
STATUTORY INSTRUMENTS

2021 No. 891

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021

Amendment of regulation 12 (safe care and treatment)

5. In regulation 12, after paragraph (2), insert—

“(3) For the purposes of paragraph (2)(h), a registered person (“A”) in respect of a regulated activity specified in paragraph 2 of Schedule 1 (accommodation for persons who require nursing or personal care) in a care home must secure that a person (“B”) does not enter the premises used by A unless—

- (a) B is a service user residing in the premises used by A;
- (b) B has provided A with evidence that satisfies A that either—
 - (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; or
- (i) B is under the age of 18.

(4) A registered person provided with information as evidence in accordance with paragraph (3) may process that information.

(5) Nothing in this regulation authorises the processing of personal data in a manner inconsistent with any provision of data protection legislation.

(6) In this regulation—

“authorised vaccine” means a medicinal product—

- (a) authorised for supply in the United Kingdom in accordance with a marketing authorisation; or

- (b) authorised 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⁽¹⁾

for vaccination against coronavirus;

“care home” has the meaning given in section 3 (care homes in England) of the Care Standards Act 2000⁽²⁾;

“complete course of doses” means the complete course of doses specified—

- (a) in the summary of product characteristics approved as part of the marketing authorisation for the authorised vaccine; or
- (b) in the instructions for usage approved as part of the authorisation by the licensing authority on a temporary basis under regulation 174 of the Human Medicines Regulations 2012 for the authorised vaccine;

“coronavirus” means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

“data protection legislation” and “personal data” have the meaning given in section 3 (terms relating to the processing of personal data) of the Data Protection Act 2018;

“marketing authorisation” has the meaning given in regulation 8(1) (general interpretation) of the Human Medicines Regulations 2012;

“medicinal product” has the meaning given in regulation 2 (medicinal products) of the Human Medicines Regulations 2012; and

“the licensing authority” has the meaning given in regulation 6(2) (the licensing authority and the Ministers) of the Human Medicines Regulations 2012.”.

⁽¹⁾ [S.I. 2012/1916](#), to which there are amendments not relevant to these Regulations.

⁽²⁾ [2000 c. 14](#). Section 3 was amended by paragraph 4 of Schedule 5 to the Health and Social Care Act 2008 ([c. 14](#)). There are other amendments to section 3 which are not relevant to these Regulations.