



The Duty of Candour Consultation Questions

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

Date of issue: 20th September 2022

Action required: Responses by 13th December 2022

The Duty of Candour

The Duty of Candour means NHS organisations have a Duty to be open and honest with people they are caring for when things go wrong, and harm has occurred. And they should try and put things right if they have caused harm.

The Candour process will build on the work that has already been started in Wales as part of the 'Putting Things Right' (PTR) process to embed candid behaviour by making openness and transparency with people in relation to their care and treatment a normal part of their culture across these organisations in Wales. It also adds to the existing individual professional Duty of Candour that clinicians already have as part of their professional regulations.

The purpose of this consultation is to invite views on the guidance and Regulations that are necessary to implement the Duty of Candour namely:

- the [Duty of Candour Guidance](#), and
- the [Duty of Candour Procedure \(Wales\) Regulations 2023 \("the Candour Procedure Regulations"\)](#),

When the Duty of Candour is applied

The Act provides that the Duty of Candour will apply when two conditions are met:

- i. firstly, a service user to whom health care is being or has been provided by a NHS organisation has suffered an adverse outcome; and
- ii. secondly, the provision of health care was or may have been a factor in the service user suffering that outcome.

Part 4 of the guidance describes when the Duty of Candour procedure applies.

Question 1

Is the Guidance on when the Duty of Candour applies clear?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

[Annex A](#) explains the Duty of Candour trigger review process as a flow chart

Question 2

Is the flowchart at Annex A, a useful tool for determining whether the Duty has been triggered?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

A condition that needs to be satisfied before the Duty applies is the service user must suffer an adverse outcome. A service user suffers an adverse outcome if the user experiences, or if the circumstances are such that they could experience; any unexpected or unintended harm that is more than minimal.

Practical guidance in relation to this in the [Guidance at pages 8-9](#) and [Annex H case study 9](#).

Question 3

Are the guidance and case studies useful in determining what is meant by harm that 'could' be experienced?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

Welcome the inclusion of a number of pharmacy, prescribing and medication examples in the case studies. However, further guidance should be offered to clarify the organisation responsibility for Duty of Candour and individual professional actions and responsibility (as set out by the professional regulator). This would be helpful throughout the guidance.

The Act, states that more than minimal harm is necessary to trigger the Duty of Candour. The proposal is that the meaning of more than minimal harm is 'moderate harm, severe harm and death'

[Annex B](#) explains what is meant by moderate harm, severe harm, and death

Question 4

Do you agree that setting the threshold for triggering the Duty of Candour at moderate harm, severe harm or death reaches the right balance between informing Service Users and not overburdening NHS providers?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

The examples in case studies are helpful to clarify

Question 5

Does the harm framework at Annex B provide useful guidance on the type of harm that will fall into the categories of moderate, severe harm or death?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

Question 6

Do you consider the case study examples set out in Annex H to be sufficiently comprehensive to explain when the Duty of Candour would be generated?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

A good range of examples is available

The relationship with professional duties

Part 2 of the guidance also explains how the Duty of Candour under the Act interrelates with the professional duties of Candour that many clinicians (including GPs, hospital doctors, dentists, nurses, pharmacists, ophthalmic practitioners, allied health professionals etc.) are obliged to follow

Question 7

Is the relationship between the professional Duty of Candour that many health professionals are subject to and the statutory Duty of Candour clear?

Yes

No ✓

Please provide any comments or further explanation (in particular if response is no).

Further clarification on how the individual and organisational duties inter-relate would be helpful, including the investigation and reporting requirements. Should an individual professional report be submitted via their employer (or contractor) organisation?

The Duty of Candour procedure

- Part 7 of the guidance provides some further explanation of the intended operation of the Duty of Candour procedure

Annexes C and F1 explain the process.

Question 8

Is the guidance on the operation of the Duty of Candour procedure at page 11 of the guidance clear?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Question 9

Are the flow charts at Annexes C and F1 useful as an aid to understanding how the procedure will operate?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Commissioned Services

an NHS organisation is responsible for complying with the Duty of Candour in relation to all health care which it actually provides:

- Where a local health board enters into arrangements with a primary care provider (such as a GP) for the provision of NHS services, it is the primary care provider that is subject to the Duty

If a local health board entered into an arrangement with an independent provider for the provision of services, the Duty would remain with the local health board.

[Section 11 of the guidance](#) clarifies which organisation will be responsible for complying with the Duty of Candour in situations where health services are provided by one organisation on behalf of another.

Question 10

Is the guidance clear on how the Duty of Candour applies to commissioned services?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

As noted above, this could be made clearer

Question 11

The procedure flow chart at Annex A1 shows the procedure to follow when services are commissioned. Is the process clear?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

A contractual arrangement with an independent community pharmacy contractor may be for an NHS service or a private health care service. To be clear, is the NHS service an LHB duty of candour and the private service the responsibility of the contractor?

Harm that occurs to Service Users whilst waiting for diagnostics or care from the NHS

There will be occasions when the Duty of Candour is triggered because of moderate, severe harm or death being suffered by people waiting for treatment on waiting lists. This would be where the harm caused that was 'unintended or unexpected'

- 1) which goes over and above what might reasonably be expected or intended considering factors such as the person's condition, the number of people waiting for treatment and the availability of resources to provide that treatment.
or
- 2) for the purposes of Duty of Candour an error occurred in the process of administration or in the admission to the list or subsequent care during the waiting list process.

For more detailed information read the section in the [guidance on page 20](#)

Question 12

Is the guidance clear when harm to Service Users that occurs whilst waiting for diagnostics and treatment triggers the Duty of Candour?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Question 13

What further clarification do you consider would be helpful for NHS organisations and service users with regards to harm sustained whilst waiting for diagnostics and treatment?

Please provide any comments or further explanation

Annual reporting of Duty of Candour:

The Act also provides for NHS organisations to report annually on whether the Duty of Candour has come into effect in relation to the NHS organisation during the reporting year (each financial year). Guidance in relation to the reporting requirements is set out in part 11 of the Guidance, with an explanatory flow chart at [Annex G](#).

Question 14

Is the requirement for Local Health Boards, NHS Trusts, and Special Health Authorities, to publish their Candour reports clear?

Yes ✓ (*although clarity for contracted NHS services would be helpful*)

No

Please provide any comments or further explanation (in particular if response is no).

Question 15

In relation to the reporting flow chart set out in Annex G, is the process clear?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

The Act states that reports on Candour must be published as soon as practicable we have said for primary care providers this is no later than 30th Sept and for Health Boards, Trusts, and Special Health Authorities no later than 31st Oct.

This is in line with the 6 months of investigation time for incidents under 'Putting Things Right'.

Question 16

Are the annual reporting dates of 30th Sept for primary care providers and 31st October for Local Health Board's, NHS trusts and Special Health Authorities' reasonable?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

Question 17

Is it reasonable to suggest the Duty of Candour report should be aligned to the existing annual PTR report already in place to avoid duplication?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

Notification of Duty of Candour

The Regulations require the NHS organisation to notify the service user or someone acting on their behalf at the point it first becomes aware that the Duty of Candour has been triggered.

Guidance on what is meant by 'on first becoming aware' is set out at pages 11 of the guidance. This is the point, at which it is known that harm (moderate, severe or death) to a service user during their NHS care has occurred, or may do, and the care is likely to have been the cause.

Question 18

Is the explanation of 'on first becoming aware' in the guidance sufficiently clear to enable NHS organisations to know when the Candour procedure must start?

Yes ✓ (*though would be helpful to reinforce the importance of a timely response, from the date of procedure/intervention, as stated*)

No

Please provide any comments or further explanation (in particular if response is no).

The notification may be made to a person who is acting on the service user's behalf, where the:

- service user has died

- or in the opinion of the NHS organisation, lacking in capacity or otherwise unable to make decisions about the service provided
- or where a service user with capacity has asked for someone else to act on their behalf.

Question 19

In circumstances where the service user is unable or unwilling to be notified the Duty of Candour has been triggered, are the provisions setting out who may act on the service user's behalf sufficiently comprehensive?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

When you cannot get hold of the service user or they do not want to be contacted Regulation 7(2 & 3) requires the NHS organisation to make a record of attempts to contact or communicate with the service user and keep records.

Read more detail on regulation 7 in the [Regulations](#)

Question 20

Are the provisions at regulation 7(3) which allow an NHS organisation to record when it will not be engaging with a service user or a person acting on their behalf, either because:

- (i) they have made reasonable attempts to contact them and failed; or
- (ii) where the service user has determined, they do not wish to communicate about the Duty, proportionate?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

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Question 21

Do regulations 7(2) and 7(3) strike the right balance between the needs of Service Users or persons acting on their behalf and level of burden placed on NHS organisations?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

The ‘in person notification’

Regulation 4 of the Regulations requires an NHS organisation to make an ‘in person notification’ to the service user or a person acting on their behalf.

This is ‘communication that is made by telephone call, audio visual communication or a face-to-face meeting’.

Question 22

Do you agree that ‘in person’ notification is appropriate and proportionate when informing a service user or their representative that the Duty of Candour has been triggered?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

New page

When deciding which method to use the Regulations specify the criteria to be considered when making this decision such as:

- the severity of the harm caused
- the nature and complexity of what has happened
- the personal circumstances of the service user and their preferred method of communication.

Question 23

Do you agree that it is appropriate and proportionate that the NHS organisation has the choice of which form of ‘in person’ notification is most appropriate, considering these factors above?

Yes (*with decision-making clearly documented and adjusted when service user preference is available*)

No

Please provide any comments or further explanation (in particular if response is no).

The apology

To support NHS organisations in saying sorry, the guidance (section 7e) provides some further guidance to NHS organisations on how to make a personal, meaningful apology.

Additional resources are available in [Annex E](#)

Question 24

Does the guidance on how to make a meaningful apology set out at section 7e and Annex E of the guidance provide sufficient information and advice to ensure a personal, meaningful apology is conveyed?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Written notification

In accordance with Regulation 5, the NHS organisation must follow the in-person notification with a written notification within 2 working days. This is to ensure the service user or person acting on their behalf has a written record of what was discussed which will aid their understanding of the process.

Question 25

Do you agree that 'in person' notification should be followed up by a written notification?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Question 26

Do you agree the requirement placed on NHS organisations to take all reasonable steps to send the written notification within two working days from the date of the in-person notification is reasonable and proportionate?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Training and support of staff

Regulation 8 details the requirements for staff training and support. Regulation 8(1) sets out which staff must receive training on the Duty of Candour.

Further information on the type of staff that will be trained is in the Regulations

Question 27

Do the training requirements cover all the staff that require training?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

All staff must be made aware of the statutory requirements (part of mandatory training?)

Question 28

What type of training do you think would be required by NHS staff in addition to the current NHS training for the Duty of Candour to be successful?

Please provide any comments or further explanation.

Regulation 8(2) provides that an NHS organisation must provide staff who are involved in a notifiable adverse outcome with details of services which may aid the member of staff – taking account of the circumstances of the notifiable adverse outcome and the staff member's needs.

Further information on the support of staff involved is in the Regulation 8

Question 29

Are the provisions related to staff support proportionate?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Organisational governance and oversight of the Duty of Candour

Regulations 10 and 11 set out the requirements to assist NHS organisations in devising a governance structure to ensure compliance with the Duty.

Further detail on these requirements are in Regulations 10 and 11.

Question 30

Do Regulations 10 and 11 assist NHS organisations in establishing an effective governance structure to ensure compliance with the Duty of Candour procedure?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Question 31

Do the regulations assist an organisation in providing the right level of leadership to fulfil its Duty of Candour responsibilities?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

Duty of Candour and the PTR procedure

The PTR Regulations are extended to apply from the date the NHS organisation makes the in-person notification, rather than the date that the NHS Organisation received notification of the concern. This designed so that the Duty of Candour being triggered and the link to the 'Putting Things Right' process work in sequence and avoid duplication.

An overview of the Candour procedure and review process steps that need to be followed is in Annex C in the guidance and the [PTR Regulation amendments](#).

Question 32

Do you agree the time limits under the PTR Regulations should, when the Duty of Candour is triggered, run from the date of the in-person notification rather than the date the NHS Organisation would have been notified of the incident?

Yes ✓

No

Please provide any comments or further explanation (in particular if response is no).

'Putting Things Right' says that you can decide not to tell someone if harm was caused if it is in their best interest. The NHS would still need to write up details of this. And say why they decided not to tell the person.

Now 'Putting Things Right' says that the person must be told if something went wrong with their care, and Duty of Candour is being used.

But they do not need to be involved in the process or the investigation, if that is what is best for them.

Question 33

Do you think changing the 'Putting Things Right' rules like this will cause problems?

For example, do you think it would be better to not tell the person what has happened if it is in their best interest?

Yes ✓ as long as rationale is clearly documented and the time line for investigation (usual started on notification) runs from the date of that decision

No

Please add any other comments you have.

A flow chart is available in [Annex F1](#)

Question 34

Is the link between the Duty of Candour and the PTR process clear in the guidance and Annex F1?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Duty of Candour and the PTR Amendment Regulations

A summary of the changes to be made to the guidance in relation to the Duty of Candour and the [PTR Amendment Regulations](#)

Question 35

Are the proposed changes to the [PTR guidance](#) in respect of the Duty of Candour and PTR Amendment Regulations clear?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Question 36

Do you think that the changes made to the PTR guidance are sufficient to provide clarity on how Duty of Candour interacts in the PTR procedures?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

Integrated Impact Assessments

It is fundamental to the policy making process to consider health disparities and to assess and understand how different groups are impacted differently by the policies that we implement.

Our consideration to date suggests that the proposals could have a disproportionate indirect impact (but not a negative impact) on people with certain characteristics – notably disability and age. The reason for this indirect impact is that people in these groups have more frequent interactions with the health care system and, as a result, more likelihood of the Duty of Candour being triggered.

Question 37

What are your views on how the proposals in this consultation might impact?

- on people with protected characteristics as defined under the Equality Act 2010¹;
- on health disparities; or on vulnerable groups in our society.

Please provide your comments here:

No impact to note

Impact on Welsh language

Question 38

We would like to know your views on the effects that the Duty of Candour proposals would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favorably than English.

For example, what effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

Please provide your comments:

Choice of language to use in communications would mitigate any risk

Question 39

Please also explain how you believe the proposed Duty of Candour policy could have positive or negative effects on opportunities for people to use the Welsh language or treat it no less favorably than the English language?

Please provide your comments:

The implementation of the Duty of Candour to Welsh NHS organisations is complex however your views are essential to help us do this successfully.

Question 40

We have asked several specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:

Please provide your comments:

No further comment. The opportunity to learn and improve as a result of untoward or unexpected outcomes is well rehearsed

¹ The following characteristics are protected characteristics from the Equality Act 2010—age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief; sex; sexual orientation.

Consultation Response Form

Your name: Darrell Baker

Organisation (if applicable): Royal Pharmaceutical Society

The Royal Pharmaceutical Society is the professional body for pharmacists and pharmacy in Great Britain. We lead and support the development of the pharmacy profession to improve the public's health and wellbeing, including through advancements in science, research and education.

Option to designate citizen or service user rather than organisation

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