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Welsh Government

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Welsh Government

Consultation Document

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

Consultation on the Statutory Guidance and Regulations required to implement the Duty of Candour

Date of issue: 20 September 2022

Action required: Responses by 13 December 2022

Mae'r ddogfen hon ar gael yn Gymraeg hefyd /
This document is also available in Welsh

Overview

The Health and Social Care (Quality and Engagement) (Wales) Act 2020 places a duty of candour on NHS bodies in Wales. This Consultation seeks your views on the Regulations and Statutory Guidance needed to implement that duty.

How to respond

This consultation will close on 13 December 2022
You can respond online, by email or by post.

Online

Please complete the consultation response form on the consultation pages of the Welsh Government website.

Email

Please complete the consultation response form and send it to HSCQualityandEngagement@gov.wales

Post

Population Healthcare Division
Health and Social Care Group
Welsh Government Offices
Cathays Park
Cardiff
CF10 3NQ

Further information and related documents

Large print, Braille and alternative language versions of this document are available on request.

Contact details

For further information:

Population Healthcare Division
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Mae'r ddogfen hon ar gael yn Gymraeg hefyd

This document is also available in Welsh

UK General Data Protection Regulation (UK GDPR[1])

The Welsh Government will be data controller for any personal data you provide as part of your response to the consultation. Welsh Ministers have statutory powers they will rely on to process this personal data which will enable them to make informed decisions about how they exercise their public functions. Any response you send us will be seen in full by Welsh Government staff dealing with the issues which this consultation is about or planning future consultations. Where the Welsh Government undertakes further analysis of consultation responses then this work may be commissioned to be carried out by an accredited third party (e.g. a research organisation or a consultancy company). Any such work will only be undertaken under contract. Welsh Government's standard terms and conditions for such contracts set out strict requirements for the processing and safekeeping of personal data.

In order to show that the consultation was carried out properly, the Welsh Government intends to publish a summary of the responses to this document. We may also publish responses in full. Normally, the name and address (or part of the address) of the person or organisation who sent the response are published with the response. If you do not want your name or address published, please tell us this in writing when you send your response. We will then redact them before publishing.

You should also be aware of our responsibilities under Freedom of Information legislation

If your details are published as part of the consultation response, then these published reports will be retained indefinitely. Any of your data held otherwise by Welsh Government will be kept for no more than three years.

Under the data protection legislation, you have the right:

- to be informed of the personal data held about you and to access it
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- to (in certain circumstances) object to or restrict processing
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- to (in certain circumstances) data portability
- to lodge a complaint with the Information Commissioner's Office (ICO) who is our independent regulator or data protection. Details about the information the Welsh Government holds and its use, or if you want to exercise your rights under the UK GDPR, please see contact details below:

Data Protection Officer
Welsh Government
Cathays Park
CARDIFF
CF10 3NQ
e-mail:
Data.ProtectionOfficer@gov.wales

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF
Tel: 01625 545 745 or0303 123 1113
Website: https://ico.org.uk/

[1] General Data Protection Regulation Data protection act 2018 https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/

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Foreword by the Minister for Health and Social Services

The NHS in Wales must be a place where an open, learning, non-blame culture thrives and people are made to feel welcome and respected, whatever their background.

Inevitably when complex services are being delivered some people will suffer harm. When they do, how NHS bodies deal with these situations is very important and can make a tremendous difference to people's experience and to their on-going relationship with their care provider. This is of vital importance in health care settings where people often have long standing relationships.

In general, people want to be told honestly about what has happened and be reassured that, where applicable, lessons have been learned. Staff too need to be supported through the process.

The Duty of Candour provisions in the Health and Social Care (Quality and Engagement)(Wales) Act 2020[2] and the Duty of Candour Statutory Guidance 2023[3] and The Duty of Candour Procedure (Wales) Regulations 2023[4] that will underpin the duty are designed to support this ethos.

The candour process will build on the work that has already been started in Wales as part of the Putting Things Right (PTR)[5] 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 bodies in Wales. It also adds to the existing individual professional duty of candour that clinicians already have as part of their professional regulations.

I also wish to put on record my thanks to the Quality and Candour Steering Group and all of those who attended virtual workshop sessions and engagement events to discuss the developing policy for the implementation of the Duty of Candour. I know many NHS staff (from both primary and secondary care), independent health providers, representatives from the third sector, professional bodies and members of the public gave freely of their time to support us in this important work.

Eluned Morgan MS

Minister for Health and Social Services

[2] Health and Social Care (Quality and Engagement)(Wales) Act 2020 Health and Social Care (Quality and Engagement) (Wales) Act 2020 - Explanatory Notes (legislation.gov.uk)
[3] From this point on will be referred to as 'the Guidance'
[4] From this point on will be referred to as 'the Regulations'
[5] National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 https://www.legislation.gov.uk/wsi/2011/704/contents/made

Introduction

The Health and Social Care (Quality and Engagement) (Wales) Act 2020 ("the Act") was passed in March 2020 and received Royal Assent in June 2020.It contains four main parts.

Part 3 places a statutory Duty of Candour on NHS bodies in Wales. It is intended to bring the duty into force from 1 April 2023

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, at Enclosure 1; and
- the Duty of Candour Procedure (Wales) Regulations 2023 ("the Candour Procedure Regulations"), at Enclosure 2.

The Consultation also invites views on the changes that need to be made to The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023 at Enclosure 3. It also invites views on changes to be made to the Putting Things Right Guidance ("PTR Guidance") at Enclosure 4 as a consequence of the introduction of the Duty of Candour. These changes we consider largely minor and as such there are no specific questions on particular amendments however, we welcome responses on these amendments in the general questions on changes to PTR. The exception in these amendments is the inclusion of Statutory Health Authorities in the PTR Regulations and Guidance which we do not consider minor but again, would welcome responses in the general questions on PTR.

Overview of the Act – Legislative framework

The Act makes provision about a number of interrelated proposals relating to quality and public engagement in health and social care. Taken together the provisions are intended to have a cumulative positive benefit for the population of Wales and to put in place conditions which are conducive to improving health and well-being:

a. Part 1 of the Act provides an overview of the Act's main provisions.
b. Part 2 imposes a duty relating to improvement in the quality of health services on the Welsh Ministers and Health Boards, Trusts and Special Health Authorities in Wales.
c. Part 3 makes provision for and about a Duty of Candour in respect of health services.
d. Part 4 establishes, and makes provision about the functions of, the Citizen Voice Body for Health and Social Care, Wales, whose function is to represent the interests of the public in respect of health and social care and to provide advocacy services in respect of complaints. It also abolishes Community Health Councils and the Board of Community Health Councils.
e. Part 5 gives the Welsh Ministers the power to appoint vice-chairs of NHS Trusts.

This Consultation requests feedback on policy related to the Duty of Candour only as the Duty of Quality and the establishment of the Citizen Voice Body for Health and Social Care will be the subject of separate public consultations.

What we are hoping to achieve by the introduction of the Duty of Candour

All health and social care providers have a shared goal to deliver high quality care. There is evidence that increased openness, transparency and candour are associated with the delivery of higher quality health and social care[6] [7]. Organisations with open and transparent cultures are more likely to spend time learning from incidents, rather than trying to hide or be overly defensive about issues, and they are more likely to have processes and systems in place to listen to and support Service Users and staff when things go wrong.

Known barriers to disclosure include fear, a culture of secrecy and/or blame, a lack of confidence in communication skills, fears that Service Users will be upset and doubt that disclosure is effective in improving culture.

Health care professionals, such as doctors, nurses and allied health professionals, already have an *individual* duty of candour. Their regulatory bodies (such as the GMC, NMC and HCPC) already require them to be open and honest with patients where there have been failings in the care of patients.

The Duty of Candour, and it's underpinning Guidance and the Regulations are intended to support the further development of an open culture across NHS Wales.

The overarching intention is that in the event of a Service User suffering more than minimal harm, regardless of where the care is provided in Wales there will be open and honest communication in respect of this.

In social care, a Duty of Candour already exists for providers and responsible individuals of regulated services.

For independent health care providers in Wales, the intention is to place them under a Duty of Candour using regulation making powers under the Care Standards Act 2000[8]. Initially, the intention was to bring that duty into force at the same time as the duty on NHS bodies. However, we are now adopting a staggered approach, aiming to bring into force a Duty of Candour for independent providers in or around April 2024.

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[6] World Health Organization, Organisation for Economic Co-operation and Development, and The World Bank. Delivering quality health services: a global imperative for universal health coverage. [Internet]. Geneva; 2018. Available from: https://apps.who.int/iris/bitstream/handle/10665/272465/9789241513906-eng.pdf?ua=1

[7] Department of Health and Social Care and The Rt Hon Jeremy Hunt MP. Good care costs less [Internet]. GOV.UK. 2014 [cited 1 April 2019]. Available from: https://www.gov.uk/government/speeches/good-care-costs-less

[8] Care Standards Act 2000 https://www.legislation.gov.uk/ukpga/2000/14/contents

Part 3 of the Act contains the provisions related to the Duty of Candour. A link to the full text of the Act is below:

Health and Social Care (Quality and Engagement) (Wales) Act 2020 (legislation.gov.uk)

The provisions in the Act are not subject to consultation – they are fixed as they were considered by the Senedd as part of the legislative process.

The primary purpose of the Act's candour provisions is to help achieve a system wide approach to being open and honest when a person suffers harm.

We believe the successful implementation of the duty of candour across the NHS in Wales will encourage better decision making and ultimately deliver better outcomes for all people who access health services. Your views are an important part of the implementation process.

Chapter One

Statutory Guidance Duty of Candour

Aim of the Statutory Guidance

The guidance aims to provide a framework of best practice to assist providers of NHS services in the implementation of the Duty of Candour. It addresses the key implementation issues, which may be experienced as a result of the introduction of the new duty.

It is intended to provide practical support to NHS bodies who will be applying the duty, providing guidance on what the Duty of Candour means, and to whom and how it applies. It has been developed taking into account learning from other parts of the UK that have already implemented a Duty of Candour. In particular, it contains a library of case studies at Annex H, which provide practical examples of scenarios across different areas of clinical practice showing incidents that will trigger the duty of candour as well as those that will not.

Although aimed at clinicians, and NHS bodies, the Guidance will also act as a useful tool for third sector organisations who may wish to learn more about the duty and for members of the public. However, the intention is to publish a leaflet (including an easy read leaflet), as well as a short video, that will inform members of the public about the new duty and what it means for them.

Enclosure 1 contains the statutory duty of candour guidance document.

There are a number of consultation questions below which, specifically relate to the Guidance.

When the Duty of Candour is triggered

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 body 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.

A Service User is treated as having suffered an adverse outcome if the Service User experiences, or if the circumstances are such that the Service User could experience, any unexpected or unintended harm that is more than minimal.

It is also relevant to note the duty is triggered where the provision of the health care was or may have been a factor in the Service User suffering the outcome. The outcome must therefore relate to the provision of the care by the NHS body rather than being solely attributable to the person's illness or underlying condition. It need not, be certain that the health care caused the harm. It is sufficient that the health care may have been a factor.

Part 4 of the Guidance provides the guidance on 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 of the Guidance sets out, in flow chart form, a duty of candour trigger review process.

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).

As set out above, one of the conditions 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.

In order for the duty to be properly understood and implemented it is important there is a clear understanding of what "could experience" means.

We have attempted to provide some practical guidance in relation to this in the Guidance at pages 8-9 and have included some examples of cases where harm could occur in the future in the library of case studies at Annex H (case studies 9, 10 and 11).

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).

The Act, states that more than minimal harm is necessary to trigger the duty of candour. Following Stakeholder workshops and Service User/patient representative focus sessions held between October 2021 and January 2022 the proposal is to set the meaning of more than minimal harm to mean "moderate harm, severe harm and death". This is in line with the thresholds set for duties of candour England and Scotland[9] and in Wales under the Putting Things Right arrangements

Your attention is drawn to part 6 page 9 of the guidance document and Annex B of the Guidance the levels of harm framework which explains what is meant by moderate harm, severe harm and death. Also, Annex H of the Guidance includes various case studies that demonstrate incidents where the duty of candour would and would not be applied.

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).

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).

[9] Where the statutory duties of candour apply to harm that is moderate and above. Duty of Candour (England) https://www.gov.uk/government/publications/nhs-screening-programmes-duty-of-candour/duty-of-candour Duty of Candour (Scotland) https://www.gov.scot/policies/healthcare-standards/duty-of-candour/

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).

The relationship with professional duties
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 (please see Part 2 of the guidance, page 6 and 7). The aim of the statutory duty is to complement this existing professional duty.

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).

The Guidance at Enclosure 1 provides some further explanation of the intended operation of the duty of candour procedure (at pages 10 -20).

Feedback from the stakeholder engagement events on the implementation of the duty also indicated that flow charts setting out the procedure to be followed when the duty of candour is triggered would be useful. Flow charts that explain the process are set out at Annexes C and F1.

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

Section 10 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 body on behalf of another.

In summary:

(i) an NHS body is responsible for complying with the duty of candour in relation to all health care which it actually provides. Therefore, for example, 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. Similarly, if a local health board enters into arrangements with a Trust in Wales for the provision of services it is the Trust that is subject to the duty;

(ii) if an NHS body enters into an arrangement for the provision of services with someone other than another NHS body, the duty to comply with the duty of candour rests with the NHS body. Therefore, for example, 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.

The Duty of Candour only applies where the health care is delivered in Wales as part of an NHS service. If, for example, a local health board enters into arrangements with an English provider for the provision of health care services, it is the English Duty of Candour under the Health and Social Care Act 2008[10] that will apply in relation to that care.

Question 10

Is the guidance clear on how the duty of candour applies to commissioned services?

[10] Health and Social Care Act (2008) accessed at https://www.legislation.gov.uk/ukpga/2008/14/contents

Yes

No

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

Question 11

The procedure flow chart set out in Annex A1 sets 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).

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

Since the Global SARS-CoV-2 Pandemic there has been continued pressure on resources within the NHS and subsequently many more patients are awaiting diagnostics, procedures and care on NHS waiting lists.

Where a service user suffers harm whilst on a waiting list, this could **potentially** trigger the duty of candour. For a Service User to be on a waiting list there must usually be a referral which involves an assessment and clinical decision – so they have almost invariably been provided with health care in order to get on the list. In addition, when a referral is received the service user is usually considered to be under the care of a consultant and there is often active monitoring of the waiting list which involves an element of clinical input and judgment which also amounts to the provision of health care. If so, then a person is being provided with healthcare following the referral.

However, the other key components that must be satisfied before the duty is triggered is that the service user to whom health care is being or has been provided by the body has suffered an “adverse outcome”, and that the provision of the health care was or may have been a factor in the service user suffering that outcome. 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. Waiting lists across all areas are managed and a key aspect of waiting list management is to manage lists to minimise harm to persons waiting for treatment. However, it is acknowledged that due to increasing demand for services and finite resource (made worse by the backlog caused by the pandemic) people do have to wait for treatment and, in many cases, their condition will deteriorate whilst they wait for that treatment. This deterioration is not unexpected for the purposes of the triggering of the Duty of Candour.

For example: a Service User is on a waiting list for a heart bypass, and they have a heart attack while on the waiting list this is not unexpected and is a risk that has been explained to the patient as to why they need surgery and so the duty would not apply.

That said, if the Service User had been missed off the list or incorrectly prioritised and this therefore created a delay resulting in harm then the Duty would apply since the resulting harm would be unexpected. There may also be other occasions where a service user suffers harm that is more than minimal whilst waiting for treatment on a waiting list and the harm that is suffered is considered to be "unexpected or unintended" i.e. which goes over and above what might reasonably be expected or intended taking into account factors such as the person's condition, the number of people waiting for treatment and the availability of resources to provide that treatment.

It is a bit more complex if a person is assessed by body A then referred to body B who puts them on a waiting list. This is often the case with referrals between general practice and hospital care.

In this case it is less clear, as if the person has been provided with health care as part of their assessment, the health care will have been provided by body A, the GP, so they have not been provided with health care "by the body" who is responsible for the delay. Whether it is met depends on what action body B takes when they receive the referral and whether there is any action taken that may amount to the provision of health care by Body B. It is strongly encouraged that the NHS bodies involved work together in partnership to deliver the duty of candour procedure and are fully involved in the process.

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 bodies 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 bodies to report annually on whether the duty of candour has come into effect in relation to the NHS Body 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

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 after the end of the financial year. The Act states that primary care providers must send their candour reports to the Health Board with whom they have entered into arrangements for the provision of NHS services. Health Boards, NHS Trusts and Special Health Authorities must publish the candour report on services they provide.

In order to give Local Health Boards time to compile the summary for inclusion in their report, primary care providers must provide their reports to their Local Health Board no later than **30th September** each year. This then enables Health Boards, Trusts and SHAs to include their candour reports in the annual accounts and performance report which is finalised and published no later than **31st** October each year. This is in line with the 6 months of investigation time for incidents under PTR. It should be published as a distinct section in the Putting Things Right Report.

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).

CHAPTER 2

Candour Procedure Regulations

The Act provides the Welsh Ministers must make Regulations that set out the procedure that must be followed by an NHS Body when the duty of candour applies. The Duty of Candour Procedure (Wales) Regulations 2023, attached at Enclosure 2 are supported by Part 7 of the Guidance which explains the candour procedure.

The Regulations require the NHS body 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;

(i) that the duty has come into effect,
(ii) of the identity of a 'nominated individual who will act as point of contact in respect of the candour procedure; and
(iii) of any further enquiries carried out by the body in respect of the circumstances in which the duty came into effect.

Guidance on what is meant by "on first becoming aware" is set out at pages 10 to 11 of the Guidance at Enclosure 1. 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 bodies to know when the candour procedure must start?

Yes

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;
- is 16 or over and lacks capacity (within the meaning of the Mental Capacity Act 2005) in relation to the matter;
- is under 16 and not competent to make a decision in relation to their care or treatment, or
- where a Service User with capacity has nominated 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).

Regulation 7(3) recognises that there will be situations where an NHS Body, despite taking reasonable steps, is unable to contact the Service User or person acting on their behalf to notify them the duty of candour has been triggered. It also caters for the possibility that a Service User or person acting on their behalf may decide they do not wish to communicate with the NHS Body about the duty of candour.

If this happens, the regulation requires the NHS Body to make a record of attempts to contact or communicate with the Service User/person acting on their behalf and provides that it is not required to communicate any further with the Service User/person acting on their behalf about the notifiable adverse outcome (i.e. the incident that triggered the application of the duty).

Question 20

Are the provisions at regulation 7(3) which allow an NHS Body 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).

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 bodies?

Yes

No

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

Regulation 4 of the Candour Procedure Regulations also requires an NHS body to make an “in person notification” to the Service User or a person acting on their behalf. “In person notification” must be by “in-person communication. An “in person communication” is defined as “communication that is made by telephone call, audio visual communication or a face-to-face meeting”. This was designed following feedback from the engagement events held.

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).

The NHS Body has discretion in which of these options is the most appropriate in any given case. The Guidance 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 and the personal circumstances of the Service User. This may also include any communication already undertaken with the Service User (or person acting on their behalf) and their preferred method of communication.

Question 23

Do you agree that it is appropriate and proportionate that the NHS Body has the choice of which form of “in person” notification is most appropriate, taking into account these factors above?

Yes

No

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

At the 'in person notification', the NHS Body must communicate the information set out at regulation 4(3) which means it must:

(a) give an account, as far as it is able to, of the circumstances of the notifiable adverse outcome

(b) explain why it thinks the duty of candour has been triggered;

(c) provide an apology;

(d) provide the name and contact details of the person nominated as the point of contact for the Service User or person acting on their behalf;

(e) provide an explanation of the further enquiries and actions that the NHS Body (or where services have been commissioned from a non-NHS Body the provider of the service) will take to investigate or review the circumstances of the notifiable adverse outcome, including any actions to be taken under the PTR Regulations,

(f) details of any services or support which the NHS body reasonably considers may provide assistance to the Service User or person acting on their behalf, taking into account their needs, and

(g) where the in person notification 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.

Regulation 13 makes it explicit that 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. This is an important point to emphasise that concerns about saying sorry to act must not act as a barrier to the successful implementation of the duty of candour.

To support NHS bodies in saying sorry, the Guidance at Enclosure 1 (section 7e) provides some further guidance to NHS bodies on how to make a personal, meaningful apology.

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).
In accordance with regulation 5, the NHS body must follow the in-person notification with a written notification. The rationale for a follow up written notification 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. The NHS Body must take all reasonable steps to send the written notification within two working days of the in-person notification.

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 bodies 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.

Training materials will be developed by the Welsh Government in conjunction with colleagues from NHS Shared Services Partnership and will be accessible online for NHS bodies (both primary and secondary care). The aim of the training will be to provide those who will need to know when the duty of candour is triggered and what the procedure is, with the knowledge and skills to enable them to fulfil the requirements of the duty.

Persons who must be trained are staff involved in the provision of care and treatment; those who investigate or manage "adverse outcomes"; and any other members of staff who are involved in the duty of candour procedure. Further information on the type of training that will be provided (the intention is to have graded training, so staff receive training appropriate to their roles in delivering the duty of candour) is set out at 7h of the Guidance at Enclosure 1.

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

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).

Question 28

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

Please provide any comments or further explanation

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 for oversight of the candour procedure. They are included to assist NHS bodies in devising a governance structure to ensure compliance with the duty. For consistency, the provisions are closely modelled on the existing provisions for oversight that are set out in the PTR Regulations.

Regulation 10 requires NHS bodies to designate a person to be responsible for maintaining a strategic oversight of the operation of the candour procedure set out in the Candour Procedure Regulations. Where the NHS body is a local health board, a Trust or a Special Health Authority (including NHS Blood and Transplant in relation to

its Welsh functions) the person must be one of its non-officer members or non-executive directors or Independent Members, as appropriate.
Primary Care providers are free to choose who is most suitable in their organisation to undertake this role.

Regulation 11 requires NHS bodies to designate a Responsible Executive Officer to ensure the organisation complies with the provisions of the Regulations.

Regulation 11(2) prescribes whom is to be appointed, for each “type” of NHS Body. The underlying principle is that the Responsible Executive Officer must be someone of sufficient seniority to ensure compliance with the provisions of the Regulations within their organisation.

Regulation 11(3) does allow the functions of the Responsible Officer to be delegated to another person provided that person is under the direct control and supervision of the Responsible Officer.

Regulation 12 sets limits on the disclosure of information – making it clear that the Candour Procedure Regulations do not require or permit a NHS Body to disclose any information which would prejudice a criminal investigation or prosecution or would contravene any restriction on disclosure arising by virtue of an enactment or rule of law. For example, this means that a NHS body would not have to release information that it holds under a duty of confidence or if releasing such information would result in a breach of GDPR.

Question 30

Do regulations 10 and 11 assist NHS bodies 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

Part 8 of the Guidance describes how the review of the circumstances that led to the duty of candour being triggered and the link to the Putting Things Right process work in sequence. The PTR Regulations already require NHS bodies[11] to investigate incidents concerning patient safety. Therefore, there is no duplication in terms of investigation as incidents that trigger the Duty of Candour should already be being investigated in accordance with the PTR process.

Annex C and F1 of the Guidance also provides an overview of the candour procedure and review process to set out the steps that need to be followed

Regulation 14 of the Candour Procedure Regulations makes amendments to the PTR Regulations that are required for the introduction of the Duty of Candour.

The principal amendments set out in regulation 14(5), (6) and (8) have the effect that where the duty of candour applies, the existing time limits in regulations 24, 26, and 33 of the PTR Regulations are extended to apply from the date the NHS Body makes the in person notification, rather than the date that the NHS Body received notification of the concern. This would be the date they realised an incident meeting the criteria for triggering the Duty of Candour had occurred.

The reason for this is with the advent of the duty of candour it was considered advantageous for both the NHS Body and the Service User/the person representing them, for time limits for investigation and production of reports to run from the date of the in-person notification. This is to give the NHS Body and the Service User an opportunity to discuss what had happened before the investigation begins. In reality, due to the need for an NHS Body to notify the Service User/person acting on their behalf on first becoming aware the duty of candour has been triggered the delay is not likely to be significant.

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 Body would have been notified of the incident?

Yes

No

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

[11] Apart from NHS Blood and Transplant and Special Health Authorities in Wales. Special Health Authorities in Wales will be added to the scope of the PTR Regulations by the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales)Regulations 2023.

Chapter 3 Further Amendments to the PTR Regulations

The Duty of Candour has a lot in common with Putting Things Right. Sometimes these laws will work together and impact one another.

Because of this some changes will need to be made to Putting Things Right, to make sure they work with the Duty of Candour. For example, 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, in accordance with the objective behind the Duty of Candour

But they do not need to be involved in the process or the investigation, if that is what is best for them. Usually, people will be involved in investigations. But sometimes this may cause more stress or harm.

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 ☐

No ☐

Please add any other thoughts you have in the box.

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).

Chapter 4 – Amendments and updates to PTR Guidance

The PTR Guidance is intended to provide practical advice and support to NHS bodies that are subject to the provisions of the PTR Regulations and provide guidance to Service Users and their advocates.

As set out above, there have been some changes to the PTR Regulations as a result of the introduction of the duty of candour such as providing that when the duty of candour applies, the time limits for providing reports on investigations into care and treatment should run from the date of the in-person notification under the Candour Procedure Regulations[12].

The changes to the PTR Guidance also reflect, that the PTR Amendment Regulations 2023 add Special Health Authorities to the bodies that come within the scope of the PTR Regulations In 2011, when the PTR regulations were published, there were no Special Health Authorities in Wales.

All of the changes in the PTR Regulations are reflected in the PTR Guidance as are the consequential changes in regulation 14 of the Candour Procedure Regulations.

As it has been a number of years since the PTR Guidance was last amended the opportunity is also being taken to update it so that it is reflective of current practice in relation to, for example, compliance with GDPR and the introduction of new arrangements like the Medical Examiners' Service.

A summary of the changes to be made to the Guidance **in relation to the Duty of Candour and the PTR Amendment Regulations** is attached at Enclosure 4.

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

[12] Regulation 14 of the Statutory Candour Procedure Regulations

No

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

Chapter 5 – Integrated Impact Assessments

It is fundamental to the policy making process to undertake a robust consideration of health disparities and to assess and understand how different groups are impacted differently or disproportionately by the policies that we implement.

Throughout the development of these proposals, we have placed a high importance on taking equalities into consideration, including the impact of these changes on different groups, particularly those with protected characteristics under the Equality Act 2010[13].

From the work that we have done to date, including the engagement with groups with protected characteristics as part of our stakeholder and focus group sessions, we are of the view that the proposals are unlikely to have a direct negative impact on any one group. The duty of candour will benefit all users of NHS services in Wales. However, further information on the impact on groups with protected characteristics is sought as part of this consultation. The consultation responses will be analysed and will inform decisions taken on the proposals.

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. Our assessment is that this indirect impact would be a beneficial one.

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 2010[14];**
- **on health disparities; or**
- **on vulnerable groups in our society.**

[13] The Equality Act 2010 accessed at https://www.legislation.gov.uk/ukpga/2010/15/contents

[14] 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.

Please provide your comments here:

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 here:

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 here:

Question 40

We have asked a number of 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 here:

Consultation Response Form

Your name:

Organisation (if applicable):

Option to designate citizen or Service User rather than organisation

email / telephone number:

Your address:

Please enter here:

Responses to consultations are likely to be made public, on the internet or in a report. If you would prefer your response to remain anonymous, please tick here: