

DRAFT STATUTORY INSTRUMENTS

**2021 No.**

**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<sup>(1)</sup>

for vaccination against coronavirus;

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

“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.”.

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(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.