



Putting Things Right Guidance 2023

The Health and Social Care (Quality and Engagement) (Wales) Act
2020,

Date of issue: 20th September 2022

Action required: Responses by 13th December 2022

AMENDMENTS AND UPDATES TO THE PUTTING THINGS RIGHT (PTR) GUIDANCE

The original PTR guidance can be found [here](#). Several amendments will be made to the document to cover:

- Changes made because of the introduction of the Duty of Candour
- Changes made because of the PTR Amendment Regulations

We are grateful to the many stakeholders who have been involved in reviewing the guidance and suggesting changes. Because the focus of this consultation is the introduction of the Duty of Candour, it has not been possible to include all changes requested but stakeholders are assured that the Minister for Health and Social Services has committed to a full review of the Putting Things Right Regulations and Guidance in the future.

A Welsh version of these amendments has not been provided as the original PTR guidance was not translated. The future review of PTR mentioned above will look to translate the Regulations and Guidance as they are issued.

The amendments listed here are related to the introduction of the Duty of Candour and the amendments to PTR Regulations:

Section of PTR Guidance	Changes to guidance
Executive Summary, Page 7, fourth paragraph, insert	From 1 April 2023, the Regulations and, therefore, the Guidance also apply to Special Health Authorities in Wales.
Section 1, Introduction, paragraph 1.8, “Welsh NHS Body”, insert after first sentence	The Regulations and, therefore, the Guidance also apply to Special Health Authorities in Wales. However, the application of the Regulations are limited to the provision of health care by Health Improvement and Education Wales (“HEIW”).
Section 1, Introduction, paragraph 1.8, insert definition	“representative” has the following meaning: :

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of “representative” at end of definitions	<p>A concern may be notified by a person (in this regulation referred to as a representative) acting on behalf of a person who:</p> <ul style="list-style-type: none"> (a) has died; (b) is a child; (c) is unable to notify the concern themselves because they lack capacity within the meaning of the Mental Capacity Act 2005(1); or (d) has requested the representative to act on their behalf.
Section 1, Introduction – concerns dealt with at the point of service delivery, paragraph 1.11 delete third sentence and insert.	This now includes any concerns which have resolved to the satisfaction of the person who notified by the end of the next working day, (previously this only included concerns notified verbally).
Section 3, Organisational Development and Training, after paragraph 3.5 insert	In accordance with the Duty of Candour Procedure (Wales) Regulations 2023, staff will undergo relevant training to ensure they are aware of and are able to implement the requirements of the duty of candour. The training is graded: ranging from all staff basic training to more detailed training for staff who manage concerns.
Section 4, General Principles and Requirements – Principles that apply to the handling of concerns, insert after the first sentence of paragraph 4.1	<p>Responsible bodies must not provide personal data to persons who are not the data subject (unless that person is a representative of the data subject). “Data subject” and “personal data” have the same meaning as in the Data Protection Act 2018 (see section 3 of that Act).”</p> <p>NB. This is not a change to the current policy position but rather a terminology change.</p>
Section 4, General Principles and Requirements – Principles that apply to the handling of concerns, after paragraph 4.13 insert	When the duty of candour is triggered the time period for responding to a concern runs from the date the NHS body makes the ‘in person’ notification to the service user or person acting on their behalf under Regulation 4 of the Candour Procedure Regulations.
Section 5, Raising a Concern – How a concern can be raised, after paragraph 5.4 insert	It should be noted that Regulation 9 the Duty of Candour Procedure (Wales) Regulations 2023 requires NHS bodies to keep an accurate written record for each notifiable adverse outcome in respect of which the candour procedure is

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	<p>followed. The written record must include every document and piece of correspondence relating to the notifiable adverse outcome, including but not limited to:</p> <ul style="list-style-type: none"> • the notification of the duty; • attempts to contact the service user/person acting on their behalf. • any decision by the service user/person acting on their behalf not to be contacted in relation to the duty of candour; and • all documentation relating to the investigation of the and review of the notifiable adverse outcome, that is undertaken by the NHS body, giving rise to the triggering of the duty, including the response or interim report issued under regulations 24, 26 or 31 of the PTR Regulations. <p>It is considered good practice to record any decision not to trigger the duty (where triggering was contemplated). It is important that accurate records are kept supporting quality assurance mechanisms needed to identify areas for learning and improvement and also to enable NHS bodies to comply with their reporting requirements under the Act which are considered in part 11 below.</p> <p>It is envisaged that the Datix Cymru system will be utilised for the purposes of reporting and recording keeping.</p>
<p>Section 5, Raising a Concern – Who can raise a concern, paragraph 5.6 delete first bullet point and change (to replace ‘a person’ with ‘a patient’</p>	<ul style="list-style-type: none"> • a patient who is receiving or has received services from a responsible body”
<p>Section 5, Raising a Concern – Who can raise a concern, paragraph 5.6 delete sixth and seventh bullet point and change (to replace ‘a third party’ with ‘a representative’</p>	<ul style="list-style-type: none"> • a representative acting on behalf of a person who is unable to raise a concern e.g. a young child or someone who lacks capacity to act on their own behalf; or because that person wants someone else to represent them; • a representative on behalf of a person who has died.

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Section 5, Raising a Concern – Concerns raised by a third party, delete heading and change (to replace ‘third party’ with ‘representative’)	Concerns raised by a representative
Section 5, Raising a Concern – Concerns raised by a third, paragraph 5.7, delete this wording from the first sentence	Delete – ‘a third-party acts as’
Section 5, Raising a Concern – Concerns raised by or about children and young people, paragraph 5.9, delete the last sentence	Delete - The Responsible Body is under no obligation to provide a response to the person who raised the concern in the first place.
Section 5, Raising a Concern – Concerns raised by staff, after paragraph 5.11 change to	<p>Where a concern is notified by a member of staff and initial investigation determines that it has resulted in moderate or severe harm or death, the patient must be:</p> <ul style="list-style-type: none"> • notified of the concern unless they have already been notified under Regulation 4(1) of the Duty of Candour Regulations; and • Involved in the investigation of the concern unless it is in their best interests not to be involved under Regulation 12 (8).
Section 5, Raising a Concern – Concerns – what people <u>cannot</u> raise as concerns under these arrangements, para 5.13, change third bullet to add the following after ‘Wales’.	<ul style="list-style-type: none"> • unless the responsible body considers it appropriate to consider the concern following the conclusion of the Ombudsman’s investigation.
Section 5, Raising a Concern – Concerns – what people <u>cannot</u> raise as concerns under these arrangements, para 5.13, delete sixth bullet point and replace with.	<ul style="list-style-type: none"> • any concern resolved to the satisfaction of the person who notified by the end of the next working day is excluded (previously this exclusion only applies to concerns notified verbally that were satisfied).
Section 5, Raising a Concern – Concerns – what people	<ul style="list-style-type: none"> • Concerns, in respect of which court proceedings have already been issued, including the pre-action stage of those

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<p><u>cannot</u> raise as concerns under these arrangements, para 5.13, change ninth bullet to.</p>	<p>proceedings. If court proceedings are issued when a concern is already under investigation in accordance with the Regulations, all further investigation of the concern must stop (see Regulation 14(1)(i) and Regulation 2(5)(c) of the 2023 Regulations.</p>
<p>Section 5, Raising a Concern – Concerns – what people <u>cannot</u> raise as concerns under these arrangements, para 5.13, insert new bullet point at end.</p>	<ul style="list-style-type: none"> • where the responsible body is Health Education and Improvement Wales, a concern which does not relate to the provision of health care by that body.
<p>Section 6, Handling and Investigating Concerns, after paragraph 6.30 insert new wording in place of paragraphs 6.31 and 6.32</p>	<p>Duty of Candour</p> <p>The underpinning principles of these arrangements are openness and transparency. It is important to ensure that when incidents occur that the patient or their representative is involved as much as possible in the investigation and is assured about lessons learned. This is also the same for any complaint received. Engagement and excellent communication is essential to the successful management of any concern, regardless of grade or complexity.</p> <p>In addition to the Being Open principles, the Health and Social Care (Quality & Engagement) (Wales) Act (the Act) places a legal duty of candour on NHS providers. The duty seeks to promote a culture of openness and improves the quality of care within the health service by encouraging organisational learning.</p> <p>Where a service user suffers an adverse outcome which has or could result in unexpected or unintended harm that is more than minimal (moderate or severe harm or death), and the health care was or may have been a factor, the Responsible Body must, in accordance with the Act and the regulations made thereunder notify the service user or his or her representative of the concern. This should be managed in accordance with the organisation’s Duty of Candour procedure and advice set out in the Duty of Candour Guidance.</p>

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	<p>There also remains a requirement in Regulation 12(7) to advise the patient to whom the concern relates, or his or her representative, of the notification of the concern where the Responsible Body's initial investigation determines that there has been moderate or severe harm or death. However, if the patient or their representative has already been notified of the concern in accordance with the Duty of Candour Regulations there is no requirement to inform the patient or their representative again. Regulation 12(7) also requires that the Responsible Body involves the patient or his or her representative in the investigation of the concern unless Regulation 12(8) applies and it is not in the interests of the patient to involve them in the investigation. This may be the case for example, if involving them could cause deterioration in their physical and/or mental health. In line with the general principles of the Duty of Candour, there, is still a need to <u>inform</u> a patient of the concern.</p>
<p>Section 6, Responding to a concern, amend first sentence of existing paragraph 6.75</p>	<p>A Responsible Body should attempt to issue a final response under Regulation 24 within <u>30 working days</u> beginning with the later of the day upon which it received notification of the concern, or, where the duty of candour comes into effect in relation to the subject matter of the concern, the day upon which the 'in-person' notification under Regulation 4(1) of the Duty of Candour Regulations was given.</p>
<p>Section 6, Handling and Investigating Concerns – Final responses which exceed 30 working days, amend existing paragraph 6.79.</p>	<p>Final responses under Regulation 24 should be issued within working 30 days beginning on whichever is the later, either:</p> <ul style="list-style-type: none"> • the day upon which it received notification of the concern; or • if triggered by the duty of candour, the day upon which 'in-person' notification was given under regulation 4(1) of the Duty of Candour Regulations. <p>If it is not possible to provide a response within 30 working days, the person raising the concern must be informed and provided with an explanation for the delay. The response must then be sent as soon as possible and within 6 months beginning on whichever is the later, either:</p> <ul style="list-style-type: none"> • the day upon notification of the concern was received; or

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	<ul style="list-style-type: none"> where the duty of candour is triggered, the day upon which the 'in-person' notification under Regulation 4(1) of the Duty of Candour Regulations was given.
<p>Section 6, Handling and Investigating Concerns – Interim response under Regulation 26, amend existing paragraph 6.81</p>	<p>Where an NHS body considers there is or may be a qualifying liability which, in accordance with Regulation 29, would attract financial compensation of £25,000 or less, an interim report under Regulation 26 needs to be issued within <u>30 working days</u> of whichever is the later, either:</p> <ul style="list-style-type: none"> the day upon notification of the concern was received; or where the duty of candour is triggered, the day upon which the 'in-person' notification under Regulation 4(1) of the Duty of Candour Regulations was given
<p>Section 6, Handling and Investigating Concerns – Interim responses which exceed 30 working days, amend existing paragraph 6.84</p>	<p>The interim report under Regulation 26 needs to be issued within <u>30 working days</u> of whichever is the later, either:</p> <ul style="list-style-type: none"> the day upon notification of the concern was received; or where the duty of candour is triggered, the day upon which the 'in-person' notification under Regulation 4(1) of the Duty of Candour Regulations was given. <p>If this is not possible the person raising the concern must be informed of the reason for delay and the interim report should be sent within 6 months of whichever is the later, either:</p> <ul style="list-style-type: none"> the day upon notification of the concern was received; or where the duty of candour is triggered, the day upon which the 'in-person' notification under Regulation 4(1) of the Duty of Candour Regulations was given.
<p>Section 7, Redress, amend second sentence in existing paragraph 7.1 to the following.</p>	<p>If at anytime during the management and investigation of a concern it is considered that a qualifying liability that would attract financial compensation of £25,000 or less exists or may</p>

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	<p>exist (a Welsh NHS body must not offer Redress in the form of compensation when the value of the qualifying liability exceeds £25,000), a Welsh NHS body must determine whether or not an offer of Redress should be made.</p>
<p>Section 7, Redress – Tariff, remove existing paragraphs 7.36 to 7.38 and replace</p>	<p>The assessment of general damages for pain, suffering and loss of amenity is calculated solely on a common law basis. Welsh NHS bodies are advised to consult Legal & Risk Services for support when determining the amount of damages a concern attracts.</p>
<p>Section 7, Redress – communicating the decision, amend existing paragraph 7.41</p>	<p>The offer of Redress or decision not to make an offer must be communicated to the person raising the concern, or their representative, within 12 months of whichever is the later, either:</p> <ul style="list-style-type: none"> • the day upon notification of the concern was received; or • where the duty of candour is triggered, the day upon which the ‘in-person’ notification under Regulation 4(1) of the Duty of Candour Regulations was given.
<p>Section 7, Redress – investigation report, amend existing paragraph 7.48</p>	<p>Where a person is seeking Redress, the findings of the investigation must be recorded in an investigation report. The investigation report, in accordance with Regulation 26, must be provided to the person who raised the concern and is seeking Redress as soon as reasonably practicable and <u>within 12 months</u> of whichever is the later, either:</p> <ul style="list-style-type: none"> • the day upon notification of the concern was received; or • where the duty of candour is triggered, the day upon which the ‘in-person’ notification under Regulation 4(1) of the Duty of Candour Regulations was given.
<p>Appendix N – Template interim response under Regulation 26, amend first sentence.</p>	<p>Regulation 26 - Interim Report template – where there is or there may be qualifying liability (to be issued within <u>30 working days</u> of whichever is the later, either</p> <ul style="list-style-type: none"> • the day upon notification of the concern was received; or

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	<ul style="list-style-type: none"> where the duty of candour is triggered, the day upon which the 'in-person' notification under Regulation 4(1) of the Duty of Candour Regulations was given.
Appendix Q – Tariff for the Assessment of claims below £25,000	Remove Appendix Q