
STATUTORY INSTRUMENTS

2015 No. 64

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

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

Made - - - - 26th January 2015
Laid before Parliament 28th January 2015
Coming into force - - 1st April 2015

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

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

Citation and commencement

1. These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 and come into force on 1st April 2015.

Amendment of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

2. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014(2) are amended as follows.

Amendment of regulation 1

3. In regulation 1 (citation and commencement), after paragraph (5) insert—
“(6) These Regulations cease to have effect after 31st March 2022.”

(1) [2008 c. 14](#). See section 97(1) of the Health and Social Care Act 2008 (“the 2008 Act”) for the definitions of “prescribed” and “regulations”. Section 20 of the 2008 Act was amended by sections 81 and 95 of the Care Act [2014 \(c. 23\)](#). Section 161(3) of the 2008 Act was amended by section 294(4) of the Health and Social Care Act [2012 \(c. 7\)](#).
(2) [S.I. 2014/2936](#).

Amendment of regulation 2

4. In regulation 2(1) (interpretation), at the end of the definition of “shared lives scheme” insert “, 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””.

Amendment of regulation 4

5. In regulation 4 (requirements where the service provider is an individual or partnership)—
- (a) after “qualifications”, where it appears in both paragraphs (5) and (6), insert “, competence”, and
 - (b) after paragraph (6) insert—

“(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.”

Amendment of regulation 5

- 6.—(1) Regulation 5 (fit and proper persons: directors) is amended as follows.
- (2) For paragraph (1) substitute—

“(1) This regulation applies where the service provider is a body other than a partnership.”
 - (3) In paragraph (2)—
 - (a) for “the service provider”, in the first place it appears, substitute “a service provider”, and
 - (b) in sub-paragraph (b), omit “such”.

Amendment of regulation 6

7. In regulation 6 (requirement where the service provider is a body other than a partnership)—
- (a) in paragraph (3)(b), after “qualifications” insert “, competence”, and
 - (b) after paragraph (3) insert—

“(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.”

Amendment of regulation 7

8. In regulation 7 (requirements relating to registered managers)—
- (a) in paragraph (2)(b), after “qualifications” insert “, competence”, and
 - (b) after paragraph (2) insert—

“(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.”

Amendment of regulation 8

9. In regulation 8 (fundamental standards: general), for “9 to 19”, in each place it appears, substitute “9 to 20A”.

Amendment of regulation 20

- 10.—(1) Regulation 20 (duty of candour) is amended as follows.

(2) In paragraph (1), for “A health service body” substitute “Registered persons”.

(3) In the following provisions, for “health service body” and “health service body’s” substitute “registered person” and “registered person’s” respectively—

- (a) paragraph (2),
- (b) paragraph (3)(a), (b), (c) and (e),
- (c) paragraph (5), and
- (d) paragraph (6).

(4) In paragraph (7)—

(a) for the definition of “notifiable safety incident” substitute—

““notifiable safety incident” has the meaning given in paragraphs (8) and (9);”,

(b) after that definition insert—

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

(c) in sub-paragraph (c) of the definition of “relevant person” omit “(as determined in accordance with sections 2 and 3 of the 2005 Act)”.

(5) After paragraph (7) insert—

“(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).”

Requirement as to display of performance assessments

11. After regulation 20 insert—

“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)(3).

(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.

(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.”

(3) Section 46 of the 2008 Act was substituted by section 91(2) of the Care Act 2014.

Amendment of regulation 22

- 12.**—(1) Regulation 22 (offences) is amended as follows.
- (2) In paragraph (1)—
- (a) omit the “or” at the end of sub-paragraph (b), and
- (b) at the end of paragraph (c) insert—
- “(d) “(d) regulation 20(2)(a) and (3), or
- (e) regulation 20A.”
- (3) Omit paragraph (3).
- (4) In paragraph (4), omit “, or (in the case of regulation 20(2)(a) and (3)) a health service body,”.

Amendment of regulation 23

- 13.**—(1) Regulation 23 (offences: penalties) is amended as follows.
- (2) In paragraph (5), for “16(3) or 17(3)” substitute “16(3), 17(3) or 20(2)(a) and (3)”.
- (3) After paragraph (5) insert—
- “(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.”
- (4) Omit paragraph (6).

Amendment of regulation 25

- 14.**—(1) Regulation 25 (revocations) is amended as follows.
- (2) The existing provision is to become paragraph (1).
- (3) After that paragraph insert—
- “(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(4) (Human Rights Act 1998: provision of regulated care or support etc a public function).”

Amendment of regulation 26

- 15.** Omit paragraph (2) of regulation 26 (transitional and transitory provision).

Amendment of regulation 27

- 16.**—(1) Regulation 27 (review) is amended as follows.
- (2) In paragraph (1), for “the end of each review period” substitute “1st April 2020”.
- (3) Omit paragraphs (3) and (4).

Amendment of Schedule 5

- 17.**—(1) Schedule 5 (fixed penalty offences) is amended as follows.
- (2) In the first column of the table, for “Regulation 22(3) of these Regulations” substitute “Regulation 22(1)(d) of these Regulations”.
- (3) After that row insert—

(4) 2014 c. 23.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

“Regulation 22(1)(e) of these Regulations Contravention of, or failure to comply with, requirements in regulation 20A”

Signed by authority of the Secretary of State for Health.

26th January 2015

Norman Lamb
Minister of State
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (“the 2014 Regulations”).

Regulation 3 provides that the 2014 Regulations (as amended by these Regulations) are to cease to have effect after 31st March 2022 (seven years after they come fully into force on 1st April 2015). As a consequence of the Regulations ceasing to have effect at that time, regulation 16 amends regulation 27 of the 2014 Regulations to provide for a review of the operation and effect of the 2014 Regulations within five years of 1st April 2015, rather than every five years. Following the review it will fall to the Secretary of State to consider whether the Regulations should be allowed to expire as provided, be revoked early, or continue in force with or without amendment. A further instrument would be needed to continue the Regulations in force with or without amendments or to revoke them early.

Regulation 4 amends regulation 2 of the 2014 Regulations to make provision for the purposes of section 20A of the Health and Social Care Act 2008 (Care Quality Commission functions relating to processing of information by registered persons), to reflect a difference in terminology between the 2014 Regulations and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (“the 2010 Regulations”).

Regulations 5, 7 and 8 amend regulations 4, 6 and 7 respectively of the 2014 Regulations. These amendments: (a) add a requirement for the following persons to have competence for their role: individual service providers, partners in a partnership which is a service provider, nominated individuals and registered managers; and (b) make provision as to matters to be considered when assessing the character of such persons for the purposes of those roles.

Regulation 6 amends regulation 5 of the 2014 Regulations (fit and proper persons: directors) to provide that directors of all service providers that are a body other than a partnership, not just health service bodies, have to meet a fit and proper person test.

Regulation 10 amends regulation 20 of the 2014 Regulations (duty of candour) to extend the requirement to be candid when a notifiable safety incident occurs to apply to all service providers, not just health service bodies. Regulation 10(5) sets out the type of safety incidents that, when they occur, will result in the duty of candour applying.

Regulation 11 inserts a new regulation 20A into the 2014 Regulations. This new provision requires registered persons to display, at their premises and on their websites, ratings of the service provider’s performance given by the Care Quality Commission (“CQC”). Service providers’ websites must also show the CQC’s website address and the place on CQC’s website where the assessment and ratings of the provider’s performance may be accessed.

Regulation 9 amends regulation 8 of the 2014 Regulations to make further provision consequential on the extension of both the duty of candour to all service providers, not just health service bodies, and the insertion of new regulation 20A into the 2014 Regulations.

Regulation 12 amends regulation 22 (offences) of the 2014 Regulations to make it an offence to breach the requirements imposed by new regulation 20A. Regulation 13 amends regulation 23 (offences: penalties) of the 2014 Regulations to provide for a penalty for those who commit such an offence. Regulations 12 and 13 also make provision consequential on the extension of the duty of candour to all service providers by regulation 10.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Regulation 14 amends regulation 25 of the 2014 Regulations (revocations) to make a saving provision in relation to the definitions of “nursing care” and “personal care” used in the 2010 Regulations, 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).

Regulation 15 amends regulation 26 of the 2014 Regulations (transitional and transitory provision) to remove paragraph (2) of regulation 26, which will cease to have effect on the day that these Regulations come into force.

Regulation 17 amends Schedule 5 of the 2014 Regulations to provide for a breach of new regulation 20A to be a fixed penalty offence for the purposes of section 86 of the Health and Social Care Act 2008 and for the amount of the penalty. It also makes provision consequential on the extension of the duty of candour to all service providers.

A full impact assessment of the costs and benefits of this instrument is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS (www.gov.uk/government/organisations/department-of-health) and is published alongside this instrument and its Explanatory Memorandum at www.legislation.gov.uk.