—<sup>F48</sup>(1) .....

<sup>F48</sup>(2) .....

<sup>F48</sup>(3) .....

(4) A person guilty of an offence under regulation 22(1) for breach of regulation 11 or an offence under regulation 22(2) is liable on summary conviction to [<sup>F49</sup>a fine] .

(5) A person guilty of an offence under regulation 22(1) for breach of regulation [<sup>F50</sup>16(3), 17(3) or 20(2)(a) and (3)] is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale.

[<sup>F51</sup>(5A) A person guilty of an offence under regulation 22(1) for breach of regulation 20A is liable, on summary conviction, to a fine not exceeding level 2 on the standard scale.]

<sup>F52</sup>(6) .....

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### Textual Amendments

- F48** Reg. 23(1)(2)(3) omitted (12.3.2015) by virtue of The Legal Aid, Sentencing and Punishment of Offenders Act 2012 (Fines on Summary Conviction) Regulations 2015 (S.I. 2015/664), reg. 1(1), **Sch. 4 para. 85(2)** (with reg. 5(1))
- F49** Words in reg. 23(4) substituted (12.3.2015) by The Legal Aid, Sentencing and Punishment of Offenders Act 2012 (Fines on Summary Conviction) Regulations 2015 (S.I. 2015/664), reg. 1(1), **Sch. 4 para. 85(3)** (with reg. 5(1))
- F50** Words in reg. 23(5) substituted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **13(2)**
- F51** Reg. 23(5A) inserted (1.4.2015) by The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **13(3)**
- F52** Reg. 23(6) omitted (1.4.2015) by virtue of The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (S.I. 2015/64), regs. 1, **13(4)**

## PART 5

### Penalty Notices

#### Penalty notices

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

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

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

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

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

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

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

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

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

(10) A penalty notice must state—

- (a) the name and address of the person to whom the notice is given,
- (b) the amount of the penalty,
- (c) the period during which proceedings will not be taken for the offence,

- (d) that payment within that period will discharge any liability for the offence,
  - (e) the consequences of the penalty not being paid before the expiration of the period for paying it,
  - (f) the person to whom and the address at which the penalty may be paid and to which any correspondence about the penalty may be sent, and
  - (g) the means by which payment of the penalty may be made.
- (11) The Commission may withdraw a penalty notice by giving written notice of the withdrawal to the person to whom the notice was given if—
- (a) the Commission determines that it ought not to have been given or it ought not to have been given to the person to whom it was addressed, or
  - (b) it appears to the Commission that the notice contains material errors.
- (12) A penalty notice may be withdrawn in accordance with paragraph (11) whether or not the period for payment referred to in paragraph (3) has expired, and whether or not the penalty has been paid.
- (13) Where a penalty notice has been withdrawn in accordance with paragraph (11), the Commission must—
- (a) repay any amount paid by way of penalty in pursuance of that notice to the person who paid it, within 14 days beginning with the day on which written notice of the withdrawal was given, and
  - (b) remove from publication any information about the payment of the penalty which has been published in accordance with regulations made under section 89 of the Act, within 7 days beginning with the day on which written notice of the withdrawal was given.
- (14) Except as provided in paragraph (15), no proceedings may be instituted or continued against the person to whom a penalty notice was given for the offence to which the penalty notice relates where that notice has been withdrawn in accordance with paragraph (11).
- (15) Where a penalty notice has been withdrawn under paragraph (11)(b), proceedings may be instituted or continued for the offence in connection with which that penalty notice was issued if a further penalty notice in respect of the offence has been given and the penalty has not been paid before the expiration of the period for payment referred to in paragraph (3).
- (16) In this regulation—
- “debit card” means a card the use of which by its holder to make a payment results in a current account of the holder at a bank, or at any other institution providing banking services, being debited with the payment;
- “credit card” means a card which is a credit-token within the meaning of section 14 of the Consumer Credit Act 1974 <sup>M16</sup>;
- “electronic communication” has the same meaning as in the Electronic Communications Act 2000 <sup>M17</sup>;
- “working day” means any day other than—
- (a) a Saturday or Sunday,
  - (b) Christmas Day or Good Friday, or
  - (c) a day which is a bank holiday in England and Wales under the Banking and Financial Dealings Act 1971 <sup>M18</sup>.

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### Marginal Citations

- M16** 1974 c. 39.  
**M17** 2000 c. 7. See section 15(1) (general interpretation), as amended by the [Communications Act 2003](#) (c. 21), [section 406\(1\)](#) and paragraph 158 of Schedule 17.  
**M18** 1971 c. 80. See section 1 and paragraph 1 of Schedule 1.

## PART 6

### Miscellaneous

#### Revocations

**25.**—<sup>[F53]</sup>(1) The following are revoked—

- (a) the 2010 Regulations,
- (b) the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2011 <sup>M19</sup>,
- (c) regulation 11 of the Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 <sup>M20</sup>, and
- (d) the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 <sup>M21</sup>.

<sup>[F54]</sup>(2) Despite the revocation in paragraph (1)(a), the definitions of “nursing care” and “personal care” in regulation 2 of the 2010 Regulations (interpretation) are to continue to have effect so far as necessary for the purposes of section 73 of the Care Act 2014 (Human Rights Act 1998: provision of regulated care or support etc a public function).]

### Textual Amendments

- F53** Reg. 25 renumbered as reg. 25(1) (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015](#) (S.I. 2015/64), regs. 1, [14\(2\)](#)  
**F54** Reg. 25(2) inserted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015](#) (S.I. 2015/64), regs. 1, [14\(3\)](#)

### Marginal Citations

- M19** S.I. 2011/2711.  
**M20** S.I. 2012/921.  
**M21** S.I. 2012/1513.

#### Transitional and transitory provision

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

- (a) was the subject of a warning notice given by the Commission in accordance with regulation 27(2)(a) of the 2010 Regulations (offences), and



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- (b) occurred during the period ending with the time specified in that notice within which the registered person must take action to secure compliance in accordance with section 29(2)(c)(ii) of the Act.

F55(2) .....

**Textual Amendments**

**F55** Reg. 26(2) omitted (1.4.2015) by virtue of [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **15**

**Review**

- 27.—(1) Before [<sup>F56</sup>1st April 2020], the Secretary of State must—
- (a) carry out a review of these Regulations,
  - (b) set out the conclusions of the review in a report, and
  - (c) publish the report.
- (2) The report must in particular—
- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations,
  - (b) assess the extent to which those objectives are achieved, and
  - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

F57(3) .....

F57(4) .....

**Textual Amendments**

**F56** Words in [reg. 27\(1\)](#) substituted (1.4.2015) by [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **16(2)**

**F57** [Reg. 27\(3\)\(4\)](#) omitted (1.4.2015) by virtue of [The Health and Social Care Act 2008 \(Regulated Activities\) \(Amendment\) Regulations 2015 \(S.I. 2015/64\)](#), regs. 1, **16(3)**

Signed by the authority of the Secretary of State for Health.

Department of Health

*Norman Lamb*  
Minister of State,

**Changes to legislation:**

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**Changes and effects yet to be applied to :**

- Sch. 1 para. 4(4)(a) word omitted by [S.I. 2024/374 Sch. 5 para. 23\(a\)\(i\)](#)
- reg. 12(4) words substituted by [S.I. 2022/15 reg. 4\(3\)](#) (This amendment not applied to Legislation.gov.uk - amending S.I. 2022/15 revoked on 15.3.2022 by S.I. 2022/206, reg. 3)
- reg. 12(6) words omitted by [S.I. 2022/15 reg. 4\(4\)\(c\)](#) (This amendment not applied to Legislation.gov.uk - amending S.I. 2022/15 revoked on 15.3.2022 by S.I. 2022/206, reg. 3)
- reg. 12(6) words substituted by [S.I. 2022/15 reg. 4\(4\)\(a\)](#) (This amendment not applied to Legislation.gov.uk - amending S.I. 2022/15 revoked on 15.3.2022 by S.I. 2022/206, reg. 3)
- reg. 12(6) words substituted by [S.I. 2022/15 reg. 4\(4\)\(b\)](#) (This amendment not applied to Legislation.gov.uk - amending S.I. 2022/15 revoked on 15.3.2022 by S.I. 2022/206, reg. 3)

**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 1 para. 4(4)(a)(xv) and word inserted by [S.I. 2024/374 Sch. 5 para. 23\(a\)\(ii\)](#)
- Sch. 1 para. 4(4)(g) inserted by [S.I. 2024/374 Sch. 5 para. 23\(b\)](#)
- Sch. 4A inserted by [S.I. 2022/15 reg. 4\(5\)](#) (This amendment not applied to Legislation.gov.uk - amending S.I. 2022/15 revoked on 15.3.2022 by S.I. 2022/206, reg. 3)
- reg. 12(3)-(3K) substituted for reg. 12(3)-(3D) by [S.I. 2022/15 reg. 4\(2\)](#) (This amendment not applied to Legislation.gov.uk - amending S.I. 2022/15 revoked on 15.3.2022 by S.I. 2022/206, reg. 3)