STATUTORY INSTRUMENTS

2014 No. 2936

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

PART 3

Requirements in relation to Regulated Activities

SECTION 2

Fundamental Standards

Duty of candour

20.—(1) A health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must—

(a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and

(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

(3) The notification to be given under paragraph (2)(a) must—

(a) be given in person by one or more representatives of the health service body,

(b) provide an account, which to the best of the health service body's knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification,

(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate,

(d) include an apology, and

(e) be recorded in a written record which is kept securely by the health service body.

(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—

(a) the information provided under paragraph (3)(b),

(b) details of any enquiries to be undertaken in accordance with paragraph (3)(c),

(c) the results of any further enquiries into the incident, and

(d) an apology.

(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body—

(a) paragraphs (2) to (4) are not to apply, and

(b) a written record is to be kept of attempts to contact or to speak to the relevant person.

(6) The health service body must keep a copy of all correspondence with the relevant person under paragraph (4).

(7) In this regulation—

"apology" means an expression of sorrow or regret in respect of a notifiable safety incident;

"moderate harm" means—

(a) harm that requires a moderate increase in treatment, and

(b) significant, but not permanent, harm;

"moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

"notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

(b) severe harm, moderate harm or prolonged psychological harm to the service user;

"prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf—

(a) on the death of the service user,

(b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or

(c) where the service user is 16 or over and lacks capacity (as determined in accordance with sections 2 and 3 of the 2005 Act) in relation to the matter;

"severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.