
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.

Draft Legislation: This is a draft item of legislation. This draft has since been made as a UK Statutory Instrument: The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2022 (revoked) No. 15

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](https://www.gov.uk).