
DRAFT STATUTORY INSTRUMENTS

2021 No.

**The Health and Social Care Act 2008 (Regulated Activities)
(Amendment) (Coronavirus) (No. 2) Regulations 2021**

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

3.—(1) Regulation 12 (safe care and treatment) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014⁽¹⁾ is amended as follows.

(2) In paragraph (3), for the words from “in a care home” to the end, substitute—

“carried on in a care home must secure that a person (“B”) is permitted to enter premises used as a care home by A only if—

- (a) one or more of the conditions in paragraph (3B) is satisfied, or
- (b) B satisfies the condition in paragraph (3C) (but see paragraph (3A)).”.

(3) After paragraph (3) insert—

“(3A) In paragraph (3), sub-paragraph (b) ceases to apply in respect of B at the end of the period specified in paragraph (3D).

(3B) The conditions are that—

- (a) B is a service user residing in the premises used by A;
- (b) B has provided A with evidence satisfying A that—
 - (i) B has been vaccinated with the complete course of doses of an authorised vaccine, or
 - (ii) that for clinical reasons B should not be vaccinated with any authorised vaccine;
- (c) it is reasonably necessary for B to provide emergency assistance in the premises used by A;
- (d) it is reasonably necessary for B to provide urgent maintenance assistance with respect to the premises used by A;
- (e) B is attending the premises used by A in the execution of B’s duties as a member of the emergency services;
- (f) B is a friend or relative of a service user and that service user is or has been residing in the premises used by A;
- (g) B is visiting a service user who is dying;
- (h) it is reasonably necessary for B to provide comfort or support to a service user in relation to a service user’s bereavement following the death of a friend or relative;
- (i) B is under the age of 18;
- (j) B has provided A with evidence satisfying A that B has participated, or is participating, in—

⁽¹⁾ S.I. 2014/2936, amended by S.I. 2015/64, 2016/765, 2019/1094, 2020/1550, 2021/891.

- (i) a clinical trial of a vaccine for vaccination against coronavirus carried out in accordance with the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004⁽²⁾,
 - (ii) a clinical trial regulated in the United States of America by the Food and Drugs Administration of a vaccine for vaccination against coronavirus, or
 - (iii) phase 2 (therapeutic exploratory studies) or phase 3 (clinical efficacy studies) of a clinical trial of a vaccine for vaccination against coronavirus which is regulated by—
 - (aa) the European Medicines Agency, or
 - (bb) a regulatory authority (other than such an authority in the United Kingdom or the United States of America) which is designated as a Stringent Regulatory Authority by the World Health Organization⁽³⁾.
- (3C) The condition is that B—
 - (a) was not previously employed or otherwise engaged by A for the purposes of the provision of the regulated activity specified in paragraph (3), and
 - (b) has provided A with evidence satisfying A that B has been vaccinated with one dose of an authorised vaccine that was administered at least 21 days before the day B is employed or otherwise engaged by A for the purposes of the provision of that regulated activity.
- (3D) The period of 10 weeks beginning with the day on which B was vaccinated as specified in paragraph (3C)(b).”.
- (4) In paragraph (4), for “paragraph (3)” substitute “paragraphs (3) to (3D)”.
- (5) After paragraph (5) insert—

“(5A) For the purposes of this regulation, B has been vaccinated with the complete course of doses of an authorised vaccine if—

 - (a) B has received the complete course of doses specified—
 - (i) in the summary of product characteristics approved as part of the marketing authorisation for the authorised vaccine, or
 - (ii) in the instructions for usage approved as part of the authorisation by the licensing authority on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc) of the Human Medicines Regulations 2012⁽⁴⁾ for the authorised vaccine, or
 - (b) B has received one dose of an authorised vaccine and another dose of a different authorised vaccine.”.
- (6) In paragraph (6)—
 - (a) after the definition of “care home” insert—

““clinical trial” has the meaning given in regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004;”;
 - (b) omit the definition of “complete course of doses”.

(2) [S.I. 2004/1031](#), to which there are amendments not relevant to these Regulations.

(3) The process used by the World Health Organization to designate a Stringent Regulatory Authority is set out here: <https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs>.

(4) [S.I. 2012/1916](#), to which there are amendments not relevant to these Regulations.

