The Duty of Candour Statutory Guidance 2023

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

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CONTENTS

GLOSSARY

Interpretation, in this guidance:

- the 2006 Act, means the National Health Service (Wales) Act 2006;
- the 2011 Regulations, means the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011;
- the Act means the Health and Social Care (Quality and Engagement) (Wales) Act 2020;
- apology, means an expression of sorrow or regret in respect of the notifiable adverse outcome;
- candour procedure means the procedure set out in the Candour Procedure Regulations that an NHS body must follow in relation to a notifiable adverse outcome;
- Candour Procedure Regulations means The Duty of Candour Procedure (Wales) Regulations 2023;
- Harm, includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child;
- health care, means services provided in Wales under or by virtue of the 2006 Act for or in connection with—
    - (a) the prevention, diagnosis or treatment of illness;
    - (b) the promotion and protection of public health;
- illness, has the meaning given in section 206 of the 2006 Act;
- NHS body means—
    - (a) a Local Health Board;
    - (b) an NHS Trust;
    - (c) a Special Health Authority;
    - (d) a primary care provider;

- notifiable adverse outcome occurs when the duty of candour comes into effect by virtue of section 3 of the Act, NHS body;
- service user, means a person, to whom health care is being or has been provided by an NHS body, that has suffered an adverse outcome;
- Special Health Authority means a body established under section 22 of the 2006 Act; but does not include any cross-border Special Health Authority (within the meaning of section 8A (5) of the 2006 Act) other than NHS Blood and Transplant.
- A person is a primary care provider in so far as (and only in so far as) the person provides health care on behalf of a Local Health Board by virtue of a contract, agreement or arrangement under Part 4, 5, 6 or 7 of the 2006 Act between the person and the Local Health Board.
- 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.

FOREWORD

The introduction of the duty of candour through the Health and Social Care (Quality and Engagement) (Wales) Act 2020[1] ('the Act'), highlights the Welsh Government's commitment to safe, effective and person-centred health services. The duty is placed on NHS bodies, (Health Boards, Trusts, Welsh Special Health Authorities and NHS Blood and Transplant in relation to their Welsh functions) and on primary care providers in Wales in respect of services they provide under a contract or arrangements with a Local Health Board.

The focus of the duty in the Act is ultimately to serve service users by ensuring that 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, and the provision of health care was or may have been a factor, the service user, (or person acting on their behalf), is informed, provided with an apology and offered details of relevant services or support. The NHS body is also required to provide the service user/or person acting on their behalf with an explanation of the actions that the responsible body or the provider will take, and further enquiries that the responsible body or the provider will carry out, to investigate or review the circumstances of the notifiable adverse outcome, including any actions to be taken under the 2011 Regulations

Wales is not the only UK jurisdiction to have a duty of candour. In England, the duty is set out at Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014[2]. In Scotland, it is set out in Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016[3].

Our overarching policy objective, in line with our aspirations in a Healthier Wales[4] for more integrated care, is to ensure that whether a person receives care from the NHS, or from a regulated provider of health care services, that person can be assured that they will be dealt with in an open and honest way by their care provider.

In social care, a duty of candour already exists for providers and responsible individuals of regulated services under the 2017 Regulations[5].

Separate work is being taken forward to make Regulations to place a duty of candour on providers of independent health care in Wales, using powers under the Care Standards Act 2000[6]. We have enjoyed very positive engagement with representatives of the independent health care sector in Wales and it is intended to work with them to introduce a duty of candour that applies to the independent health care sector in Wales, with a projected coming into force date of April 2023.

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[1] https://www.legislation.gov.uk/asc/2020/1/contents

[2] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (SI 2008/2936). Available from: https://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/20

[3] Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016. London: HMSO

4 https://gov.wales/healthier-wales-long-term-plan-health-and-social-care

[5] The Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 (legislation.gov.uk)

[6] Care Standards Act 2000 (legislation.gov.uk)

We know the overwhelming majority of providers of health care services, want to deliver high quality, safe and compassionate care. However, equally, we know that despite these intentions, inevitably in complex and multi-faceted services, from time to time, people will suffer harm.

When they do, the way in which NHS bodies, deal with these situations becomes very important, and can make a huge difference to people's experience and to their ongoing relationship with their care provider. This is particularly important in health care settings where people often have long standing relationships with their care providers. Trust is hard to gain, but easy to lose. Being open and honest should be at the heart of every relationship between those providing, receiving and/or experiencing treatment and care.

1. INTRODUCTION

1.1 The Act will come into force on 1 April 2023. It is a lever for improving and protecting the health, care and well-being of the current and future population of Wales. It aims to ensure a stronger citizen voice and to improve the accountability of services to deliver a better experience and quality of care. Doing so contributes to a healthy and more prosperous country. In totality, the Act is intended to have a cumulative positive benefit for everyone in Wales, supporting a culture and the conditions that focus on driving improvements in health care.

1.2 This statutory guidance is aimed at helping the NHS bodies to deliver the requirements of the duty.

1.3 The legal basis for the duty is set out in Part 3 of the Act. Section 3 prescribes when the duty of candour applies. Section 4 requires the Welsh Ministers to make Regulations, which set out the procedure that NHS bodies must follow when the duty of candour is triggered. Sections 5 to 8 prescribe the reporting requirements.

These sections of the Act are considered in more detail later on in the guidance.

1.4 Compliance with the duty of candour will also facilitate compliance by Local Health Boards, NHS Trusts and Special Health Authorities with:

- the duty of quality contained in section 2 of the Act, requiring bodies to exercise their functions with a view to securing improvement in the quality of health services;
- the socio economic duty[7] introduced by the Equality Act 2010[8], requiring bodies to have due regard to the desirability of exercising of exercising their functions in a way that is designed to reduce the inequalities of outcome which result from socio-economic disadvantage; and
- the well-being duty within the Well-being of Future Generations Act (Wales) Act[9] 2015 to carry out sustainable development.

1.5 The duty of candour supports all people in Wales, and information about it is accessible to them. It encourages better decision making and ultimately aims to deliver better outcomes for all people who access health services. It requires NHS bodies to involve people in decisions that affect them and to facilitate preventative action, thereby improving the quality of services and looking to the long term.

1.6 In addition, the evidence and data gathered through the duty of candour will feed into our Value Based Healthcare system. Through our Value Based Healthcare approach in Wales we will ask people about their outcomes and create a data-driven system which seeks to provide the timely information to citizens, clinical

[7] https://business.senedd.wales/documents/s113354/CLA5-07-21%20Paper%2023.pdf
[8] Equality Act 2010 (legislation.gov.uk)
[9] https://www.futuregenerations.wales/wp-content/uploads/2017/01/WFGAct

teams and organisations to inform the decision-making that leads to those outcomes in a way that is financially sustainable.

1.7 The prevailing intention is therefore to build on the work that has already been done to develop and support the culture of openness within the NHS in Wales, (such as better reporting and proportionate investigation of incidents, in line with the new National Patient Safety Incident Reporting Policy[10], the introduction of the Putting Things Right[11] process for investigating concerns, which is based on Being Open principles), and move to implement a more structured organisational duty of candour that is supported by statutory guidance and the Candour Procedure Regulations.

[10] Patient Safety Incidents - Delivery Unit (nhs.wales)
[11] https://gov.wales/nhs-wales-complaints-and-concerns-putting-things-right

2. PURPOSE OF THE GUIDANCE

2.1 Being open with service users and their representatives should feel like the right thing to do. The duty of candour is designed to create a safe environment that is supportive and empowering to those providing, receiving and/or experiencing NHS treatment and care.

2.2 In this guidance the word **must** refers to actions that are a legal requirement as set out in the Candour Procedure Regulations or in Part 3 of the Act. The remainder of the guidance is designed to provide a framework of best practice to assist NHS bodies in the implementation and application of the duty.

2.3 In accordance with section 10 of the Act, NHS bodies must have regard to the guidance when exercising functions related to the duty of candour.

2.4 The guidance contains illustrative examples and case studies to assist NHS bodies to understand when the duty of candour is triggered and offers step by step procedure flow charts.

2.5 It also includes guidance for NHS bodies on compliance with the duties placed upon them with regard to reporting, which are a key element of the duty of candour.

2.6 It provides the foundation for NHS bodies to develop local policies and procedures, and training and support requirements that are tailored to the body and/or the particular services they provide and will help to achieve consistency of approach and equity of response: an 'All-Wales model'.

2.7 The guidance will be complemented by an online training package devised by NHS Shared Services Partnership and Welsh Government to support NHS bodies with the implementation of the duty. Building on the work that has already been started as part of the Putting Things Right process to embed candid behaviour, the Welsh Government training programme considers how to encourage the "cultural shift" by making openness and transparency a normal part of the culture across NHS bodies in Wales.

2.8 The guidance is also intended as a reference for service users and their representatives. Easy read leaflets are available to ensure that everyone in our community can access materials that will empower them to ask questions about the care and services they receive, to help them understand what the duty of candour means, and what they can expect from their care providers.

2.9 It is not intended to be a definitive interpretation of the legislation on duty of candour. The Act, Candour Procedure Regulations and guidance should be read together.

2.10 We also recognise the Act, Regulations and the framework around it, whilst important, is only one part of the process. It is also necessary to overcome the known barriers to an open and honest culture for the duty of candour to become

truly embedded. The barriers include fear, a culture of secrecy and/or blame, lack of confidence in communication skills, fears that people will be upset and doubt that disclosure is effective in improving culture. Disclosure can also be inhibited by fear of blame, professional or institutional repercussions, legal liability, negative reactions and a lack of accountability.

2.11 A system without artificial barriers between NHS bodies, where care and support are person centred, where staff are supported to improve care rather than just manage or deliver it, and where there is an emphasis on accountability, will help to overcome these barriers.

2.12 For the purposes of this guidance and making the links with the Candour Procedure Regulations the term service user/person acting on their behalf is referred to in the Regulations as ‘relevant person’. NHS body is referred to in the Regulations as ‘responsible body’.

3 STATUTORY DUTY OF CANDOUR AND EXISTING PROFESSIONAL DUTIES OF CANDOUR.

3.1 There have been calls to place a duty of candour[12][13][14][15]on NHS bodies, separate from, and building on the non-statutory duties of candour that apply to a range of healthcare professionals as part of their professional regulation.

3.2 The introduction of the statutory duty of candour for NHS bodies in Wales will complement the existing professional duty of candour required of individual healthcare professionals by the Nursing and Midwifery Council, the General Medical Council and many other professional regulatory bodies. Although, it should be acknowledged that professional guidance applies in more situations than the organisational Duty of Candour.

3.4 Healthcare professionals who are subject to a professional duty of candour have to be open and honest with service users, colleagues, their employers and relevant organisations, and must take part in reviews and investigations when requested. They must support and encourage each other to be open and honest[16].They must also be open and honest with their regulators, raising concerns where appropriate. The fundamental principles of a duty of candour are therefore already embedded across a wide section of NHS bodies.

3.5 The statutory duty of candour and the professional duties of candour have the same aims – to be open and transparent with people receiving care and treatment. The strong links between the statutory and professional duties of candour will empower staff to speak openly about concerns, and seamlessly encourage learning to improve the quality of care provision.

3.6 The statutory duty will promote a system wide culture of openness and honesty. It also places a requirement, at an organisational level for NHS bodies, to follow a set procedure, underpinned by the Candour Procedure Regulations to evidence that a series of prescribed actions have been undertaken when the duty is triggered. These actions are described in point 7 below, which is supported by a procedure flow chart found in **Annex C**. This infrastructure will help create

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[12] Kennedy, I and others. The Bristol Royal infirmary inquiry. Learning from Bristol - The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 [Internet]. Crown; 2001. Available from: https://webarchive.nationalarchives.gov.uk/20090811143822/http:/www.bristol-inquiry.org.uk/final_report/the_report.pdf

[13] Donaldson, L. Making Amends - A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS [Internet]. Department of Health Publications; 2003. Available from: https://webarchive.nationalarchives.gov.uk/20120809195448/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4060945.pdf

[14] Francis, R and others. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry [Internet]. Staffordshire NHS Foundation Trust; 2013. Available from: https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry

[15] Evans, K. "Using the Gift of Complaints" - A REVIEW OF CONCERNS (COMPLAINTS) HANDLING IN NHS WALES [Internet]. 2014. Available from: https://gweddill.gov.wales/docs/dhss/publications/140702complaintsen.pdf

[16] https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/read-the-professional-duty-of-candour/#about_guidance

the conditions for NHS bodies to discharge the duty of candour with confidence when triggered.

3.7 By way of example, Registered pharmacists, pharmacy technicians and persons working under their supervision in a retail pharmacy should continue to be mindful of the provisions of the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018[17]. Pharmacy professionals are at risk of prosecution under section 63 (adulteration of medicinal products) and section 64 (sale of any medicinal product which is not of the nature or quality demanded by the purchaser) of the Medicines Act 1968[18] in the event that they prepare or dispense medicines erroneously.

3.8 In order to benefit from the new defences in section 67B (defence to offence of contravening section 63(a) or (b): product bought or sold) and section 67C (defence to an offence of contravening section 64) of the Medicines Act, the conditions for benefitting from the defences must be satisfied, including the conditions relating to notification of the person to whom the product was intended to be administered.

3.9 Consequently, the requirements of the Order need to be considered alongside and in addition to the statutory duty of candour.

4 WHO DOES THE DUTY OF CANDOUR APPLY TO?

4.1 The duty of candour within Part 3 of the Act applies to the following NHS bodies which are listed within section 11(3), and defined by reference to section 11(4) and (7):

- Local Health Boards;
- Primary Care providers in Wales (i.e. General Practitioners, dentists, optometrists and pharmacists) in respect of the services they provide under a contract or arrangement with a Local Health Board (i.e. it applies to the NHS services provided by primary care providers);
- NHS Trusts in Wales;
- Welsh Special Health Authorities, and NHS Blood and Transplant in relation to the functions it exercises in relation to Wales.

[17] SI 2018/181
[18] 1968 c. 67.

5 WHEN DOES THE DUTY OF CANDOUR PROCEDURE APPLY?

5.1 When the duty of candour applies is governed by Part 3, Section 3 of the Act. **Annex A** sets out in flow chart form a trigger review process.

5.2 The duty comes into effect in relation to an NHS body if it appears to the body that **both** of the following conditions are met:

(1) The **first condition** is that a person (the "service user") to whom health care is being or has been provided by the body has suffered an adverse outcome.

'Health care' means services provided in Wales under or by virtue of the National Health Service (Wales) Act 2006 i.e. as part of any NHS service, for or in connection with:

- the prevention, diagnosis or treatment of illness; or
- the promotion and protection of public health.

"Illness" includes any disorder or disability of the mind and any injury or disability requiring medical or dental treatment or nursing.

The meaning of health care is deliberately widely drawn to capture all of the services provided in Wales under the NHS umbrella.

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.

As set out in the Explanatory Notes to the Act, the duty may be triggered by an action taken by an NHS body during the provision of health care or by a failure to take action.

For the purpose of the duty of candour, harm includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child (section 11(7) of the Act).

(2) The **second condition** is that the provision of the health care was or may have been a factor in the service user suffering that 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, however, be certain that the health care caused the harm. It is sufficient that the health care may have been a factor.

In the Candour Procedure Regulations when both of these conditions are satisfied and the duty is triggered, it is called a "notifiable adverse outcome".

What does harm the service user 'could experience" mean?

5.3 It is important to note that the duty is triggered not only when harm is known to have occurred, but also in cases **where the circumstances are such that a person could experience harm that is more than minimal in the future.** For example, where an error in the administration of medication may cause harm that is more than minimal at a future point.

5.4 NHS bodies will have to reach a judgment about whether the circumstances are such that the user could experience harm that is more than minimal. In the example of an error in the administration of medication, whether or not such an error may give rise to harm that is more than minimal may be dependent upon the nature of the medication that was given in error or the circumstances of the particular patient.

5.5 To put this in context for practitioners, this has been explained by the GMC in their professional duty of candour guidance as, 'in situations where a patient 'may yet suffer harm' as a result of an adverse outcome.

5.6 **Annex H** contains illustrative case studies that set out detailed examples of instances that would trigger the duty of candour and those that would not. It also contains examples of cases that demonstrate the duty being triggered where harm could occur in the future. (Case studies, 9, 10 & 11).

6 NEAR MISS INCIDENTS

6.1 Near miss incidents are **not** considered a trigger for the duty of candour procedure. The duty is designed to capture more than minimal harm that is apparent at the time of the incident or may appear later. With a near miss incident, harm (or the potential for future harm) is averted. However, due to their serious nature and the need to learn from such incidents and prevent their recurrence, near miss incidents should be managed following the normal reporting processes[19].

6.2 Even though the statutory duty of candour under the Act is not triggered by a near miss, individual practitioners should familiarise themselves with the guidance on near misses provided by their professional regulatory bodies. For example, both the Nursing and Midwifery Council[20] and the General Medical Council [21] provide guidance and support to practitioners on when and how to speak to service users about near miss incidents.

[19] Patient Safety Incidents - Delivery Unit (nhs.wales)
[20] Openness and honesty when things go wrong: the professional duty of candour (nmc.org.uk)
[21] Being open and honest with patients in your care, and those close to them, when things go wrong - GMC (gmc-uk.org)

7 MORE THAN MINIMAL HARM

7.1 More than minimal harm is not defined in the Act. It was always the intention to set the definition following consultation. Supporting the existing processes for Putting Things Right and Being Open and also aligning with the Datix Cymru system, incident reporting module, **more than minimal harm is defined as moderate harm, severe harm and death**. Therefore, in practice, the duty of candour is triggered if the service user experiences, or the circumstances are such that the user could experience, unexpected or unintended harm that is moderate or above and the provision of health care was (or may have been) a factor in the service user suffering that outcome. A level of harm framework, providing explanations of harm that are considered moderate and above, is included in **Annex B**.

8 CANDOUR PROCEDURE

8.1 The Candour Procedure Regulations prescribe the actions that **must** be taken by an NHS body when the duty of candour is triggered.

8.2 This section of the guidance needs to be read in conjunction with those Regulations, and the procedure flow chart included in **Annex C**.

Notification

8.3 The Act and Candour Procedure Regulations require NHS bodies to notify on **'first becoming aware'** that the duty of candour has come into effect and not to wait for the findings of any initial investigation before notification.

8.4 It is important to note that regulation 4 of the Candour Procedure Regulations requires the NHS body to notify the **service user** who has suffered a notifiable adverse outcome or a **person who is acting on their behalf** (in the Candour Procedure Regulations, this person is called the "relevant person").

8.5 Notification may be made to a person who is acting lawfully on the service user's behalf, where the service user:

- has died;
- NHS body is 16 or over and lacks capacity (within the meaning of the Mental Capacity Act 2005) in relation to the matter; or
- is under 16 and not competent to make a decision in relation to their care or treatment.

8.6 The Candour Procedure Regulations also allow a service user with capacity to nominate a trusted person to act on their behalf in relation to the duty of candour, recognising that not everyone to whom the duty applies will want to engage personally with the process.

8.7 It is important to ensure that at all times the requirements of GDPR are adhered to when accessing, processing and disclosing service user information. In cases where a representative is acting on behalf of a service user with capacity, consent for the representative to act should be obtained in writing and be kept under review throughout the process.

What does on 'first becoming aware' mean?

8.8 The requirement to notify the service user/person acting on their behalf on first becoming aware the duty has been triggered means that the NHS body should reflect and make a considered decision as to whether the conditions as set out in part 4 above have been met. Once determined that the conditions as set out in part 4 above have been met, this would be considered to be the point at which the NHS body 'first becomes aware' that the duty has been triggered.

8.9 This is the start date for the duty of candour procedure (referred to in this Guidance and the appendices as "the procedure start date"), which must be followed, starting with the 'in person' notification to the service user/person acting on their behalf.

8.10 Each NHS body should have a robust and consistent process in place for determining whether reported adverse outcomes (incidents) trigger the duty or not. **This does not mean that NHS bodies investigate the circumstances of the reported incident before making this decision.** There will need to be some reflection and decision making on the part of the NHS body before deciding if the duty has been triggered, but not a detailed investigation.

8.11 The use of the Datix Cymru system is not mandatory. However, its rollout and development has been designed to support the implementation of the duty of candour and it is available, without charge, to all NHS bodies. Consequently, it is anticipated, and encouraged, that most NHS bodies will report incidents through the Datix Cymru system. There is a prompt on the system to ask those completing/and or reviewing the incident report whether or not the duty of candour has been triggered.

8.12 NHS bodies will need to develop a system for locally reviewing those incidents that have initially been reported as meeting the criteria for triggering the duty of candour, i.e. the conditions as set out in part 4 above have been met. If it is determined that the duty of candour has not been triggered, it would be good practice to record a note of the reasons for reaching such a decision on the incident report. This could, for example, be as simple as recording that on review and after consideration, it was agreed that the threshold for more than minimal harm has not been met or that the harm that was suffered was not related to the provision of the health care.

8.13 To clarify, if it is determined that the duty of candour has been triggered, this would be considered to be the point at which the NHS body first becomes aware. This is the start date for the duty of candour procedure, which must be followed,

starting with the ‘in person’ notification to the service user/person acting on their behalf.

8.14 Where the ‘in-person’ notification is made later than 30 working days after the date the NHS body first becomes aware of a notifiable adverse outcome, which would be the candour procedure start date, an explanation should be provided and the reason for the delayed notification should be recorded on the incident report.

8.15 Therefore, the duty of candour procedure start date is the date on which an NHS body first becomes aware of a notifiable adverse outcome.

8.16 Considering how this would apply in practice, the “sequence of events” would be as follows:

- a service user suffers harm related to (or potentially related to) treatment;
- staff are free to apologise, explain what has happened to the service user/family as they should do to comply with their professional duties of candour;
- they report the “incident” (in the majority of cases using Datix Cymru);
- Datix Cymru prompts consideration of whether the duty of candour is triggered;
- If, in the view of the person reporting the incident, it is felt that the duty is triggered by recording on the Datix Cymru system that moderate or above harm has been caused or could be caused, an openness and transparency section will automatically open allowing the reporter to record further information in line with the duty of candour procedure requirement.
- If it is determined that the duty of candour has not been triggered, even though the moderate or above harm has been caused or could be caused, a note of the reasons for reaching such a decision should be recorded on the incident report.
- All incidents are reviewed internally by the NHS body;
- For those where it is agreed the conditions for meeting the duty of candour (set out at part 4 above) are met, this would be the point at which an NHS body is deemed to first become aware that a notifiable adverse outcome has occurred, and the duty of candour procedure, as set out under the Candour Procedure Regulations is then initiated and the duty of candour procedure start date commences.

How to notify

8.17 Notification to the service user or person acting on their behalf should be ‘in person’[22] which means communication on the telephone, via audio-visual communication (such as a video call) or face to face. It is considered many service users would be surprised to receive a letter in the post advising them the duty had been triggered and may have questions/worries that will need to be answered/alleviated immediately. Leaving voice messages, is also not considered appropriate when making the ‘in person’ contact. Experience from

[22] In accordance with regulation 4 of the Candour Procedure Regulations.

recent reviews also demonstrates that an 'in person' approach for the first contact is most appropriate.

8.18 However, NHS bodies have a discretion as to which method of 'in person' communication is most appropriate. It is not considered proportionate (or achievable in practical terms) for there to be a face-to-face meeting with everyone in relation to whom the duty of candour has been triggered.

8.19 The factors that a NHS body must consider when determining which form of 'in person' notification is most appropriate are:

a) severity of the harm;
b) nature and complexity of the notifiable adverse outcome;
c) personal circumstances of the service user (if known);
d) any communication already undertaken with the service user/person acting on their behalf and
e) any known preferred method of communication of the service user. This is particularly important where the service user may require support, for example BSL or foreign language interpreter.

8.20 In some situations, the initial notification via the telephone may suffice; in more complex cases it is likely to be more appropriate for a face-to-face meeting with the service user/person acting on their behalf to be arranged.

8.21 The NHS body must take reasonable steps to establish the preferred method of communication. They must also take reasonable steps to ensure that communication is in a manner that the service user/person acting on their behalf can understand[23]. NHS bodies are subject to Welsh Language Standards requirements as set out in the Welsh Language Standards (No. 7) Regulations 2018[24]

8.22 It is recognised that in some instances, the preferred method of communication or service user contact preference, may not be known at the outset; establishing contact via the telephone may be necessary in the first instance to begin dialogue on what steps might need to be taken to allow the duty of candour procedure to be followed.

Who notifies and the purpose of the notification

8.23 The NHS body will need to determine the most appropriate person or persons to make the initial 'in person' notification to the service user/person acting on their behalf. Part 7b above, sets out helpful factors for the NHS body to consider when determining the most appropriate person or persons to make the initial 'in person' notification to the service user/person acting on their behalf.

[23] See regulation 7 of the Candour Procedure Regulations.
[24] 2018/441 (W.77).

8.24 First and foremost, the initial contact with the service user/person acting on their behalf, is to acknowledge what has happened and offer a meaningful, personalised apology and provide advice on what will happen next.

8.25 The NHS body must nominate a person with sufficient experience and knowledge and understanding of the duty of candour procedure to be able to assist the service user/their representative with any questions that may arise as they go through the process, this is the "nominated point of contact".

8.26 Regulation 4 of the Candour Procedure Regulations prescribes what **must** be covered in the initial 'in person' notification.

8.27 The person making the initial contact with the service user/person acting on their behalf must:

- clearly explain what information they know so far about what has happened;
- outline why the NHS body is of the view the duty of candour has been triggered;
- provide an apology. Guidance on how to make a meaningful, personalised apology is set out at 7E below and in Annex E;
- provide their contact details if they are to remain the nominated point of contact for the NHS body or provide the appropriate contact details if the nominated point of contact is different to the person making the initial contact. The nominated point of contact is the person the service user/person acting on their behalf will contact if they have any questions about the duty of candour process.
- provide an explanation of the actions and further enquiries the NHS body will undertake to investigate or review the circumstances of the notifiable adverse outcome. This includes any actions the NHS body (or where services have been commissioned from an independent provider in Wales, the provider) will take under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011[25] ("the 2011 Regulations"). The investigation or review of the notifiable adverse outcome is considered further at point 8 below.
- communicate to the service user/person acting on their behalf details of any services or sources of support which the NHS body reasonably thinks may be of assistance to them, taking account of their needs. **Annex D** sets out useful contacts for support options.

8.28 Regulation 4 also requires the person making the 'in person' notification to provide an explanation to the service user/person acting on their behalf if the date on which the 'in person' notification is made NHS body is more than 30 working days after the date on which the NHS body first became aware of the notifiable adverse outcome. This is to explain any delay in notification that could arise, for example, following a retrospective case review. It does not mean that NHS bodies routinely have 30 working days from the date the notifiable adverse outcome occurred to make the 'in person' notification.

[25] SI 2011/704 (W.108).

8.29 It is also good practice to establish what the service user/person acting on their behalf understands about what has happened in this conversation. The person making the notification on behalf of the NHS body should also demonstrate they understand the circumstances and the impact for the person affected. They should not question the extent of harm suffered by the person affected or the circumstances of the 'incident'.

8.30 This may be the starting point for longer conversations with the service user/person acting on their behalf and it will be important for all involved that this initial contact is carried out in the true spirit of the duty, with openness, empathy and sincerity.

Things to consider – ***Before the 'in person' notification takes place:***

- has someone from the NHS body already been in contact with the service user/person acting on their behalf?
- what discussions or information exchange have already taken place (if any)?
- what is known about what has happened and the level of harm sustained or could be sustained?
- is the preferred method of notification known? e.g. verbal, written, electronic;
- who will be the nominated point of contact within the NHS body following the initial notification?
- what support is available to the service user/person acting on their behalf, to assist them during the notification process and afterwards?
- ensure that communication is in a manner that the service user or the person acting on their behalf, can understand.

Follow up in writing

8.31 Following the 'in person' notification, regulation 5 of the Candour Procedure Regulations requires the NHS body to take all reasonable steps to write to the service user/person acting on their behalf (unless they have indicated they do not wish to engage in the candour process) within two working days. Notification in writing includes notification via email.

8.32 The written notification must include:

- a description of any initial consideration of the notifiable adverse outcome NHS body
- a reiteration of the verbal apology,
- the information provided in the in-person notification, which for completeness is as follows:
- the reason that the NHS body considers that the duty of candour has been triggered.

- the name and contact details of the person at the NHS body nominated as the point of contact for the service user/person acting on their behalf in respect of the duty of candour procedure,
- an explanation of the actions that the responsible body or the provider will take, and further enquiries that the responsible body or the provider will carry out, to investigate or review the circumstances of the notifiable adverse outcome, including any actions to be taken under the 2011 Regulations
- a reiteration of the offer of details of relevant services or support, and
- where the 'in-person' notification is made later than 30 working days after the date on which the NHS body first became aware of the notifiable adverse outcome, an explanation of the reason for the delay.

8.33 The aim of the written notification is to confirm in writing what has been discussed at the 'in person' notification. This is to aid the understanding of the service user/person acting on their behalf, and also to provide the NHS body with a record of what has been discussed.

8.34 Consideration should be given to personalising the notification letter with a handwritten signature. It has been suggested during focus sessions with members of the public that a handwritten signature has a positive impact when an apology of this nature is being conveyed.

8.35 The NHS body must take all reasonable steps to send the written notification to the service user/person acting on their behalf within **two working days** following the 'in person' notification.

8.36 It is important to acknowledge that delayed or poor communication makes it more likely that the service user/person acting on their behalf, will seek information in a different way, for example, by making a complaint or taking legal action. It may also mean that they will not feel that there has been openness and honesty in the process from the outset.

The apology

8.37 Making a meaningful, personalised apology is a key part of the 'in person' notification process. **Annex E** provides further information on making an apology as part of the duty of candour procedure.

8.38 A meaningful, personalised apology can be a practical way of restoring trust. When conveyed with empathy, sincerity and understanding, an apology can be effective and powerful and it is crucial for everyone involved when the duty of candour is triggered, including the service user/person acting on their behalf, and the staff who care for them. The impact on everyone involved when the duty of candour is triggered must not be underestimated. For the service user/person acting on their behalf, an apology is usually the most important action that any one individual and organisation can take.

8.39 People who feel that they have not been informed openly and honestly from the outset are more likely to feel that the harm they have suffered has been compounded and can lead to the loss of trust in their health care provider. This

can result in feelings of anger and cause a break down in the relationship. It may also mean that escalated action is taken.

8.40 We recognise that there may be misconceptions and misunderstanding that the provision of an apology equates to an acceptance of blame, culpability or even legal liability.

8.41 This is not the case, and it should not give rise to any such assumption.

8.42 "Apology" is defined within regulation 2 of the Candour Procedure Regulations as:

apology means an expression of sorrow or regret in respect of the notifiable adverse outcome.

8.43 Regulation 12 specifically provides that an apology or any other step taken in accordance with the candour procedure does not amount to an admission of negligence or to a breach of statutory duty.

8.44 The giving of an apology acknowledges what has happened and provides assurance, the matter is being taken seriously and opportunities for learning will be taken to prevent similar circumstances from arising in the future.

8.45 We recognise that sometimes staff can find it difficult to say sorry when harm has occurred or may occur at some point in the future. They may be unclear if they can say sorry and worry that the timing for doing this will not be right, or that they will make things worse, especially as the service user/person acting on their behalf, may be angry and upset. **Annex E** aims to provide guidance to support staff in this regard.

8.46 It is good practice to document the verbal apology in the patient care record. This means that the entire clinical team will know when an apology has been given and can avoid duplication.

Notification of results of further enquiries

8.47 Regulation 6 of the Candour Procedure Regulations requires NHS bodies to notify the service user/person acting on their behalf of the results of any further enquiries carried out by the NHS body that may have been referred to 'in-person' notification.

8.48 In practice, in the vast majority of cases once the service user/person acting on their behalf has been notified, the NHS body will undertake further enquiries and investigate the circumstances in which the duty of candour came into effect in accordance with the provisions of the 2011 Regulations. NHS bodies will be familiar with this process as it governs the way in which incidents are currently investigated.

8.49 Communication with the service user/person acting on their behalf under the provisions of the 2011 Regulations, which includes a requirement to outline in writing the outcome of investigations, will also satisfy the requirements of regulation 6 of the Candour Procedure Regulations, so avoiding duplication.

8.50 As set out below in part 8, the 2011 Regulations do not apply to all NHS bodies – for example, they do not apply to NHS Blood and Transplant. Additionally, there may be exceptional circumstances where the 2011 Regulations do not apply. In these circumstances, NHS bodies should ensure that they have arrangements in place to enable them to comply with the notification requirements in regulations 4, 5 and 6.

Communication with service user/person acting on their behalf

8.51 Regulation 7 prescribes what an NHS body must do if it is unable to make contact with the service user or a person acting on their behalf to:

(i) make the 'in person' notification (regulation 4),
(ii) the written notification (regulation 5),
(iii) to notify of results of further enquiries (regulation 6),

or if the service user or person acting on their behalf refuses to communicate.

8.52 If the NHS body, having taken reasonable steps, is unable to make contact, the attempts to make contact must be recorded as part of the information that is required to be kept by virtue of regulation 9 (Records), see part 7i below. Ideally the information should be recorded on the incident record.

8.53 If the service user/person acting on their behalf, indicates that they do not wish to communicate with, or receive information from the NHS body, this must also be clearly recorded in accordance with regulation 9 and the person's wishes respected. Again, good practice would be to record this on the incident record, and also on the service user's medical notes.

8.54 In accordance with regulation 7(3)(b) NHS bodies are not required to provide information to or communicate with the service user/person acting on their behalf in these circumstances where the service user/person acting on their behalf indicates that they do not wish to communicate with or receive information from the NHS body. However, the review of the incident giving rise to the triggering of the duty must continue so that lessons can be learned, and quality improvements made.

8.55 The NHS body should inform the service user/person acting on their behalf that they can contact the NHS body should they change their mind about their involvement in the process.

8.56 The NHS body must take reasonable steps to ascertain the service user/person acting on their behalf's preferred method of communication and, where reasonably practicable, communicate with them by this method.

8.57 Allied to this, the NHS body must take reasonable steps to ensure that any communication with the service user/person acting on their behalf is in a manner they can understand.

Support and Training

8.58 NHS staff go to work to provide high quality care to those in need of care and treatment. When a service user suffers an adverse outcome and the duty of candour is triggered, it is important to recognise that staff involved in the care of the service user will also be impacted and may require support.

8.59 Regulation 8 of The Candour Procedure Regulations sets out the requirements in relation to training and support.

8.60 The requirements are for relevant training and guidance to be given to all staff involved in:

- the provision of health care; and
- investigating or managing notifiable adverse outcomes, and
- any other relevant members of staff who are involved in performing or exercising functions in connection with the duty of candour procedure.

8.61 As well as all clinical staff, in practice this would include senior staff (including board level staff) responsible for overseeing the management of adverse outcomes in their organisations, those directly involved with the investigation, management and/or notification of notifiable adverse outcomes and any other staff who deal with complaints and concerns. At primary care level this would include practice managers.

8.62 Training modules will be developed by Welsh Government in liaison with NHS Wales Shared Services and will be available via Learning for Wales and ESR platforms.

8.63 This guidance document and annex documents provides all the relevant support documents to assist NHS bodies in discharging their duty in respect of ensuring staff awareness of the duty of candour. In addition, the Welsh Government training programme considers how to encourage the “cultural shift” to support this guidance and the implementation of the duty.

8.64 The Candour Procedure Regulations also set out that the NHS body must provide a member of staff who is involved in a notifiable adverse outcome with details of services or support available, taking into account:

- the circumstances relating to the notifiable adverse outcome; and
- the staff member’s needs.

8.65 NHS bodies will have mechanisms in place and local support services available to pro-actively offer the appropriate provision of support and assistance to staff members through their Employee Wellbeing Service/Occupational Health/Employee Assistance Programmes, in addition there are several national support services available via the Health Education & Improvement Wales

(HEIW) website[26], such as Health for Health Professionals, SilverCloud and Samaritans. Local Line Managers, Workforce and OD professionals (including employee wellbeing and occupational health colleagues) and Trade Union representatives will also be able to signpost staff to appropriate support services.

Record keeping

8.66 Section 4(3)(c) of the Act requires the Candour Procedure Regulations to prescribe the records that NHS bodies must keep in relation to the discharge of the duty.

8.67 Regulation 9 of the Candour Procedure Regulations requires NHS bodies to keep an accurate written record for each notifiable adverse outcome in respect of which the candour procedure is followed. The written record must include every document and piece of correspondence relating to the notifiable adverse outcome, not limited to:

- 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.

8.68 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 to support 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.

8.69 It is envisaged that the Datix Cymru system will be utilised for the purposes of reporting and recording keeping.

Oversight of arrangements.

8.70 It is considered important that NHS bodies appoint senior leads to have strategic oversight of and accountability for the operation of the procedure that is required to be followed pursuant to the Candour Procedure Regulations.

8.71 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 or non-executive directors, as appropriate.

[26] Home - HEIW (nhs.wales)

8.72 Primary care providers have discretion in relation to whom to assign such roles.

8.73 Regulation 11 requires NHS bodies to designate a person who has overall responsibility for the effective day to day operation of the procedure under the Candour Procedure Regulations (the "responsible officer"). 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 responsible officer must be one of its officer members or executive directors, as appropriate.

8.74 For primary care providers, it must be the person who acts as the chief executive of the body. If there is no chief executive, it is:

- the person who is the sole proprietor.
- in cases of a partnership, a partner; or
- in any other case a director or person responsible for management.

8.75 The Candour Procedure Regulations allow for 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. However, accountability will rest with the responsible officer themselves.

8.76 It is considered good practice for the persons designated in accordance with regulations 10 and 11 of the Candour Procedure Regulations to be the same persons nominated, respectively, under regulations 6 and 7 of the 2011 Regulations[27] due to the close linkages between the candour procedure and the procedure for investigating concerns in the 2011 Regulations.

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

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

8.78 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.

[27] Reg 6 of the 2011 Regulations requires a person to be appointed to maintain a strategic oversight of the arrangements for dealing with concerns under those Regulations and regulation 7 requires a person to be appointed to have responsibility for ensuring effective day to day operation of the arrangements for dealing with concerns in an integrated manner.

8.79 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.

8.80 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 isn’t unexpected and is a risk that has been explained to the patient as to why they need surgery and so the duty wouldn’t apply.

8.81 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.

8.82 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.

8.83 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 haven’t 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.

9 THE REVIEW

9.1 When notifying the service user or person acting on their behalf that the duty of candour has been triggered, an NHS body must (in accordance with regulations 4(3)(e) and 5(3)(c)) of the Candour Procedure Regulations also give an explanation of the actions and further enquiries it will take to investigate or review the circumstances of the notifiable adverse outcome.

9.2 In the vast majority of cases, this means following the procedure for investigating concerns that is set out in the 2011 Regulations. “Concerns” as defined in the 2011 Regulations includes patient safety incidents.

9.3 However, there will be instances where, even though the duty of candour applies, a review/investigation will not be carried out in accordance with the 2011 Regulations. For instance, the 2011 Regulations do not apply to NHS Blood and Transplant, they will follow their internal procedures for investigating patient safety incidents.

9.4 In relation to an investigation under the 2011 Regulations, as is currently the case, the investigation must be proportionate, conducted openly and efficiently and the focus should be on improving quality, safety and sharing learning.

9.5 The service user/person acting on their behalf should be invited to contribute to the terms of reference of the review and contact should be maintained throughout the review process, if this is what has been agreed. The preference of the service user/person acting on their behalf should be considered as not everyone will want to be involved to this extent.

9.6 The outcome of the review will be communicated to the service user or their representative in accordance with regulation 24 of those Regulations or, in the case of care provided by Health Boards, NHS Trusts or Welsh Special Health Authorities, in line with regulations 26 and 31 where the redress arrangements have been applied.

9.7 Consideration should be given to whether the incident should be reported to ‘others’ e.g. an employer or professional regulator.

9.8 Staff involved in the treatment or care that resulted in the duty being triggered should, where appropriate, be involved with the review process and also be advised of the final outcome. Further information in relation to the review and record keeping can be found in **Annex F**.

9.9 There have been some amendments to the 2011 Regulations to make them compatible with the duty of candour. The principal amendments are set out in regulation 14 of the Duty of Candour Procedure Regulations and their effect is, where the duty of candour applies, to make the existing time limits in regulations 24, 26 and 33, for responding to concerns etc apply 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.

10 WHERE MORE THAN ONE NHS BODY MAY BE INVOLVED IN THE DUTY OF CANDOUR PROCEDURE.

10.1 It is often the case that a range of NHS bodies are involved in an episode of care where the duty of candour is triggered. **Annex H** has case study examples for reference. (Case studies 13 – 17).

10.2 Although not all of the bodies involved in the provision of an episode of care will necessarily be the 'providing body' in terms of the legislation (i.e. their provision of health care did not or does not have the potential to trigger the duty of candour) they may need to become involved in providing information as part of a review or providing support for the service user/person acting on their behalf. All parties are expected to co-operate fully in an open and facilitative manner throughout the duty of candour procedure and share any learning identified as a result of the subsequent investigation/ review, including any actions to be taken with a view to preventing similar circumstances from arising in the future.

10.3 There may also be occasions where several NHS bodies (i.e. several providing bodies), each decide to activate the duty of candour procedure for multiple 'notifiable adverse outcomes' where the duty of candour has been triggered in relation to a single course of treatment. **Annex H** has case study examples for reference. (Case studies 16 and 17).

10.4 In such circumstances, it would be good practice for the NHS bodies to seek to communicate with the service user/person acting on their behalf to gain the appropriate consent, in line with GDPR, to undertake a co-ordinated approach to notification. Otherwise, there is a risk the service user or person acting on their behalf will feel overwhelmed or confused by the process if they get multiple notifications.

10.5 The aim should be to make the process as easy as possible for those involved and, in particular, for the service user or person acting on their behalf.

10.6 However, each NHS body (providing body) still has its own responsibility under the Candour Procedure Regulations and must ensure and be able to evidence that, as individual organisations, they have complied with the requirements of those Regulations.

10.7 Where following the procedure of notification under the Candour Procedure Regulations an investigation is undertaken pursuant to the 2011 Regulations, regulation 17 of the 2011 Regulations applies. Regulation 17 deals with concerns involving more than one responsible body. It places a duty on responsible bodies (subject to obtaining the relevant consents from the service user or person acting on their behalf) to cooperate for the purposes of coordinating the handling and investigation of concerns and the provision of a coordinated response.

10.8 If an NHS body discovers that an incident that would trigger the duty of candour procedure has occurred in a different NHS body, the NHS body that discovers the 'incident' should inform the NHS body where the 'incident' occurred, who must then implement the duty of candour procedure. The NHS body that

discovers the ‘incident’ must also be open and transparent with the service user about what they have discovered. However, they are not required to carry out the specific duty of candour procedure; this should be carried out by the responsible NHS body, i.e. the ‘providing body’ where the duty of candour was triggered.

11 APPLICATION OF THE DUTY OF CANDOUR PROCEDURE TO COMMISSIONED SERVICES.

11.1 Section 1 of the Act (as read with section 11) clarifies which organisation will be responsible for complying with the duty of candour in situations where services are provided by one body on behalf of another. The position, in relation to different arrangements is set out below:

Services commissioned by an NHS body from another NHS body in Wales

11.2 An NHS body in Wales is responsible for complying with the duty of candour in relation to all care which it actually provides. Therefore, for example, where a health board enters into arrangements with a primary care provider for the provision of NHS services, it is the primary care provider who is subject to the duty.

11.3 Similarly, if a Health Board enters into arrangements with an NHS Trust in Wales for the provision of services, the duty rests with the NHS Trust.

Services commissioned from non-NHS bodies in Wales

11.4 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 enters into an arrangement with an independent provider for the provision of services, the duty will apply to the local health board.

11.5 In these circumstances, it would be for the NHS body to notify the service user or person acting on their behalf for both the ‘in person’ notification in accordance with regulation 4, and the written notification in accordance with regulation 5.

11.6 The provisions of the 2011 Regulations apply to persons who provide services under arrangements with an NHS body. Therefore, as is the case currently, it would be for the independent provider to investigate the circumstances of the notifiable adverse outcome and communicate the result of that investigation to the service user/person acting on their behalf.

11.7 NHS bodies should ensure that their commissioning arrangements with non-NHS independent providers in Wales require the independent provider to notify them when they are of the view that the duty of candour has been triggered, so that the NHS body can comply with its obligations in relation to notification under the

Act. The commissioning arrangements will also need to require the independent provider to provide sufficient information to the NHS body to enable them to comply with their reporting obligations under section 7 of the Act.

Application of the duty of candour to care commissioned outside of Wales

11.8 The duty of candour under the Act only applies where 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 in England, it is the English duty of candour, under the Health and Social Care Act 2008 that will apply in relation to that care.

11.9 **Annex A1** sets out the procedure flow chart for services that are commissioned.

12 REPORTING REQUIRMENTS

12.1 Under the duty, NHS bodies will be required to report annually on compliance with the duty and publish their reports. Local Health Boards will be required to collate this information from those primary care providers with whom they enter into a contract or arrangements for services and publish a combined report. **Annex G** includes a flow chart setting out the reporting, publication and monitoring requirements.

12.2 When reporting, NHS bodies will be required to specify if the duty of candour has been triggered in the reporting year (defined as each period of 12 months ending on 31st March, (each financial year), and if it has:

1. state how often the duty of candour has been triggered during the reporting year.
2. give a brief description of the circumstances in which the duty was triggered; and
3. specify any steps taken by the body with a view to preventing similar circumstances from arising in the future.

12.3 The report must be prepared as soon as practicable after the end of each financial year.

12.4 To streamline annual reporting in Wales and reduce duplication of content whilst ensuring all regulatory requirements are met**,** Health Boards, Trusts and SHAs should include their candour reports in the Putting Things Right Report which should be published pursuant to regulation 51 of the 2011 Regulations[28] by **31st October** each year.

12.5 Regulation 51 requires NHS bodies to prepare an annual report on information regarding concerns, (where concerns is taken to include complaints, patient safety incidents and claims). For primary care providers, this includes sending

[28] The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (SI 2011/704). Available from: http://www.legislation.gov.uk/wsi/2011/704/contents/made

their report to the Local Health Board with whom they have entered into arrangements with, allowing for collation and publication within a Local Health Board's Annual Putting Things Right report[29], and considered within each organisation's Annual Quality Statement.

Primary Care providers: duty to report

12.6 Primary Care providers must prepare a report in respect of the health care they provide under a contract or other arrangement with their health board. The report must state whether during the reporting year (defined as each period of 12 months ending on 31st March, (each financial year)), the duty of candour has been triggered in respect of the provision of health care by the primary care provider. If it has, the report must:

1. specify how often this has happened during the reporting year,
2. give a brief description of the circumstances in which the duty was triggered,
3. describe any steps taken by the provider with a view to preventing similar circumstances from arising in future.

12.7 The prepared report must be supplied to the Local Health Board on completion.

12.8 If the Primary Care provider has provided health care on behalf of two or more Local Health Boards, a separate report is to be prepared and supplied to each Local Health Board on completion.

12.9 Local Health Boards receiving the report must prepare a summary of the reports received from the Primary Care providers in the candour report that they publish.

12.10 Consequently, in order to give Local Health Boards time to compile the summary, such reports must be provided to the relevant Local Health board by no later than **30th September** each year.

12.11 Although the use of the Datix system is not mandated, functionality on Datix will facilitate the collation of information necessary to satisfy the reporting requirement.

Publication of reports

12.12 The annual reports on the duty of candour must be published as soon as practicable after the end of the financial year. In the case of Local Health

[29] Welsh Government. Putting things right - Guidance on dealing with concerns about the NHS from 1 April 2011 [Internet]. Welsh Government; 2013. Available from: http://www.wales.nhs.uk/sites3/Documents/932/Healthcare%20Quality%20-%20Guidance%20-%20Dealing%20with%20concerns%20about%20the%20NHS%20-%20Version%203%20-%20CLEAN%20VERSION%20%20-%2020140122.pdf

Boards, their report must include the summary of the reports provided by primary care providers providing services on the Local Health Board's behalf.

12.13 The Local Health Board will therefore be responsible for publishing information relevant to the duty of candour in respect of its own services and the services provided by primary care providers in its area. This will mean that all the information about the duty of candour in respect of the Local Health Board area will be published together.

12.14 As set out above, such reports should be published by **31st October** each year.

13 BOARD ASSURANCE AND MONITORING ARRANGEMENTS

13.1 Breach of the duty of candour is not a criminal offence. We want the focus of the duty to be on learning and improving, not on punitive sanctions when NHS bodies fall short in their application of the duty.

13.2 However, NHS bodies should consider how monitoring of the effective implementation of the actions required by the duty of candour can be integrated into existing corporate governance frameworks, processes and procedures. Assurance should be sought to confirm that all elements of the procedure are being implemented when they should be, and that there are ways of supporting continuous improvements and refinements in the way that the NHS body discharges its legal responsibilities.

13.3 Leaders and managers within the NHS body should ensure that the implementation of the duty of candour forms a key part of the learning systems within their service areas, and that the necessary integration and alignment with processes and procedures has taken place and reinforces the values expected in their service area.

13.4 In respect of Health Boards, Trusts and Special Health Authorities, the expectation is that there will be local ownership and accountability with regular updates being provided via Quality and Safety Committee meetings, where independent members can seek assurance, the duty is being discharged and learning is being taken forward and concerns are escalated to the Board if appropriate.

13.5 Implementation of, and compliance with the duty will also be scheduled for discussion at quality and delivery group meetings between Welsh Government and individual NHS bodies, the national quality and delivery group and will inform the Joint Executive Team (JET) meetings and the Minister for Health and Social Service's appraisals with the Chairs of Health Boards, Trusts and Special Health Authorities.

13.6 The Welsh Government will monitor the content of the annual reports alongside other sources of information which will help triangulate the application of the

duty with, for example, consideration of serious incidents reported in line with the new National Patient Safety Incident Reporting policy.

13.7 Compliance with the duty will also form part of the matters considered by Healthcare Inspectorate Wales (HIW) when inspecting and reviewing the NHS.

13.8 The annual reporting requirements will also provide information to the public and the Welsh Government about the duty, which will help to make the process transparent and accessible to the public and bodies such as the Citizen Voice Body for Health and Social Care.

14 CONFIDENTIALITY

14.1 It is important to ensure that at all times the requirements of GDPR are adhered to when accessing, processing and disclosing service user information. Reports and publications must not identify any person to whom health care is being or has been provided by or on behalf of the NHS body, or any person acting on behalf of a service user.

14.2 Care must also be taken not to unwittingly enable a person to be identified from the information provided within a report. It is not necessary to name a person in order for them to be identifiable if, for example, a case has received media attention or, to cite another example, where a person has a very rare medical condition and simply naming the condition could render the person identifiable.

14.3 **Annex I** includes a section covering frequently asked questions.