

2023 No. (W.)

**NATIONAL HEALTH
SERVICE, WALES**

**The Duty of Candour Procedure
(Wales) Regulations 2023**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision regarding the candour procedure to be followed by NHS bodies under Part 3 of the Health and Social Care (Quality and Engagement) (Wales) Act 2020.

Regulation 2 defines the terms used within these Regulations.

Regulation 3 makes provision in respect of whom the NHS body is required to notify and communicate with under the candour procedure. These Regulations refer to this person as the “relevant person” and refer to the NHS body that owes the duty of candour to the relevant person as the “responsible body”.

Regulation 4(1) requires the responsible body, on first becoming aware of a notifiable adverse outcome, to notify the relevant person by telephone, audio-visual communication (such as a video call), or a face-to-face meeting. Regulation 4(3) makes provision in respect of the information to be included in such notification.

Regulation 5 requires the responsible body to provide written notification to the relevant person within two working days of the in-person notification provided under regulation 4(1). Regulation 5(2) makes provision regarding what the written notification must include.

Regulation 6 requires a responsible body to notify the relevant person of the results of any further enquiries carried out by the body in respect of the circumstances in which the duty of candour came into effect.

Regulation 7 makes further provision in respect of communication between the responsible body and the

relevant person required by virtue of these Regulations.

Regulation 8 requires the responsible body to provide training and information about services which can provide assistance and support to staff.

Regulation 9 provides that the responsible body must keep a written record (which includes an electronic record) for each notifiable adverse outcome in respect of which the candour procedure is followed.

Regulation 10 requires the responsible body to designate a person to be responsible for maintaining strategic oversight of its operation of the candour procedure.

Regulation 11 requires the responsible body to designate a responsible officer to take overall responsibility for the effective day to day operation of the candour procedure and to ensure that the responsible body complies with the requirements of these Regulations.

Regulation 12 sets out limitations on the provision of information.

Regulation 13 provides that an apology or other step taken in accordance with the candour procedure is not an admission of negligence or breach of a statutory duty.

Regulation 14 makes amendments to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 in consequence of these Regulations.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from Welsh Government, Cathays Park, Cardiff, CF10 3NQ and is published on www.gov.wales.

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**The Duty of Candour Procedure
(Wales) Regulations 2023**

Made

Laid before Senedd Cymru ***

Coming into force ***

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 4, 25(2), 28(1) and (2) of the Health and Social Care (Quality and Engagement) (Wales) Act 2020⁽¹⁾.

Title and commencement

1.—(1) The title of these Regulations is the Duty of Candour Procedure (Wales) Regulations 2023.

(2) These Regulations come into force on ** 2023.

Interpretation

2.—(1) In these Regulations—

“the 2006 Act” (“*Deddf 2006*”) means the National Health Service (Wales) Act 2006⁽²⁾;

“the 2011 Regulations” (“*Rheoliadau 2011*”) means the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011⁽³⁾;

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

(1) 2020 asc 1.

(2) 2006 anaw 42, to which there are amendments not relevant to these Regulations.

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

“apology” (“*yddiheuriad*”) 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” (“*ymdiriedolaeth 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 by virtue of 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;

“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⁽¹⁾.

Relevant person

3. In these Regulations the “relevant person” means—

- (a) the service user, or
 - (b) if the service user—
 - (i) has died,
 - (ii) is 16 or over and lacks capacity (within the meaning of the Mental Capacity Act 2005⁽²⁾) in relation to the matter,
 - (iii) is under 16 and not competent to make a decision in relation to their care or treatment, or
 - (iv) has informed the responsible body that they have nominated a person to act on their behalf,
- a person acting on behalf of that service user.

In-person notification

4.—(1) On first becoming aware of a notifiable adverse outcome, a responsible body must notify the relevant person in accordance with this regulation.

(1) 2000 c. 7, to which there are amendments not relevant to these Regulations.

(2) 2005 c. 9, to which there are amendments not relevant to these Regulations.

(2) Notification under paragraph (1) must be by in-person communication.

(3) The notification under paragraph (1) must include—

- (a) an account of the circumstances of the notifiable adverse outcome, in so far as the responsible body is aware of the facts at the date the notification is provided,
- (b) the reason that the responsible body considers that the conditions set out in section 3(2) and (3) of the Act have been met,
- (c) an apology,
- (d) the name and contact details of the person at the responsible body nominated as the point of contact for the relevant person in respect of the candour procedure,
- (e) an explanation of the actions that the responsible body or the provider will take, and further enquiries that the responsible body or the provider will carry out, to investigate or review the circumstances of the notifiable adverse outcome, including any actions to be taken under the 2011 Regulations,
- (f) details of any services or support which the responsible body reasonably considers may provide assistance to the relevant person, taking into account the relevant person's needs, and
- (g) where the notification under paragraph (1) is made later than 30 working days after the responsible body first became aware of the notifiable adverse outcome, an explanation of the reason for the delay.

(4) In this regulation, “in-person communication” means communication that is made by telephone call, audio-visual communication or a face-to-face meeting.

Written notification

5.—(1) The responsible body must notify the relevant person in writing in accordance with this regulation.

(2) The responsible body must take all reasonable steps to send the written notification under paragraph (1) to the relevant person within two working days beginning with the date that the responsible body notifies the relevant person under regulation 4(1).

(3) The written notification under paragraph (1) must include—

- (a) a description of any initial consideration of the notifiable adverse outcome,
- (b) an apology, and

- (c) the information provided under regulation 4(3)(b), 4(3)(d), 4(3)(e), 4(3)(f) and, if relevant, 4(3)(g).

Notification of results of further enquiries

6. The responsible body must notify the relevant person of the results of any further enquiries referred to in regulation 4(3)(e).

Communication with relevant person

7.—(1) The responsible body must take reasonable steps to ascertain the relevant person's preferred method of communication and, where reasonably practicable, communicate with the relevant person by this method.

(2) The responsible body must take reasonable steps to ensure any communication with the relevant person is in a manner that the relevant person can understand.

(3) If the responsible body, having taken reasonable steps, is unable to contact the relevant person to give notification under any of regulations 4, 5 or 6, or the relevant person declines to communicate with the responsible body—

- (a) the responsible body must ensure that the record kept under regulation 9 includes information about the attempts made to contact or to communicate with the relevant person, and
- (b) regulations 4, 5 and 6 cease to apply.

Training and support

8.—(1) The responsible body must ensure that the members of staff specified in paragraph (2) receive relevant training and guidance on the candour procedure.

(2) For the purposes of paragraph (1), the members of staff are—

- (a) those involved in the provision of health care;
- (b) those involved in investigating or managing notifiable adverse outcomes;
- (c) any other relevant members of staff who are involved in performing or exercising functions in connection with the candour procedure.

(3) The responsible body must provide a member of staff who is involved in a notifiable adverse outcome with details of any services of which the responsible body is aware which may provide assistance or support to any such member of staff, taking into account—

- (a) the circumstances relating to the notifiable adverse outcome, and

- (b) the member of staff's needs.

(4) In this regulation, a “member of staff” is any person who works for an NHS body, whether under a contract of employment, a contract for services or as a volunteer, or agency workers (within the meaning of regulation 3 of the Agency Workers Regulations 2010⁽¹⁾) working under the supervision and direction of an NHS body.

Records

9.—(1) The responsible body must keep a written record for each notifiable adverse outcome in respect of which the candour procedure is followed.

(2) The record required by paragraph (1) must include every document and piece of correspondence relating to the notifiable adverse outcome, including but not limited to—

- (a) records of notifications given under regulations 4, 5 and 6,
- (b) records of attempts to contact the relevant person,
- (c) any decision by the relevant person not to be contacted in relation to the candour procedure, and
- (d) all documentation relating to the investigation and review of the notifiable adverse outcome undertaken by the responsible body, including any responses or interim reports issued by the responsible body under regulation 24, 26 or 31 of the 2011 Regulations.

Strategic oversight of the candour procedure

10.—(1) Each responsible body must designate a person to be responsible for maintaining a strategic oversight of its operation of the candour procedure.

(2) Where the responsible body is a Local Health Board, an NHS Trust or a Special Health Authority, that person must be one of its non-officer members or non-executive directors, as appropriate.

Responsible officer

11.—(1) Each responsible body must designate a person (the “responsible officer”) to take overall responsibility for the effective day-to-day operation of the candour procedure, and in particular to ensure that the responsible body complies with the requirements of these Regulations.

(2) The responsible officer must be—

(1) S.I. 2010/93 reg. 3.

- (a) in the case of a Local Health Board, NHS Trust or Special Health Authority, a person who is an officer member or executive director of that body, as appropriate;
- (b) in the case of a primary care provider, the person who acts as the chief executive officer of that body or, if there is none—
 - (i) the person who is the sole proprietor of the responsible body;
 - (ii) where the responsible body is a partnership, a partner;
 - (iii) in any other case, a director of the responsible body, or a person who is responsible for managing the responsible body.

(3) The functions of the responsible officer may be performed by that person or by any person authorised by the responsible body to act on his or her behalf provided that the person so authorised is under the direct control and supervision of the responsible officer.

Limitations on provision of information

12. These Regulations do not permit or require a responsible body to disclose any information which—

- (a) would prejudice any criminal investigation or prosecution, or
- (b) would contravene any restriction on disclosure arising by virtue of an enactment or rule of law.

Apology

13. An apology or other step taken in accordance with the candour procedure does not amount to an admission of negligence or a breach of a statutory duty.

Amendment of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

14.—(1) The 2011 Regulations are amended as follows.

(2) In regulation 2(1) (interpretation) at the appropriate places insert—

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

““the 2023 Regulations” (“*Rheoliadau 2023*”) means the Duty of Candour Procedure (Wales) Regulations 2023;”.

(3) For regulation 12(7) (persons who may notify concerns), substitute—

“(7) Where a concern is notified by a member of the staff of the responsible body, the responsible body must, where its initial investigation determines that there has been moderate or severe harm or death—

(a) unless notification under regulation 4(1) of the 2023 Regulations has already been given, advise the patient to whom the concern relates of the notification of the concern, and

(b) unless paragraph (8) applies, involve the patient in the investigation of the concern.”

(4) In regulation 12(8) (persons who may notify concerns), omit “informed of or”.

(5) In regulation 24 (response)—

(a) in paragraph (3), for “on the day upon which it received notification of the concern” substitute—

“with the later of—

(a) the day upon which it received notification of the concern, or

(b) where the duty of candour under section 3 of the 2020 Act comes into effect in relation to the subject matter of the concern, the day upon which the notification under regulation 4(1) of the 2023 Regulations was given.”;

(b) in paragraph (4)—

(i) for “thirty working days in accordance with” substitute “the period specified in”;

(ii) for subparagraph (b) substitute—

“(b) send the response as soon as reasonably practicable and within six months beginning with the later of—

(i) the day upon which it received notification of the concern, or

(ii) where the duty of candour under section 3 of the 2020 Act comes into effect in relation to the subject matter of the concern, the day upon which the notification under regulation 4(1) of the 2023 Regulations was given.”

(6) In regulation 26 (response to an investigation under regulation 23 where it is decided that there is or there may be a qualifying liability)—

- (a) in paragraph (2) for “day on which it received notification of the concern” substitute—

“later of—

- (a) the day upon which it received notification of the concern, or
- (b) where the duty of candour under section 3 of the 2020 Act comes into effect in relation to the subject matter of the concern, the day upon which the notification under regulation 4(1) of the 2023 Regulations was given.”;

- (b) in paragraph (3), for subparagraph (b) substitute—

“(b) send an interim report as soon as reasonably practicable and within six months beginning with the later of—

- (i) the day upon which it received notification of the concern, or
- (ii) where the duty of candour under section 3 of the 2020 Act comes into effect in relation to the subject matter of the concern, the day upon which the notification under regulation 4(1) of the 2023 Regulations was given.”

- (c) for paragraph (5) substitute—

“(5) The investigation report referred to in regulation 31 must be provided to the person who notified the concern or his or her legal representative as soon as reasonably practicable and within twelve months beginning with the later of—

- (a) the day upon which the Welsh NHS body received notification of the concern, or
- (b) where the duty of candour under section 3 of the 2020 Act comes into effect in relation to the subject matter of the concern, the day upon which the notification under regulation 4(1) of the 2023 Regulations was given.”

- (7) In regulation 30 (suspension of the limitation period)—

- (a) in paragraph (2)(b) for “(e)” substitute “(f)”;
- (b) in paragraph (4) for “(f)” substitute “(g)”.

- (8) For regulation 33 (redress – communication of a decision) substitute—

“33. Redress — communication of a decision

Where a Welsh NHS body decides to make an offer of redress by way of financial compensation or entry into a contract to provide

care or treatment or both or determines that it will not make an offer of redress on the basis that there is no qualifying liability, it must—

- (a) send the offer, or the notification of the decision not to make an offer, to the person who notified the concern within twelve months beginning with the later of—
 - (i) the day upon which the Welsh NHS body received notification of the concern; or
 - (ii) where the duty of candour under section 3 of the 2020 Act comes into effect in relation to the subject matter of the concern, the day upon which the notification under regulation 4(1) of the 2023 Regulations was given;
- (b) if exceptional circumstances mean that the twelve month period referred to in paragraph (a) cannot be adhered to, advise the person who notified the concern, or his or her, legal representative, of the reasons for the delay and when a decision in respect of the application for redress will be made;
- (c) advise that person or his or her legal representative that he or she must respond to the offer of settlement or a decision not to make an offer of settlement within six months of the date that it is notified;
- (d) subject to paragraph (e), advise that if, as a result of exceptional circumstances, it will not be possible to respond to the offer of settlement, or the decision not to make an offer of settlement, within six months of the date of the offer or decision not to make an offer, the Welsh NHS body must be advised by the person who notified the concern or his or her legal representative of the reasons for the delay in responding and when a response will be submitted;
- (e) advise that person or his or her legal representative that if an extension of time is sought to respond to an offer of settlement or a decision not to make an offer of settlement, a response is required within nine calendar months of the date of the offer or decision as that is the time when, in accordance

with regulation 30(3) and (5),
limitation starts to run;

- (f) advise, if an offer is made, that the settlement period proposed by the offer will be by way of a formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates;
- (g) advise that, in appropriate circumstances, the settlement agreement proposed will be subject to approval by a court in cases such as those where the person to whom the qualifying liability relates—
 - (i) is a child; or
 - (ii) lacks capacity within the meaning of the Mental Capacity Act 2005;
and
- (h) advise that where court approval of a settlement is required, the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.”

Name

Minister for Health and Social Services, one of the
Welsh Ministers

Date