
WELSH STATUTORY INSTRUMENTS

2023 No. 274

The Duty of Candour Procedure (Wales) Regulations 2023

Interpretation

2.—(1) In these Regulations—

“the 2006 Act” (“*Deddf 2006*”) means the National Health Service (Wales) Act 2006⁽¹⁾;

“the 2011 Regulations” (“*Rheoliadau 2011*”) means the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011⁽²⁾;

“the Act” (“*y Ddeddf*”) means the Health and Social Care (Quality and Engagement) (Wales) Act 2020;

“apology” (“*ymddiheuriad*”) means an expression of sorrow or regret in respect of the notifiable adverse outcome;

“candour procedure” (“*gweithdrefn gonestrwydd*”) means the procedure set out in these Regulations that an NHS body must follow in relation to a notifiable adverse outcome;

“harm” (“*niwed*”) includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child;

“health care” (“*gofal iechyd*”) means services provided in Wales under or by virtue of the 2006 Act for or in connection with—

(a) the prevention, diagnosis or treatment of illness;

(b) the promotion and protection of public health;

“illness” (“*salwch*”) has the meaning given in section 206 of the 2006 Act;

“Local Health Board” (“*Bwrdd Iechyd Lleol*”) means a body established under section 11 of the 2006 Act;

“NHS body” means—

(a) a Local Health Board;

(b) an NHS trust;

(c) a Special Health Authority;

(d) a primary care provider;

“NHS trust” (“*ymddiriedolaeth GIG*”) means a body established under section 18 of the 2006 Act;

“notifiable adverse outcome” (“*canlyniad andwyol hysbysadwy*”) occurs when the duty of candour comes into effect in accordance with section 3 of the Act;

“responsible body” (“*corff cyfrifol*”) means an NHS body in relation to which the duty of candour imposed by section 3 of the Act has come into effect;

“service user” (“*defnyddiwr gwasanaeth*”) means a person, to whom health care is being or has been provided by an NHS body, that has suffered an adverse outcome;

(1) 2006 c. 42.

(2) S.I. 2011/704 (W. 108).

“Special Health Authority” (“*Awdurdod Iechyd Arbennig*”) means a body established under section 22 of the 2006 Act; but does not include any cross-border Special Health Authority (within the meaning of section 8A(5) of the 2006 Act) other than NHS Blood and Transplant.

(2) A person is a primary care provider, for the purposes of these Regulations, in so far as (and only in so far as) the person provides health care on behalf of a Local Health Board by virtue of a contract, agreement or arrangement under Part 4, 5, 6 or 7 of the 2006 Act between the person and the Local Health Board.

(3) A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user could experience, any unexpected or unintended harm that is more than minimal.

(4) Health care provided by one NHS body (the “providing body”) on behalf of another NHS body (“the arranging NHS body”), by virtue of a contract, agreement, or arrangement made under the 2006 Act between the providing body and the arranging body, is to be treated for the purposes of these Regulations as being provided by the providing body, not the arranging body.

(5) Health care provided by a person other than an NHS body (the “provider”), on behalf of an NHS body, whether by virtue of a contract, agreement or arrangement made under the 2006 Act or otherwise, is to be treated for the purposes of these Regulations as being provided by the NHS body, not the provider.

(6) A document or record required by virtue of these Regulations to be “written” includes an electronic communication, as defined in section 15(1) of the Electronic Communications Act 2000(3).

(3) 2000 c. 7; section 15(1) was amended by the Communications Act 2003 (c. 21).