
DRAFT STATUTORY INSTRUMENTS

2021 No.

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

**Further amendment of the Health and Social Care Act 2008 (Regulated Activities)
Regulations 2014**

4.—(1) Regulation 12 (safe care and treatment) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014⁽¹⁾ is amended as provided in paragraphs (2) to (4).

(2) For paragraphs (3) to (3D) substitute—

“(3) For the purposes of paragraph (2)(h), and subject to paragraphs (3J) and (3K), a registered person (“A”) registered in respect of—

- (a) the regulated activity specified in paragraph 2 of Schedule 1 (accommodation for persons who require nursing or personal care) 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 B—
 - (i) has provided A with evidence satisfying A that B satisfies one of the conditions specified in paragraph (3B),
 - (ii) has provided A with evidence satisfying A that B satisfies the condition specified in paragraph (3C) (but see paragraph (3A)(a)), or
 - (iii) satisfies the condition in paragraph (3F) (but see paragraph (3A)(b));
- (b) any other regulated activity, may employ or otherwise engage B for the purposes of the provision of that regulated activity only if B—
 - (i) has provided A with evidence satisfying A that B satisfies one of the conditions specified in paragraph (3B),
 - (ii) has provided A with evidence satisfying A that B satisfies the condition specified in paragraph (3C) (but see paragraph (3A)(c)), or
 - (iii) satisfies the condition in—
 - (aa) paragraph (3F) (but see paragraph (3A)(d)), or
 - (bb) paragraph (3H) (but see paragraph (3A)(e)).

(3A) In paragraph (3)—

- (a) sub-paragraph (a)(ii) ceases to apply in respect of B at the end of the period specified in paragraph (3D), unless paragraph (3E) applies;
- (b) sub-paragraph (a)(iii) ceases to apply in respect of B at the end of the period specified in paragraph (3G);
- (c) sub-paragraph (b)(ii) ceases to apply in respect of B at the end of the period specified in paragraph (3D), unless paragraph (3E) applies;

⁽¹⁾ S.I. 2014/2936, amended by S.I. 2015/64, 2016/765, 2019/1094, 2020/1550, 2021/891, and paragraph 3 of these Regulations.

- (d) sub-paragraph (b)(iii)(aa) ceases to apply in respect of B at the end of the period specified in paragraph (3G);
 - (e) sub-paragraph (b)(iii)(bb) ceases to apply in respect of B at the end of the period specified in paragraph (3I).
- (3B) The conditions are that B—
- (a) has been vaccinated with the complete course of doses of an authorised vaccine;
 - (b) should not, for clinical reasons, be vaccinated with an authorised vaccine.
- (3C) The condition is that B has been vaccinated against coronavirus other than by virtue of being vaccinated with the complete course of doses of an authorised vaccine.
- (3D) The period of 10 weeks beginning with the day on which B is vaccinated as specified in paragraph (3C).
- (3E) This paragraph applies where B has provided A with evidence satisfying A that B—
- (a) has been vaccinated with one dose of an authorised vaccine in addition to being otherwise vaccinated against coronavirus, or
 - (b) has been vaccinated with a vaccine listed in column 1 of the table in Schedule 4A in accordance with the corresponding number of doses listed in column 2 of that table.
- (3F) The condition is that B—
- (a) was not employed or otherwise engaged by A before the day on which regulation 4 of the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2021 came into force for the purposes of the provision of the regulated activity referred to in—
 - (i) paragraph (3)(a), or
 - (ii) paragraph (3)(b), in circumstances where that paragraph applies (see paragraph (3K) for exceptions),
 - (b) was employed or otherwise engaged by A for the purposes of the provision of a regulated activity on or after the day on which regulation 4 of the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2021 came into force, and
 - (c) has provided A with evidence satisfying A that B has been vaccinated with one dose of an authorised vaccine administered at least 21 days before the day on which B is first employed or otherwise engaged for the purposes of the provision of the regulated activity.
- (3G) The period of 10 weeks beginning with the day on which B is vaccinated as specified in paragraph (3F)(c).
- (3H) The condition is that B—
- (a) was not employed or otherwise engaged by A—
 - (i) before the day on which the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2021 were made,
 - (ii) for the purposes of the provision of a regulated activity referred to in paragraph (3)(b), and
 - (iii) in circumstances where paragraph (3)(b) applies (see paragraph (3K) for exceptions),

- (b) was employed or otherwise engaged by A for the purposes of the provision of a regulated activity referred to in paragraph (3)(b) during the period beginning with the day on which the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2021 were made and ending with the day before the day on which regulation 4 of those Regulations came into force, and
 - (c) B has provided A with evidence satisfying A that B has been vaccinated with one dose of an authorised vaccine.
- (3I) The period of 10 weeks beginning with the day on which B is vaccinated as specified in paragraph (3H)(c).
- (3J) Paragraph (3)(a) does not apply where—
- (a) B is a service user residing in premises used by A;
 - (b) it is reasonably necessary for B to provide emergency assistance in the premises used by A;
 - (c) it is reasonably necessary for B to provide urgent maintenance assistance with respect to the premises used by A;
 - (d) B is attending the premises used by A in the execution of B’s duties as a member of the emergency services;
 - (e) 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;
 - (f) B is visiting a service user who is dying;
 - (g) 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;
 - (h) B is under the age of 18;
 - (i) B has provided A with evidence satisfying A that B has participated, or is participating, in—
 - (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⁾.
- (3K) Paragraph (3)(b) does not apply where—
- (a) B will not have direct, face to face contact with a service user;
 - (b) B is under the age of 18;

(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>.

- (c) B has provided A with evidence satisfying A that B has participated, or is participating in—
- (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,
 - (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;
 - (d) the provision of the regulated activity is part of a shared lives agreement.”.
- (3) In paragraph (4), for “paragraphs (3) to (3D)” substitute “paragraphs (3) to (3K)”.
- (4) In paragraph (6)—
- (a) for the definition of “authorised vaccine” substitute—

““authorised vaccine” has the meaning given in regulation 3A of the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021(4);”;
 - (b) for the definition of “marketing authorisation” substitute—

““marketing authorisation” has the meaning given in regulation 3A of the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021;”;
 - (c) omit the definition of “medicinal product”.
- (5) After Schedule 4 (good character and unfit person tests) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 insert—

“SCHEDULE 4A

Regulation 12(3E)(b)

Vaccine Requirements

<i>Vaccine name, manufacturer</i>	<i>Number of doses</i>
Sputnik Light, Gamaleva National Centre of Epidemiology & Microbiology	of 3 doses
Covid 19 vaccine BIBP, Sinopharm	3 doses
BBIBPV-CorV, Sinopharm	3 doses
CoronaVac, Sinovac Biotech	3 doses
Ad5-nCoV, CanSino Biologics	3 doses
Convidecia, CanSino Biologics	3 doses
Covaxin, Bharart Biotech	3 doses

(4) [S.I. 2021/582](#). Regulation 3A was inserted by [S.I. 2021/1107](#).

<i>Vaccine name, manufacturer</i>	<i>Number of doses</i>
NVX-CoV2373, Novavax	2 doses
Covovax, Novavax	2 doses
Sputnik V, Gamaleva National Centre of Epidemiology & Microbiology	of 2 doses”.
