Draft Regulations laid before Parliament under section 162(3) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2021 No. 0000

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

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

Made - - - - 2021
Coming into force in accordance with regulation 1(2) and (3)

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 20(1) to (3) and (5) and 161(3) and (4) of the Health and Social Care Act 2008(**1**).

A draft of these Regulations was laid before Parliament in accordance with section 162(3) of the Health and Social Care Act 2008 and approved by a resolution of each House of Parliament.

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.—(1) These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2021.

(2) Subject to paragraph (3), these Regulations come into force on the day after the day on which they are made.

(3) Regulation 4 comes into force at the end of the period of 12 weeks beginning with the day after the day on which these Regulations are made.

Extent and application

2.—(1) These Regulations extend to England and Wales.

(**1**) 2008 c. 14. Section 20(1) and the opening words of section 20(2) were substituted by section 1(2) of the Health and Social Care (Safety and Quality) Act 2015 (c. 28). Section 161(3) was amended by section 294(4) of the Health and Social Care Act 2012 (c. 7).

(2) These Regulations apply to England only.

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(**2**) 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—

(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(**3**),

(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—

(**2**) S.I. 2014/2936, amended by S.I. 2015/64, 2016/765, 2019/1094, 2020/1550, 2021/891.
(**3**) S.I. 2004/1031, to which there are amendments not relevant to these Regulations.

(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(**4**).

(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(**5**) 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".

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(**6**) 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—

(**4**) 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.
(**5**) S.I. 2012/1916, to which there are amendments not relevant to these Regulations.
(**6**) S.I. 2014/2936, amended by S.I. 2015/64, 2016/765, 2019/1094, 2020/1550, 2021/891, and paragraph 3 of these Regulations.

(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;

(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(**7**),

(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(**8**).

(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;

(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—

(**7**) S.I. 2004/1031, to which there are amendments not relevant to these Regulations.

(**8**) 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.

""authorised vaccine" has the meaning given in regulation 3A of the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021(**9**);";

(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

Vaccine name, manufacturer	*Number of doses*
Sputnik Light, Gamaleva National Centre of Epidemiology & Microbiology	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
NVX-CoV2373, Novovax	2 doses
Covovax, Novavax	2 doses
Sputnik V, Gamaleva National Centre of Epidemiology & Microbiology	2 doses".

Review

5.—(1) Before the end of each review period, 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 these Regulations,

(b) assess the extent to which those objectives are achieved, taking into account clinical advice and availability and accessibility of authorised vaccines, 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.

(3) In this regulation, "review period" means—

(**9**) S.I. 2021/582. Regulation 3A was inserted by S.I. 2021/1107.

(a) the period of one year beginning with the date on which regulation 4 comes into force, and

(b) subject to paragraph (4), each successive period of one year.

(4) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

(5) In this regulation, "authorised vaccine" has the meaning given in regulation 3A of the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021(**10**).

Signed by the authority of the Secretary of State for Health and Social Care

Name
Address — Parliamentary Under Secretary of State
Date — Department of Health and Social Care

(**10**) S.I. 2021/582. Regulation 3A was inserted by S.I. 2021/1107.

EXPLANATORY NOTE

(This note is not part of the Regulations)

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No.2) Regulations 2021 ("these Regulations") amend regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations") and insert Schedule 4A to the 2014 Regulations for the purposes of preventing, detecting and controlling the spread of infections, specifically in response to the effects of the coronavirus pandemic.

Regulation 12 of the 2014 Regulations makes provision in respect of conditions relating to entry into a care home where that care home is used by a registered person in respect of the regulated activity of providing accommodation for persons who require nursing or personal care.

Regulation 3(3) of these Regulations amends regulation 12 of the 2014 Regulations to make further provision in relation to entry into the care home, specifically where (a) the person wishing to enter the care home has participated or is participating in a clinical trial; and (b) where the person wishing to enter the care home has not previously been employed or otherwise engaged by the registered person in respect of that regulated activity.

The provision relating to clinical trials makes reference to a regulatory authority designated as a Stringent Regulatory Authority by the World Health Organization. The process used by the World Health Organization to designate a Stringent Regulatory Authority can be found at https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs. The relevant information can be requested in hard copy form from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

Regulation 3(5) of these Regulations amends regulation 12 of the 2014 Regulation to provide that a complete course of doses includes one dose of an authorised vaccine and another dose of a different authorised vaccine.

Regulation 4 of these Regulations makes further amendments to regulation 12 of the 2014 Regulations and comes into force after a period of 12 weeks beginning with the day after the day on which these Regulations are made.

Regulation 4(2) of these Regulations amends regulation 12 of the 2014 Regulations to make provision in respect of conditions relating to (a) permitting entry into a care home where that care home is used by a registered person in respect of the regulated activity of providing accommodation for persons who require nursing or personal care; and (b) employing or otherwise engaging a person for the purposes of the provision of any other regulated activity. The general condition is that a registered person in relation to those regulated activities must receive from a relevant person evidence which satisfies the registered person that the relevant person has been vaccinated with a complete course of doses of an authorised vaccine or should not for clinical reasons be vaccinated. Where a relevant person has not been able to provide such evidence, they may be able to satisfy alternative conditions if they can demonstrate that have been otherwise vaccinated against coronavirus. However, this alternative option stops applying after a period of 10 weeks, unless that person can demonstrate that they have satisfied additional conditions.

Alternative conditions can also be satisfied where a person has not previously been employed or otherwise engaged by the registered person. Different conditions apply depending on when that person was first engaged or employed for the purposes of the regulated activity.

Regulation 4(2) of these Regulations also amends regulation 12 of the 2014 Regulations to set out the circumstances in which these various conditions do not apply.

Regulation 4(3) of these Regulations provides that a registered person provided with information as evidence in accordance with the paragraphs inserted by regulation 4(2) may process that information.

Regulation 4(4) of these Regulations provides for the definition of "authorised vaccine" and "marketing authorisation" with reference to the Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021.

Regulation 5 of these Regulations requires the Secretary of State to review the operation and effect of these Regulations and to publish the report within one year after the date on which regulation 4 comes into force and within every year after that.

A full Impact Assessment has not been published with this instrument but will be published and laid before Parliament as soon as possible. An Impact Statement setting out the preliminary analysis of the impact of this instrument has been laid before Parliament and published on gov.uk.