Explanatory Memorandum to The Duty of Candour Procedure (Wales) Regulations 2023 and The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023

This Explanatory Memorandum has been prepared by the Health and Social Services Department of the Welsh Government and is laid before the Senedd Cymru with the above subordinate legislation and in accordance with Standing Order 27.1**.**

Minister's Declaration

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Duty of Candour Procedure (Wales) Regulations 2023 and the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023. I am satisfied that the benefits justify the likely costs.

Eluned Morgan MS

Minister for Health and Social Services

9th March 2023

Description

1. The Health and Social Care (Quality and Engagement) (Wales) Act 2020 ('the Act') uses legislation as a mechanism for improving and protecting the health, care and well-being of the current and future population of Wales. It introduces an organisational duty of candour on NHS bodies (including primary care) in Wales to be open and transparent with people when they experience more than minimum harm whilst using services.

2. The Duty of Candour Procedure (Wales) Regulations 2023 ("the Candour Regulations") are made under the Act and provide for a procedure ("the Candour Procedure") to be followed by an NHS body in relation to which the duty of candour has come into effect. The Candour Regulations also make amendments to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the 2011 Regulations") in consequence of the Candour Procedure. By way of information, the 2011 Regulations make arrangements for the notification and consideration of and response to concerns notified by persons in respect of services provided by or under arrangements with the National Health Service in Wales.

3. The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023 ("the 2023 Amendments") make a limited number of technical changes to the 2011 Regulations. Such technical changes including requiring that Welsh Special Health Authorities are subject to the requirements of the 2011 Regulations and to make clear that responsible bodies must not provide personal data to persons who are not the data subject (unless that person is a representative of the data subject).

Matters of special interest to the Legislation, Justice and Constitution Committee

4. None

Legislative Background

5. The Duty of Candour Procedure (Wales) Regulations 2023 ("the Candour Regulations") are made under section 4 of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 ("the Act"). Section 4 of the Act requires that regulations must provide for a procedure ("the Candour Procedure") to be followed by an NHS body in relation to which the duty of

candour has come into effect, and, that as part of the Candour Procedure, regulations must require an NHS:

- On first becoming aware that the duty of candour has come into effect, to give notification in accordance with the regulations to the service user concerned or someone acting on the service user's behalf;
- To notify a service user or someone acting on their behalf, in accordance with the regulations, of:
    - The identity of a person who has been nominated by the body as a point of contact for the service user in respect of the Candour Procedure;
    - Any further enquiries carried out by the body in respect of the circumstances in which the duty of candour came into effect.

6. The regulations must also make provision:

- For an apology to be offered by the body;
- For the provision of support to a service user explained in the notification;
- About accurate record-keeping.

7. Section 4(4) of the Act also provides the Welsh Ministers with a power to make any other provision in respect of the Candour Procedure that the Welsh Ministers consider appropriate.

8. The Candour Regulations are also being made under sections 25(2) and 28(1) and (2) of the Act.

9. The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023 ("the 2023 Amendments") are made under the powers conferred by sections 113(2) and (3) and 115 of the Health and Social Care (Community Health and Standards) Act 2003, and sections 1,11(2) and (3) and 12(1) of the NHS Redress (Wales) Measure 2008.

10. Both sets of regulations are subject to the negative resolution procedure.

Purpose and intended effect of the legislation

<u>The Duty of Candour Procedure (Wales) Regulations 2023</u>

11. The primary purpose of the Act's provisions is to help achieve a system-wide approach to being open and honest when things go wrong. It will achieve this by requiring NHS bodies to follow a process as set out in the Candour Regulations when:

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

12. 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. The statutory guidance provides guidance on what *"more than minimal harm"* means.

13. The duty of candour 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, therefore, be certain that the health care caused the harm; it is sufficient that the health care may have been a factor. This means that the application of the duty does not indicate that the NHS body has acted negligently.

14. The provisions place a duty on NHS bodies (i.e. Local Health Boards, NHS Trusts, Special Health Authorities (but not including cross-border SHAs other than NHS Blood and Transplant) and primary care providers) at an organisational level, and not onto individual health care staff.

15. The Act places a duty on the Welsh Ministers to set out in regulations the procedure that must be followed by an NHS body when the duty of candour is triggered. The procedure must contain the provisions set out at section 4 of the Act. Accordingly, these Regulations set out the requisite candour procedure and requires that the NHS body:

- Make an in-person notification on first becoming aware of a notifiable adverse outcome and sets out what a notification must include (e.g. an account of the circumstances, an apology, details of the point of contact at the NHS body etc).
- Make a written notification within five working days of the in-person notification.

- Notify the service user (or someone acting on their behalf) of the outcomes of further enquiries undertaken in respect of the circumstances in which the duty of candour came into effect.
- Communicates in a manner that the service user (or someone acting on their behalf) can understand.
- Members of staff receive relevant training and guidance on the candour procedure, and that members of staff involved in a notifiable adverse outcome are provided with details of relevant assistance or support.
- Keeps written records for each notifiable adverse outcome.
- Designates a person to be responsible for maintaining a strategic oversight of its operation of the candour procedure.
- Designates a responsible officer to take overall responsibility for the effective day-to-day operation of the candour procedure and to ensure that the NHS body complies with the requirements of the regulations.

16. The Candour Regulations also provide that the NHS body is not permitted to disclose any information which would prevent any criminal investigation or prosecution or would contravene any restriction on disclosure, and that an apology does not amount to an admission of negligence or breach of statutory duty.

17. Finally, the Candour Regulations also make consequential amendments to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the 2011 Regulations") to ensure that the candour procedure works in harmony with the arrangements under the 2011 Regulations, such as removing the requirement to advise the patient of a concern where the patient has already been notified under the Candour Regulations.

<u>The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023</u>

18. The additional, non-consequential amendments made to the 2011 Regulations are made principally because of the opportunity afforded by the candour work are aimed at keeping the 2011 Regulations as operational as possible ahead of a full review.

19. Of significance, the original 2011 Regulations did not reference the Special Health Authorities in Wales and although these organisations do not have as much patient interaction as the other provider bodies, this is a gap in legislative cover within the NHS. The non-consequential amendments add all

of Digital Health and Care Wales (DHCW's) activities and Health Education and Improvement Wales (HEIW) for their health-related activities.

20. The 2023 Amendments also provide that, where the Public Services Ombudsman for Wales (PSOW) has recommended that a Welsh NHS body offers a form of redress under Part 6 of the 2011 Regulations, the Welsh NHS body may undertake a further investigation of the concern under the 2011 Regulations only for the purpose of determining whether a qualifying liability exists or may exist and to offer a form of redress in accordance with the recommendations of the PSOW. This may be appropriate for example, following a concluded investigation by the PSOW if, there is additional information that means the incident may have met the requirements for redress.

21. Other amendments are considered technical and include updating references to other legislation such as the UK General Data Protection Regulation (UKGDPR). These changes are made to keep the Regulations and PTR guidance as usable as possible.

Consultation

22. In developing the Candour Regulations and the 2023 Amendment Regulations, the implementation team ran a series of stakeholder workshops aimed at developing policy thinking on key areas within the regulations and for the statutory guidance. Four workshops for NHS stakeholders and a focus group for the public were run between October and November 2021 with over 70 stakeholders attending.

23. In addition, the programme has been overseen by an Implementation Board (previously referred to as the Steering Group) made up of Welsh Government and NHS stakeholders, chaired by a senior NHS executive. This board not only oversaw the development products but has been instrumental in inputting vital NHS perspective.

24. the Candour Regulations, the 2023 Amendments Regulations and Statutory Guidance for the Candour Regulations and the amendments to the guidance for the 2011 Regulations were subject to 12 week public consultation ending on the 17 December (2022). The consultation received 135 responses from a wide range of NHS, third sector and public stakeholders. Following consultation, several changes were made to the proposed amendments detailed below.

The Duty of Candour Procedure (Wales) Regulations 2023

25. These regulations include (i) the candour procedure and (ii) amendments to the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the 2011 Regulations") which are made in consequence of the candour procedure.

(i) Candour procedure

26. **Amendment to regulation 4(3)(a):** added reference "to the relevant person".
Reason for the amendment: to make it clear that the responsible body must provide an account of the circumstances of the notifiable adverse outcome, in so far as the responsible body is aware of the facts at the date the notification is provided "to the relevant person".

27. **Amendment to regulation 4(3)(e):** removed reference to "review".
Reason for the amendment: the word "review" was redundant in that provision.

28. **Amendment to regulation 5(2):** the written notification should be made within 5 working days after the in-person notification rather than 2 working days.
Reason for amendment: to give the NHS bodies more time to respond in accordance with stakeholder feedback during the consultation and to make the position clear that the time scale for making the written notification starts to run 'after' the date of the in-person notification.

(ii) Consequential amendments to the 2011 Regulations

29. **Amendment to regulation 12(7) of the 2011 Regulations:** this regulation now includes reference to "in accordance with Part 5", and also includes reference to the patient's representative.
Reason for amendment: the current wording in regulation 12(7) already refers to "in accordance with Part 5" and so the amendment has been made to align with previous wording. The reference to the patient's representative, has been included to reflect that a representative may be acting on behalf of the patient.

30. **Amendment to regulation 22(1) of the 2011 Regulations:** the requirement to acknowledge receipt of the notification of a concern should now be made within 5 working days "after the day on which the responsible body receives it" rather than 2 working days.
Reason for amendment: to align with the 5 working days to make the written notification under candour.

31. **Addition of new regulation 22(7) of the 2011 Regulations and amendment to regulation 22(6) of the 2011 Regulations:** a new provision which makes it clear that there is no requirement to send a copy of the notification of the concern to the patient (or their representative), where in-person notification and written notification under candour has already been

given to them. Regulation 22(6) is amended to make it clear that it is subject to regulation 22(7) of the 2011 Regulations.
Reason for amendment: to prevent any duplication of notification to a patient (or their representative) if in-person notification and written notification has already been given to them, particularly for example where there has been a bereavement. Furthermore, to avoid patients (and their representatives) receiving unsubstantiated allegations by way of a Datix entry prior to investigation. The principle of transparency is achieved through the in-person and written notification under the candour procedure.

32. **Removal of amendments to regulations 24, 26 and 33 of the 2011 Regulations:** during the consultation officials consulted on amending regulations 24, 26 and 33 of the 2011 Regulations so that the timescale for e.g. sending a response to an investigation ran from the date of the in-person notification if candour is triggered. These amendments have now been removed and the original drafting in regulation 24, 26 and 33 restored such that the timescales run from "the day upon which the responsible body receives notification of the concern".
Reason for removal of amendment: The timescales should run from the same/equivalent point in time – i.e. "the day upon which the responsible body receives notification of the concern" – irrespective of whether the duty of candour is triggered or not.

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023

33. These regulations contain "other" amendments to the 2011 Regulations which are not consequential on the duty of candour.

34. **Amendment to regulation 14(1)(c) of the 2011 Regulations:** where the Public Services Ombudsman for Wales ("PSOW") has recommended that the Welsh NHS body offers a form of redress under Part 6 of the 2011 Regulations, the Welsh NHS body may undertake a further investigation of the concern under the 2011 Regulations only for the purpose of determining whether a qualifying liability exists or may exist and to offer a form of redress in accordance with the recommendations of the PSOW.
Reason for amendment: this allows the NHS body to, following an investigation by the PSOW and a recommendation in the subsequent report, reconsider a matter for redress. This may be appropriate for example, following a concluded investigation by the PSOW, if there is additional information that means the incident may have met the requirements for redress. This enables the patient to free legal advice and representation, support and an apology and benefits the NHS by allowing redress settlement rather than lengthy further litigation.

35. **Removal of amendments to regulation 29 of the 2011 Regulations:** during the consultation, we consulted on removing the role of the Welsh Ministers in determining the level of damages for pain, suffering and loss of amenity under the 2011 Regulations. This now restores the provisions in regulations 29(4) and (5) such that Welsh Ministers' maintain the

power to issue a compensation tariff, and that if they do issue a tariff in the future, it is to be used for the purpose of guidance by Welsh NHS bodies when considering the amount of financial compensation to be offered.
Reason for removal of amendment: although the current tariff has been withdrawn, it is preferable to retain the Welsh Ministers' power to issue a tariff should the Welsh Ministers wish to do so in the future.

PART 2 – REGULATORY IMPACT ASSESSMENT

6. Regulatory Impact Assessment (RIA) summary

36. A Regulatory Impact Assessment has been completed for the Candour Regulations[1] and 2023 Amendments Regulations[2] and it follows below.

37. There are no specific provisions in the Regulations or 2023 Amendments which charge expenditure on the Welsh Consolidated Fund.

Administration costs

38. Across the implementation of the Duty of Candour there are a number of administrative costs for Welsh Government related to the development and publication of guidance, awareness material and training across those duties. There are also opportunity costs for the NHS in releasing staff for training. Much of this cost is covered in the RIA produced for the Act and are not repeated in this RIA unless there has been significant change to the assumptions. The Candour Regulations will come into force in April 2023 and there will be implementation / programme costs that continue into the 2023/24 financial year.

Cost Savings

39. The principles of 'Being open', are further developed by introducing the statutory duty of candour, which may result in savings due to fewer complaints and litigation against incidents that result in harm may be further avoided. Holden, J (2009)[3] states 'saying sorry and providing an explanation to a patient or relative seldom does any harm and can often avoid a complaint.'

40. Creating an open and learning culture in the NHS was looked at a part of a review by West, M and Coia, D (2019)[4]. They looked at Mersey Care NHS Foundation Trust's 'Just and Learning Culture' which aspired to "create an environment where staff feel supported and empowered to learn when things do not go as expected, rather than feeling blamed." This approach led to "a 75% reduction in disciplinary investigations since 2016 and 92% reduction in suspensions. The Trust estimated savings of £2.5 million due to higher

[1] NHS Wales 2023 The Duty of Candour Procedure (Wales)Regulations 2023.

[2] NHS Wales 2023 Amendment of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

[3] Holden, J. (2009) Saying sorry is not the same as admitting legal liability | The BMJ, 338
[4] West, M., Coia, D., (2019) caring-for-doctors-caring-for-patients_pdf-80706341.pdf (gmc-uk.org)

productivity, reduced back fill costs due to staff suspensions, reduced time to conduct an investigation and reduced legal and termination costs.

41. Attempts to estimate what the impact and savings on litigation may be helpful but due to the paucity of available data and availability of research there are limited findings that can be made. Therefore, any cost savings have not been quantified and remain mostly unknown.

Compliance Costs

42. Compliance costs with the Candour Regulations will fall to NHS bodies in the form of opportunity costs to comply with the duty of candour. There is an opportunity cost for NHS bodies to notify the service user (or someone acting on their behalf) as soon as they become aware the duty of candour has been triggered. The requirements of the Candour Regulations are closely aligned with that in the 2011 Regulations (which contain the ”Putting Things Right (PTR) procedure”) where notification to service users is required for complaints and incidents. Because of the combination of PTR procedure requirements in the 2011 Regulations already in place and the introduction of the duty, estimating the likely impact with NHS bodies is very difficult. For the purposes of this impact assessment, the opportunity cost for compliance has been calculated based on the number of reported incidents but excluding complaints.

Benefits

43. The Candour Regulations are expected to lead to a range of benefits, although these cannot be quantified due to a high degree of variability or a lack of available data. For example, there will be benefits from improving quality and having a more open and transparent culture in health provision.

Assumptions

44. Throughout the RIA, a wide variety of academic, routine statistical and service data has been used in the assessment of benefits and costs. Where there is uncertainty, a cautious approach has been taken towards the calculation of estimated costs. This is likely to mean that in some areas the actual costs associated with implementing the legislation may be lower. In a number of places, where there is uncertainty, a range of potential costs has been applied or the rationale on why a range of costs would not be meaningful.

7. Options

45. To assess the costs and benefits a six year appraisal period has been chosen, since the costs and benefits of the Candour Regulations are expected to reach a steady state quickly. Costs have been rounded to the nearest £100, some table totals may not sum due to this rounding.

46. The RIA presents a best estimate of the costs and benefits of the Regulations and 2023 Amendments based upon the available evidence. The analysis has been informed by engagement with key stakeholders including the Local health Board's (LHBs), Special health Authorities (SHAs) and NHS Trusts. Nevertheless, it has been necessary to make a series of assumptions in order to complete the calculations. Any assumptions made are explained in the narrative.

DUTY OF CANDOUR

OPTIONS

47. Two options have been identified and explored:

Option 1: Do nothing

Option 2: Make the Candour Regulations and 2023 Amendments

Option 1: Do nothing

Description

48. Under this option no statutory duty of candour would apply to NHS providers. This option would involve the continuation of the being open requirements set out within the existing 2011 Regulations (the process for managing concerns in NHS Wales) and the non-statutory duties of candour which apply to a range of healthcare professionals as part of their professional registrations which support openness and transparency when things go wrong.

Costs

49. There would be no additional costs attached to this option.

Benefits

50. Doing nothing would deliver no additional benefits and the opportunity to build on the work already undertaken would be lost. For regulated social care settings, a 'duty of candour' already exists under RISCA[5], therefore this option would not create a unified health and social care system-wide approach to candour. For NHS bodies it would fail to address the barriers which currently exist in the system[6] which prevent candour. Separately, there is an expectation from health professionals and the public following the 2016 Welsh Labour Manifesto commitment[7] which stated Wales will bring its arrangements

[5] Regulation and Inspection of Social Care (Wales) Act 2016. London: HMSO
[6]Waring, J. Beyond blame: cultural barriers to medical incident reporting. Social Science & Medicine [Internet]. 2005;60(9):1927-1935. Available from: https://www.sciencedirect.com/science/article/pii/S0277953604004666
[7] Welsh Labour Party. Together for Wales - Welsh Labour Manifesto [Internet]. 2016. Available from:

into line with other parts of the UK. In doing nothing the benefits of creating the duty would fail to be captured, including the certainty this would provide to users of NHS services and staff coming into Wales from other parts of the UK in that NHS bodies would ensure an open, honest and supportive response when something goes wrong.

51. This option does therefore not meet the policy intent.

Option 2: Make the Candour Regulations and the 2023 Amendments Regulations.

Description

52. This option would commence the statutory duty of candour on NHS bodies to provide information and support to service users when a patient safety incident occurs resulting in an adverse outcome. The duty will apply to NHS bodies (LHBs, Trusts, SHAs (both Welsh SHAs but does not include cross-border SHAs other than NHS Blood and Transplant) and primary care providers.

53. This option would also introduce the Candour Regulations that detail the requirements being placed on NHS bodies in responding to a person who has suffered an adverse outcome. It would also make some consequential and additional amendments to the 2011 Regulations to ensure it aligns with the new duty. The 2023 Amendments Regulations also make technical amendments to the 2011 Regulations such as requiring that Welsh SHAs shall be subject to the PTR process in the 2011 Regulations.

54. The duty of candour will apply where a service user to whom health care has been provided has suffered an adverse outcome which has or could result in more than minimal harm and the provision of health care was or may have been a factor.

55. When the duty applies, NHS bodies will be required to follow the procedure which is set out in the Candour Regulations. The procedure will require the NHS body to notify the service user or their representative on becoming aware of the incident to inform them what they understand to have happened, explain will happen next, provide an apology and offer support.

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http://d3n8a8pro7vhmx.cloudfront.net/themes/56f26ee2ebad64d813000001/attachments/original/1460733418/Welsh-Labour-Manifesto2016.pdf?1460733418

56. NHS bodies will be required to report annually on the duty. The report will be required to set out whether the duty of candour has applied during the year, how often, briefly describe the circumstances of each case and describe the steps taken by the provider with a view to preventing similar circumstances from arising in the future.

Costs:

57. LHBS, Trusts and primary care providers should already have some arrangements in place in order to meet the existing requirements of being open principles within the 2011 Regulations. The resources required by an NHS body to implement the duty are therefore likely to vary depending on the maturity of their existing arrangements. However, all providers will need to ensure their staff are aware of, and where appropriate trained to discharge the new duty. Policies and procedures will also need to be written or revised. It will also be essential to make the public aware of what they can expect should something go wrong relating to their healthcare.

58. For SHAs there will be similar implementation costs such as training and policy review but compliance costs are expected to be negligible as the duty only applies in situations where health care is being or has been provided. Welsh Government have worked with the SHAs to whom the duty applies to ensure the guidance, and its application to them, is understood in relation to the small number of instances that it is likely to apply.

Awareness, training and support

59. To successfully implement the duty and Regulations there are two key areas where action is required:

i. public awareness campaign;
ii. organisational awareness and training

Description – the two areas are outlined in turn below:

i. **Public awareness campaign**:

60. Stakeholder feedback reflected the importance of a public information campaign. A campaign would aim to increase public awareness of the duty of candour, empowering individuals to ask questions about the care and

services they receive, in the knowledge they could expect openness and transparency should they suffer an adverse outcome that may result in harm.

61. The planned public awareness campaign will consist of two elements, a duty of candour awareness video that can be used on social and digital platforms and a public information leaflet.

62. An initial distribution of leaflets will be provided by the programme to NHS bodies with an initial translation into the recommended 16 languages. With support from the Welsh Government communications team, there will be an efficient public facing promotion of these materials via the Welsh government social and digital channels in April and May 2023.

ii. **Development of Organisational awareness and training**:

63. The key to encouraging and enabling candour is education and training. Therefore, moving NHS bodies further forward to a position where they are routinely and responsively open and transparent with a service user or their representative when something has gone wrong is likely to involve a combination of leadership, communication and awareness training and development. To support this, a combination of different training and learning is likely to be needed for LHBs, Trusts and Primary Care providers:

64. **Basic all staff awareness training – NHS directly employed**: The candour awareness video will include a basic level of knowledge and understanding of the duty of candour for all NHS staff and help to create a culture of openness where staff feel safe and supported to raise concerns. This video is 3 minutes long and it is therefore assumed watching it can be a part of existing training time and not create opportunity costs for staff time.

65. **Advanced specialist staff, concerns team training**: Building on the general awareness training above, key individuals within each LHB, Trust and SHA will require more in-depth training to build the knowledge and skills required when the duty comes into effect.

66. It is intended this training will build upon the approach developed with the introduction of Putting Things Right in 2011[8]. This required organisations to

[8] 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

identify clinical, nursing and managerial opinion leaders to champion the ‘Being Open’ approach. An education and training video has been prepared for specialist teams and leadership building on the Putting Things Right approach. This training is 60 mins long and is therefore calculated as an opportunity cost for staff time within the NHS.

67. **Primary Care – Basic all staff awareness training**: The same training material will be available to primary care with the bulk of staff required to completed the awareness video

68. **Primary care practice managers/ complaints leads:** To support primary care practices in implementing the duty the full education and training video will be made available to leadership, managerial and concerns / complaints personnel.

69. **Board level training**: To support and embed the principles of being open and transparent within providers of NHS services; to support staff in delivering against the duty; and to support the wider leadership, cultural and behavioural changes needed to implement the duty, Board Members will need training. This training will ensure Board Members are confident in their ability to seek assurance their organisation is doing enough to learn from patient incidents and that they are using this learning to improve services.

70. The programme team have already delivered an on average, 30 minute awareness session to all NHS bodies boards, senior management teams or members between October 2022 and January 2023. As this cost has already been incurred it is considered to be a sunk cost and is not included in this analysis. In addition, the NHS body board members will be expected to complete the full education and training video.

71. **Costs** – the three areas (administration, public awareness campaign and training) are costed in turn below:

72. The costs, unless indicated otherwise, are anticipated to be incurred in 2022 – 23 or 2023 – 24. Time, where stated, refers to the number of working days.

Administration

73. Due to the specialist nature of this work and the need to move the implementation of the duty into the NHS, the programme team adjusted the structure of the programme in late 2022. This established the new Implementation Board to represent all affected NHS bodies but also move the resources for implementation into the Welsh Risk Pool (WRP) a part of NHS Wales Shared Services Partnership (NWSSP). This was to deliberately empower the NHS to oversee and own implementation but also to acknowledge the role WRP play in the PTR process and the connection between candour and PTR.

74. To support this work, Welsh Government agreed to fund certain aspects of the WRP establishment for 6 months post April 2023 as detailed below:

Table 1 – WRP Staff Costs

Role	Annual Cost	Estimated time required	**Cost**
AfC band 8b	£90,144*	6 months	£45,100
AfC band 7	£58,932	6 months	£29,500
Total			**£74,600**

*based on actual spend for the same role in 2022/23 gross salary including oncosts or average salary on relevant NHS AfC pay band

75. In addition to the above, a clinical lead has been seconded into the programme to support implementation of the duty in the NHS. The secondee is a senior nursing specialist providing essential clinical perspective and programme support.

Table 2 – Programme Team Costs

Role	Annual Cost	Estimated time required	**Cost**
AfC band 9	£168,246[(i)]	4 months	**£48,000**
Programme Manager / grade 7 – Opportunity Cost	£86,731[(ii)]	0.3WTE 5 months	**£10,800**

[(i)]based on yearly cost on relevant NHS AfC pay band including on costs and VAT

(ii) based on average yearly cost

76. In addition to the above, there are costs associated with each element specific to its delivery. Design and translation costs are dependent on the complexity and final requirements of the products. Estimated costs are outlined below:

i. **Public Awareness Campaign**:

Table 3 – development of public awareness campaign

Activity	Cost
Publicity campaign	£14,300(i)
Production and mastering audio and Braille guides(iii)	£1,000
Print costs, including easy read leaflet, children's version(iii)	£6,200
Dispatch (iv)	£2,000
TOTAL	**£23,500**

(i)Similar to the public communication campaign costs associated with the introduction of the special procedures element of the Public Health (Wales) Act 2017[9], plus some translation and proofreading estimates
(ii) Based on the translation, design and typesetting of Putting Things Right leaflet – approximately 600 words.
(iii) Based on the redesign costs of Putting Things Right leaflet in 2017, which included the production of ten audio disks, ten braille copies, easy read and children's versions.
(iv) Based on the cost of dispatching 106,700 Putting Things Right leaflet in 2017.

ii. **Staff awareness and training**:

77. The cost of development, proof reading and translation of the training materials is included in the staff cost monies in WRP.

78. Aligned to the above, NHS Wales Shared Services Partnership has confirmed uploading and hosting the e-learning modules online would be delivered at no cost to Welsh Government.

79. The guidance would be refreshed every five years, with the first cost occurring in 2028-29, the estimated opportunity cost associated with this refresh are:

Table 4 – opportunity cost of refreshing statutory guidance

[9] The Public Health (Wales) Act 2017 available: Public Health (Wales) Act 2017 (legislation.gov.uk)

Activity	Grade[ii]	Time	Estimated opportunity cost[iii]
Opportunity cost – refreshing guidance	grade 7	10 days	£3,900
Opportunity cost – design and typesetting[i]	EO	2 days	£400
Opportunity cost – translation and proofreading[i]	HEO	7.5 days	£1,800
Total			**£6,100**

(i)*It is estimated that design and translation costs would amount to half the original costs due to number of amendments required.*

(ii) based on average yearly cost

(iii) For Welsh Government staff an assumption of 220 working days per year is used

80. There would be no printing costs for the review as it would only be produced electronically.

Opportunity cost of training:

81. There is an opportunity cost associated with staff and board members undertaking training – these are set out outlined below and calculated in Table 5. The estimated opportunity costs associated with those receiving the training are calculated on the number of staff-hours spent on the training, multiplied by the average cost per hour and are set out in the table below. This does not take into account the fact that if this training was not being undertaken many staff would undertake alternative training of some sort as part of their required continuing professional development.

82. The opportunity costs estimated below are based on the following assumptions:

83. **Basic All Staff Awareness Training – NHS directly employed**: It is estimated this training would need to be delivered to approximately 91,404[10] individuals (staff directly employed by the NHS in Wales at 30 Sept 2022). It is estimated that this awareness training will take 3 minutes and will be watched during existing training or team meetings and therefore holds an opportunity cost.

[10] Staff directly employed by the NHS: as at 30 September 2022 | GOV.WALES

84. **Basic all staff awareness training – primary care**: It is estimated the e-learning training would to be delivered to approximately 7,511[11] individuals and will take approximately 3 minutes per person and will be watched during existing training or team meetings and therefore holds an opportunity cost.

85. **Advanced Specialist / Concerns Teams training:** It is estimated this training will need to be delivered to approximately 4,500 people across the NHS bodies and will take approximately 60 minutes per person. The workforce number is based on information received from LHBs and Trusts in relation to the number of staff dealing with concerns, incidents, including senior clinical staff. 500 people per health board, 250 per trust / SHA have been assumed.

86. **Primary care practice managers/complaints leads:** It is estimated the workshops for primary care practice managers/complaints leads are delivered to approximately 2,526[11] individuals and will take approximately 60 mins to complete per person. Based on conversations with professional and policy leads, it is assumed in dental, optometry and general practice settings, it is likely a health care professional will be the person calling patients for candour conversations.

87. **Board Level Training:** This training would need to be delivered to approximately 240 individuals (based on Board membership at January 2023), and this training would take approximately 60 minutes to complete per person.

Table 5 – opportunity costs organisational awareness and training

Cohort	Staff numbers	Hours of training per person	Mean hourly rate	27% uplift representing 'on costs'(i)	Estimated opportunity cost

[11] Based on 1,410 non Dr staff in general practice Wider practice staff (headcount) by age band and local health board (gov.wales)
2,310 GP's General practice workforce: as at 30 June 2022 | GOV.WALES

956 optometrists Sensory health (eye care and hearing statistics): April 2019 to March 2021 | GOV.WALES

1,420 dentists NHS dental services: April 2021 to March 2022 | GOV.WALES
1,424 pharmacy staff based on 712 pharmacies and 2 per pharmacy Community pharmacies by LHB and year (gov.wales)

Advanced specialist and concerns team training	4,500	1	£29.25[ii]	£7.90	£167,200
Basic awareness all staff directly employed	91,404	3 mins	£18.10[iii]	£4.89	£105,100
Primary care practice managers/complaints leads:	2,526	1	£22.98[iv]	£6.21	£73,700
Basic awareness all staff primary care	7,511	3 mins	£18.10[iii]	£4.89	£8,600
Board level training	240	1	£41.44[v]	£11.19	£12,600
Total					**£367,200**

(i)As advised by Welsh Government HSS-Finance a percentage uplift of 27% has been included as the available Office for National Statistics figures do not include on costs.
(ii) The Office for National Statistics Annual Survey of Hours and Earnings for 2022 (provisional) shows the mean hourly pay (excluding overtime) for health and social services managers and directors was £29.25;
(iii) The Office for National Statistics Annual Survey of Hours and Earnings for 2022 (provisional) shows the mean hourly pay (excluding overtime) for other health professionals was £18.10. This has been used as an average for wider health workforce.
(iv) The Office for National Statistics Annual Survey of Hours and Earnings for 2022 (provisional) shows the mean hourly pay (excluding overtime) for Health Care Practice Managers was £22.98.
(v) The Office for National Statistics Annual Survey of Hours and Earnings for 2022 (provisional) shows the mean hourly pay (excluding overtime) for Chief Executives and Senior Official working in Wales was £41.44.

88. In the long term it is expected any opportunity costs associated with training will become absorbed by providers of NHS services as part of their routine business, including staff time allocated for continuing professional development and training activities, minimising any additional burden. It is anticipated providers of NHS services will continue to incorporate this training into their existing training packages for staff, for example as part of staff induction or via signposting as part of a members' continuous professional development.

Implementation and ongoing operational costs:

89. In addition to the above key areas, where action is required to successfully implement the duty of candour, there may be other supplementary costs which arise.

90. Where possible, the duty builds upon the existing systems and processes underpinning the Being Open principles**Error! Bookmark not defined.** and the 2011 Regulations**Error! Bookmark not defined.**; which are already well established within the existing organisational policies and procedures.

91. All providers of NHS services have developed implementation plans to ensure the duty is effectively introduced. This includes a review of policies and procedures to ensure the changes required by the introduction of the duty are incorporated, reported upon and adopted through organisational governance arrangements. This work is now complete with each NHS body reporting against their plans to the Implementation boards. The opportunity cost has therefore been realised and is not included in this analysis.

92. The estimated ongoing costs resulting from the duty's implementation are outlined below.

93. **Service user engagement:**

94. The procedure set out in the Candour Regulations, requires the provider to notify the service user or their representative on becoming aware of the incident to inform them what they understood to have happened, explain will happen next, provide an apology and offer support, and subsequently provide feedback on investigations and the steps taken to prevent a recurrence and keep records.

95. Providers of NHS services should already be taking some of these steps in complying with the 'Being Open' principles and the 2011 Regulations**Error! Bookmark not defined.**. These regulations require:

96. **Service user notification**:

- Regulation 12(7) outlines the duty currently on LHBs, Trusts and primary care providers to notify the service user or their representatives of a 'concern' (which includes a patient safety incident) where its initial investigation determines the service user has suffered moderate or severe harm or death. However the duty only applies where an incident is notified to the body by a staff member: and
- Regulation 12(8) provides for an exception from the duty in regulation 12(7) for cases where it would "not be interest of the patient to be informed of or involved in the investigation of the concern" – however it is only relied on in exceptional circumstances.

97. **Support**:

- Regulation 22(4)(b) outlines the availability of advocacy and support services which may be of assistance to that person.

98. **Explaining what will happen next**:

- Regulation 22(4)(a) outlines LHBs, Trusts and primary care providers must discuss with the person who notified the concern the manner in which the investigation of the concern will be handled, including consent to the use of medical records.

99. Separately, Section 9 of the Putting Things Right Guidance for NHS staff[12] and Section 6.3 of the Health and Care Standards[13] currently require providers of NHS services to have systems in place to ensure concerns, when reported, are: acted upon and responded to in an appropriate and timely manner, and are handled and investigated openly, effectively and by those appropriately skilled to do so.

100. Whilst the duty builds on these established systems in some instances changes will be needed to achieve the desired policy effect, these are:

[12] 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

[13] Health and Care Standards [Internet]. NHS Wales. 2019 [cited 3 April 2019]. Available from: http://www.wales.nhs.uk/governance-emanual/health-and-care-standards

- the duty will require providers of NHS services to be upfront with the service user or their representative when more than minimal harm has or may have occurred and not wait for an initial investigation to determine its appropriateness – as required under 12(7) within the 2011 Regulations; and
- the duty will change the nature of the communication to service user or their representatives ensuring to ensure they are supportive and advocating of learning and change.

101. Moving the duty to notify the service user to the start of the investigative process may mean the duty will be triggered more often as it will apply to all incidents when more than minimal harm may have occurred compared to only those where such harm and its cause has been established. It is not feasible to accurately calculate the possible increase as the existing 'Being Open' principles mean in nearly all instances a service user or their representative should already being notified when harm has occurred. However, the duty of candour will require providers to record information and in particular make and keep a record of the conversations had with service users following an incident and therefore more staff time may be needed to do so.

102. The number of reported incidents via Datix with more than minimal harm in Wales between April 2022 and January 2023 (9 months) was 5,939. This has been expanded to create a 12 month equivalent of 7,919 The detail of this data, parameters and caveats are available in Appendix B. Datix is an incident reporting system available to all NHS health care providers in Wales (including primary care). It is assumed that where a complaint has been made by a person using health services and that complaint includes more than minimal harm, this has been reported on Datix as a patient safety incident. The RIA for the Act used incident data from National Reporting and Learning System (NRLS) which was not consistently used across secondary care and not use at all in primary care. Although there may be some elements of underreporting in the new Datix system, by comparison the data are a significant improvement on previous estimates and represents the best available information for estimating costs.

103. We have assumed it takes 90 minutes to make and keep a record of a candour conversation. This is broken down into 60 minutes for conversation with the person and 30 mins for writing the letter. As being open is an existing requirement under PTR regulations, it is assumed that some of this process is already being undertaken. The estimates are therefore based on 30 mins being a part of existing practice and an additional 60 mins to account for duty of candour written requirements and acknowledging that conversations may be more complex with people where the organisations have initiated that

conversation. This is costed on the assumption it is completed by a member of staff on the mean hourly pay (excluding overtime) for those working in management roles in health (calculated as per Table 5, including on costs).

Table 6 – opportunity cost for providers of notifying the service user

Activity	Additional Time required	Frequency	Hourly rate	Estimated opportunity cost
Opportunity cost – communication to service user or representative	60 minutes	7,919	£37.15[(i)]	£294,200

(i)As per table 5 – the mean hourly pay and on costs for those in management roles in health.

104. **The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023** make further technical changes to the 2011 Regulations. Additional changes of significance are the inclusion of the SHAs, HEIW and DHCW in the 2011 Regulations. This extends the PTR and redress arrangements to cover all of DHCW's activities and HEIW's health related activities. Both organisations are also covered by the duty of candour and are included in the opportunity costs for implementing the new duty. Neither of the SHAs currently have direct patient contact and it is therefore assumed that beyond implementation costs already covered in the wider implementation of the new duty, there will be no practical additional workload and therefore cost. There will be a requirement for both SHAs to support other NHS bodies when an investigation requires, but this is work already supported by both organisations.

105. The other notable amendment to the 2011 Regulations is the new allowance for cases to be re-considered for redress by the NHS bodies if, after investigation by the PSOW, there is additional information that means the incident may have met the requirements for redress. If the PSOW has recommended that the Welsh NHS body offers a form of redress under Part 6 of these Regulations, the Welsh NHS body may undertake a further investigation of the concern under these Regulations only for the purpose of determining whether a qualifying liability exists or may exist and to offer a form of redress in accordance with the recommendations of the PSOW. Given the small number of cases referred to the PSOW, the likely numbers of re-considered cases and therefore increase in redress payments is low. This may reduce the instances of the PSOW recommending to NHS bodies they make compensation payments to complainants.

106. **Support from the LHB for primary care providers –** There may be a small number of instances where a LHB will be required to provide support and assistance to a primary care provider in relation to the duty. For example this may be in instances where a primary care provider needs assistance in considering if the duty should be triggered or if were a primary care provider does not have the capacity / resource to offer assistance to of support to a service user who has suffered harm.

107. However, this arrangement does not create any new burden for LHBs as they must co-operate by the very fact one commissions the other. Additionally, in relation to when something goes wrong Regulation 20 of the 2011 Regulations**Error! Bookmark not defined.** and Section 6 of the Putting Things Right Guidance[12] set out the procedure to be followed when a primary care provider requests assistance from a LHB to investigate a concern which has been notified to the primary care provider.

108. **Legal advice from Legal and Risk Services –** The Legal and Risk Services provide chargeable advice to NHS bodies in relation to redress and the 2011 Regulations. It is estimated that in the first year (2023-24) advice requests relating to the Duty of Candour would increase the current costs in respect of chargeable advice sought in respect of 2011 Regulations matters by 20% and then 10% in subsequent years. The current approximate sum billed by Legal & Risk Services to NHS bodies in respect of Putting Things Right matters is £34,500. The costs for NHS bodies are estimated to be:

Table 7 – costs of obtaining legal advice from NWSSP Legal & Risk Services

	2023-24	2024-25	2025-26	2026-27	2027-28	2028-29 (onwards)
Cost – legal costs payable to NWSSP Legal & Risk Services for chargeable work relating to advice requests	£6,900	£3,450	£3,450	£3,450	£3,450	£3,450

109. **Reporting –** Under the duty, NHS bodies will be required to report annually on compliance with the duty and publish their reports. LHBs will be required to collate this information from those primary care providers from whom they commission services and publish a combined report. The report will be required to set out whether the duty of candour has applied during the year, how often, briefly describe the circumstances of each case, and describe the steps taken by the provider with a view to preventing similar circumstances from arising in the future.

110. There are a number of requirements already in place which go a considerable way to help achieve this:

- Data on the number of current patient safety incidents is already collected in NHS Wales either via local risk management systems, including Datix Cymru and reporting to the Welsh Risk Pool via Datix Cloud IQ form (for those primary care providers who do not have access to local risk management systems). The meaning of “more than minimal” harm which will trigger the duty is set out in guidance. The thresholds for triggering the duty has been aligned with the historic NRLS thresholds; therefore this will not require the reporting and collection of any information which is not currently collected.

- In Wales, work has been undertaken to develop the Datix Cymru System to include a field to capture if the duty of candour process has been triggered, which is now an improved system for capturing, amongst other data, patient safety incidents. This will be available to all NHS Health Boards, SHAs, Trusts, LHBs and primary care providers. This development will make it easier for primary care providers to have direct access to a local risk management system to record patient safety incidents. Any future developments as a result

of the duty can be incorporated within this system and delivered at no cost to Welsh Government or NHS providers.

- Regulation 51 of the 2011 Regulations**Error! Bookmark not defined.** requires LHBs, Trusts and primary care providers 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 their report to the LHB with whom they have entered into arrangements with, allowing for collation and publication within a LHB's Annual Putting Things Right report, and considered within each organisation's Annual Quality Statement.

111. Given patient safety incidents data is already collected and, given NHS providers are already required to produce an annual report to meet the requirements of Putting Things Right[12], implementing the reporting arrangements required by the duty can be achieved at no additional cost.

112. **Cultural changes –** An effect of the duty will be one where the body further supports the development of a culture of being open and honest and encourages the notification and review of future incidents from both patients and staff. The duty will therefore change the focus of current incident reviews to one of encouragement, support and guidance for staff. The costs associated with this shift in culture are difficult to estimate, as the resource and time required to deliver this will vary amongst providers depending on how far along they are in their journey of 'Being Open' when things go wrong.

113. **Claims and complaints –** The introduction of Putting Things Right**Error! Bookmark not defined.** in 2011 ensured the principles of Being Open are at the heart of NHS Wales. It acknowledged when things go wrong patients, service users and their families or carers want to be told what happened, receive an apology and be reassured learning will take place. A duty of candour will further empower staff to be open when things go wrong.

114. As a result of this open and honest approach, as well as the ease of access and fairness to redress, this has led to a reduction of lower value claims for LHBs and NHS Trusts reaching litigation in Wales, with people instead opting to take such claims through the redress process[14]. If an

[14] NHS Wales Shared Services Partnership. Paper prepared for NHS Directors of Finance Forum, 2016

organisation is open and upfront in acknowledging harm, offering redress is less costly compared to litigation which can result in lengthy and sometimes complicated legal proceedings. Therefore, the operation of the Putting Things Right scheme**Error! Bookmark not defined.** has resulted in significant costs savings, such as lower value cases where costs often outweigh damages. The introduction of state backed indemnity for general practices from April 2019 has enabled the extension of NHS Redress**Error! Bookmark not defined.** to this element of primary care.

115. By being open it may result in further savings which are associated by introducing the duty of candour, as litigation against incidents that result in harm may be further avoided. This is true in the NHS in England, where a duty of candour currently exists, with the number of formal litigation cases has reduced year on year[15]. However, the extent to which possible savings may apply are difficult to quantify and could result in more cases being taken through the NHS Redress process**Error! Bookmark not defined.** should the subsequent investigation into the incident determine that is appropriate. These cost savings have not been quantified and are therefore unknown.

116. Although there is a risk with the possibility of increased candidness leading to an increase in litigation costs, the evidence suggests the likelihood of it occurring is low[1617].

Healthcare Inspectorate Wales:

117. HIW will be the inspectorate responsible for assessing compliance of the duty of candour on behalf of Welsh Ministers. It is not expected this will place an additional burden on HIW; as per other areas of its work, the inspectorate will prioritise its inspection programme based on intelligence, and therefore routine or regular inspections focusing on candour are not expected. Additionally, it is extremely unlikely the inspectorate would consider an organisation's response to the duty of candour in isolation but rather as part of a wider governance review. Evidence shows bodies which are not acting in a candid way may be indicative of wider governance issues. So, while compliance with the duty of candour will contribute to the overall picture and

[15] NHS Resolution, 2022, Annual Report and Accounts 2021/22, available: Corporate Reports Archive - NHS Resolution, accessed Feb 2023.
[16] Tingle, J. (2022) Improving patient communication through the duty of candour and shared decision-making | British Journal of Nursing (magonlinelibrary.com) British Journal of Nursing, Vol. 31, No.14.
[17] Birks, Y., Aspinal, F., Bloor, K. (2018) UnderstandingDriversOfLitigationInHealthServices.pdf (york.ac.uk)

assist HIW in assessing the level of concerns around a particular organisation, it will not place any additional cost burden of the inspectorate.

Regulations under the Care Standards Act 2000:

118. The aim of creating a formal duty of candour for all NHS bodies is to provide a system wide approach in relation to candour (NHS providers, regulated independent health care providers and regulated social care services). To achieve this for regulated independent health care providers, amendments are required to regulations under the 2000 Act[18]. This will be delivered separately to the Act, the Candour Regulations and the 2023 Amendments Regulations and the cost and benefit of this will be presented in a separate Regulatory Impact Assessment.

Summary of costs:

119. The costs set out above for development and delivery of a public awareness campaign, training for staff, and development distribution and review of statutory guidance are summarised in the table below.

Table 8 – cost to Welsh Government

	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28 onwards
WRP Staff Costs (Table 1)		74,600				
Opportunity cost – programme team (Table 2)		10,800				
Programme Team Costs (Table 2)		48,000				
Public awareness campaign (Table 3)	23,500					
Opportunity cost of refreshing statutory guidance (Table 20)						£6,100*
Total	**23,500**	**133,400**				**6,100**

*cost occurring every five years.

Table 9 – costs to NHS bodies

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

	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28
Opportunity cost – organisational awareness and training (Table 5)	£183,600*	£183,600*				
Opportunity cost for providers of notifying the service user (Table 6)	294,200	294,200	294,200	294,200	294,200	294,200
Legal advice from Legal and Risk Services (Table 7)	6,900	3,450	3,450	3,450	3,450	3,450
Total	**484,700**	**481,250**	**297,650**	**297,650**	**297,650**	**297,650**

*total NHS training opp cost in table 5 367,200 split over 2022-23 and 2023-24 assuming not all training will be complete prior to April 2023.

120. In addition to the above, there is a risk the stronger duty could cause some NHS providers who are already acting in a candid manner to take additional unnecessary action and go over and above to ensure they are compliant with the new statutory duty. It is not possible to quantify this risk.

Benefits

Welsh Government:

121. Creating a statutory duty of candour for all NHS bodies will help create an integrated and whole system approach to candour. It will promote a culture of openness and improve the quality of care within the health service by encouraging organisational learning, avoiding future incidents.

122. By placing a duty on NHS bodies which brings the notification to a service user or their representative upfront, and not tied to the outcome of an initial investigation to determine its appropriateness, the approach takes onus away from a member of staff, as with the professional duty, to initiate a process of being candid and places it on the organisation to do so automatically – achieving cultural change.

123. It will help ensure the known barriers to disclosure will be addressed, for example fear, cultures of secrecy and/or blame, lack of confidence in communication skills, fear people will be upset and doubt the disclosure is effective in improving culture. Additionally, by placing the duty at an organisational level reduces any fear associated with institutional

repercussions, legal liability, blame, or lack of accountability. Instead it will support the professional obligations which currently exist.

124. It supports the policy direction of an integrated approach across health and social care, aligning to the aspirations within *A* Healthier Wales[19]. Additionally, the proposed duty addresses the recommendations from the expert reviews and delivers the Government's manifesto commitment**Error! Bookmark not defined.**. This option therefore meets the policy intent.

Healthcare Inspectorate Wales:

125. Requiring NHS bodies to report annually on the duty, will allow the inspectorate to use the information to assist its insight and monitoring information and where any concerns are identified it may be considered under the Welsh Government's Tripartite escalation and intervention arrangements. As an overarching picture of quality improvement the annual reporting on candour could be built into the *Annual Quality Statements* produced by NHS Trusts, LHBs and Welsh SHAs, therefore these reports will include another strand of intelligence which the inspectorate can use to build a picture on the governance of a body. For example, high performing bodies are those which are open and honest when mistakes or errors occur and can demonstrate learning and improved outcomes as a result.

NHS bodies:

126. Placing NHS bodies under a duty of candour strengthens existing systems to support a culture of openness and transparency by changing behaviours – addressing the current barriers which prevent candour. It will help achieve a position of consistent and routine practice whereby openness and transparency with service users in relation to their care and treatment, becomes a normal part of the culture across these bodies in Wales – eliminating fear and dispelling any cultures of secrecy and/or blame.

127. It will ensure patients are consistently informed when adverse events happen – reassuring them the issues that led to the event will be addressed and lessons learnt to help prevent them recurring. It will also help to maintain public and patient trust in the health service and promote accountability for safer systems. It will also improve the quality of services by supporting the

[19] Welsh Government. A Healthier Wales: our Plan for Health and Social Care [Internet] 2018. Available from: https://gweddill.gov.wales/docs/dhss/publications/180608healthier-wales-mainen.pdf

development of a learning culture across services and empower and engage staff in improvement efforts.

128. The duty is not intended to be a punitive measure; instead it should be viewed as supportive to both patients and staff and be a further mechanism to drive organisational learning and improvement. The duty is not intended to imply fault or blame but will improve the way a body responds when things go wrong unintentionally.

129. Nevertheless, bodies may perceive the additional detail required (if the candour procedure has been followed) in their publicly available annual reports to be potentially damaging to their reputation and therefore may focus efforts to ensure fewer avoidable incidences of harm occur. If this occurs, it will act as a mechanism of prevention, as bodies strive to improve quality and learning from mistakes. Additionally, it may lead to bodies to ensure the duty of candour has been triggered when an incident has occurred, helping achieve the desired culture change. Alternatively, it may however lead to bodies not honestly reporting compliance with the duty – something which may picked up by HIW because, as explained earlier, bodies which are not acting in a candid way are likely to have wider governance issues which would raise concern for possible further investigations.

130. The inclusion of details of the duty within publication of the Annual Putting Things Right reports and Annual Quality Statements will continue to provide a system for continuous improvement across the sector by allowing bodies to learn from others – promoted and considered via existing patient experience networks. This is likely to lead to improved quality of care outcomes delivered by NHS bodies due to improvements in working practices and leading to a reduction in avoidable incidences.

131. Finally, it will provide those health and social services providers who commission care, especially across the border into England, with the benefit of having a duty of candour comparable to that in EnglandError! Bookmark not defined.. This will allow the comparison of data on incidents reported under the proposed duty, adding to a commissioner's evidence base when considering a suitable location for care.

Health and social care professionals:

132. Although individual health and social care professionals are required by their professional organisations to act openly and honestly, we want to ensure they are always supported to act in this manner by the organisations they work for. Professional obligations are crucial but insufficient by themselves to ensure a culture of candour, hence why the proposed duty is to be placed at an organisational level[20]. This will provide staff with a safe and supportive environment to raise concerns and report incidents and will separately provide the public with confidence they are being treated with respect and as partners in their own care – especially when things go wrong.

133. This option would therefore strengthen the existing systems in place to support openness and transparency. It would require NHS bodies to take action to support staff in relation to the reporting of patient safety incidents, and prevent and appropriately address bullying, victimisation and/or harassment. This places the onus on NHS bodies to instigate the investigation of concerns, complaints and redress arrangements (if applicable) rather than leaving it to individual members of staff. This will therefore build a culture allowing for staff and organisations to be able to learn from their mistakes, where they are able to reflect openly and freely when mistakes happen and create an open and learning environment rather than a blame culture.

Public:

134. When something goes wrong, the way in which organisations deal with these situations becomes very important and can make a huge difference to people's experience and to their on-going relationship with their care provider. This option would maintain public and patient trust in the health service by ensuring that when an adverse outcome occurs, service users are informed, provided with an apology and offered support, and subsequently provided with feedback on investigations and the steps taken to prevent a recurrence. For the service user, they will experience the benefit of feeling that their concerns and distress have been acknowledged – reducing the trauma felt, confidence in the openness of the communication, and the timeliness and accuracy of the information provided.

135. It will also achieve a system wide approach to candour providing a person with the assurance that should something go wrong with their care or treatment they will be dealt with in an open and honest way irrespective of

[20] Francis, R. Freedom to speak up [Internet]. 2015. Available from: NHS Resolution. Annual report and accounts 2017/18 [Internet]. NHS Resolution; 2018. Available from: 9. Health and Care Standards [Internet]. NHS Wales. 2019 [cited 3 April 2019]. Available from: http://www.wales.nhs.uk/governance-emanual/health-and-care-standards

whether they received care from the NHS, from a regulated provider of social care services or from a regulated independent health care provider.

Summary and preferred options

DUTY OF CANDOUR

136. **Option 1** proposes no change to the current legislative framework. The introduction of Putting Things Right in 2011 embedded the principles of 'Being Open' in the Welsh NHS, resulting in a gradual shift towards more a co-productive partnership between patients and professionals. However, we know barriers still exist, therefore keeping the status quo would miss out on a real opportunity to build on the success of Putting Things Right. Therefore, this option does not meet any of the policy objectives.

137. **Option 2** would make the Candour Regulations and the 2023 Amendments Regulations. In making the Candour Regulations, the Welsh Ministers would also implement the duty of candour on NHS bodies (LHBs, NHS Trusts, SHAs (Welsh SHAs but not including cross-border SHAs other than NHS Blood and Transplant) and primary care providers) which would:

a. ensure patients are informed when adverse events happen;
b. promote a culture of openness and transparency in the health service;
c. support patient care and the implementation of consistent responses to adverse incidents across health services;
d. maintain public and patient trust in the health service and promote accountability for safer systems; and
e. improve the quality of services by supporting the development of a learning culture across services and engage staff in improvement efforts.

138. This helps create an integrated/ whole system approach to candour – across the NHS and regulated health and social care system.

139. Although there are costs involved in effectively delivering Option 2, the duty builds upon existing systems and process. For Welsh Government these are in relation to effectively communicating the duty. The main cost identified is for NHS bodies, which is the opportunity cost associated with undertaking the necessary training, however this cost is likely to be occurred irrelevant to the proposed duty as many staff would undertake alternative training of some

sort as part of their required continuing professional development. In addition, the costs for NHS bodies are balanced by possible savings as a result of a reduction in the number of litigation claims, but this is difficult to quantify in advance of implementation.

140. Overall, it is felt the evidence strongly demonstrates the benefits of Option 2.

Competition Assessment

141. The competition filter test has been completed. The Regulations are not expected to affect levels of competition in Wales or the competitiveness of Welsh firms.

142. The Duty of Candour is likely to have impact across 3 markets, the health care sector in Wales, the medical legal market and third sector organisations that campaign on specific patient issues or for patient voice. With the exception of the health care sector being monopolised by public provision, the differences in the markets are minimal and the assessment below can be read across all.

The competition filter test	
Question	**Answer yes or no**
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No*
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No*
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No

The competition filter test	
Question	**Answer yes or no**
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

*health care provision in the UK is monopolised by public provision. That being said, the duty will apply equally across all NHS and non-NHS providers of health care in Wales, therefore not unfavourably affecting any individual provider.

9. Post implementation review

143. The Act is multi-faceted and will provide a legislative framework to enable action in a number of interlinked areas to drive learning and improvement and prevent healthcare associated harm. The evaluation of the Regulations has been considered within the wider Act evaluation and it is readily acknowledged that measuring and assessing the individual impact of each element of the Act in relation to the other elements is not likely to be possible.

144. The implementation approach outlined in the RIA builds, where possible, on existing planning and reporting processes to deliver an effective framework for demonstrating outcomes and impacts without excessive additional burden. This approach will underpin the monitoring and evaluation associated with the Act, making use of routinely collected administrative and survey data, complemented with qualitative evidence from key stakeholders and service recipients.

145. The Act Implementation Programme has commissioned and received the initial evaluability assessment that sets out theories of change and some suggested metrics and data sources to base the full evaluation on. This evaluability assessment considered all areas of the Act and costs £50,000.

146. The full evaluation will be commissioned early in the 2023-24 financial year

Health data and statistics

147. Activity to monitor the implementation of the Act will wherever possible be aligned to other relevant work. Data provided through surveys routinely undertaken by Welsh Government and partners will therefore be utilised in the

monitoring and evaluation of the legislation. At the same time consideration may need to be given to new data collections as necessary.

Administrative data

148. Similarly, best use will be made of the most relevant administrative data already collected. In respect of the topics covered in the Act, some examples of existing data sources include:

- Data on the number of current patient safety incidents, currently collected via the 'Once for Wales' Concerns Management System (Datix) and,

- PROMs (Patient Reported Outcome Measures) and PREMs (Patient Reported Experience Measures)[21].

- Findings from inspections and reviews undertaken by HIW.

Reviewing the implementation process

149. The multi-faceted approach outlined above will focus on the extent to which the legislation has contributed to delivering change across the range of outcomes where it would be expected to make a difference. This will include, as recommended by the Finance Committee in their 2017 'Inquiry into the financial estimates accompanying legislation[22],' consideration of the accuracy of the estimated costs, savings, benefits and dis-benefits included in the RIA.

150. However, it will also be important to complement this activity with evidence on how the legislation is being delivered across Wales and the role of key partners in delivering its objectives, as well as any other consequences. Further consideration will be given to the specific content of such evaluative activity in the coming months.

151. Costing, monitoring and evaluation without detail on scope and methods to be used is problematic. At this stage, based on costs associated with similar evaluations and reviews conducted previously – including the Public

[21] Health in Wales | PROMs, PREMs and Efficiency Programme [Internet]. NHS Wales. [cited 3 April 2019]. Available from: http://www.wales.nhs.uk/promspremsandefficiencyprogramme
[22] Finance Committee. Written Response by the Welsh Government to the report of the Finance Committee entitled Inquiry into the financial estimates accompanying legislation [Internet]. Finance Committee; 2017. Available from: http://senedd.assembly.wales/documents/s70559/Welsh%20Government%20response.pdf

Health (Minimum Price for Alcohol) (Wales) Act 2018 and Human Transplantation (Wales) Act 2013 – costs are estimated at £250,000 to £300,000 spread over five years. It is important to note the total cost of this work will inevitably depend on the balance of using and analysing routinely-available and bespoke data and research about the implementation and enforcement of the legislation.

152. The Act Implementation programme has commissioned and received the initial evaluability assessment that sets out theories of change and some suggested metrics and data sources to base the full evaluation on. This evaluability assessment considered all areas of the Act and cost £50,000.

153. The full evaluation will be commissioned early in the 2023-24 financial year

Appendix A

Nationally Reported Patient Safety Incidents

The report below from the Welsh Risk Pool details the patient safety incidents reported on Datix in Wales between 01/04/22 and 31/01/23 (9 months). This time period has been used to ensure the most up to date information is considered and because all NHS bodies in Wales had implemented the Datix system by 01/04/22. Prior to that date, there was not full coverage across NHS bodies. The data therefore, has been expanded to a 12-month equivalent.

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Gwasanaethau Cronfa Risg Cymru
Shared Services Partnership
Welsh Risk Pool Services

Welsh Government Duty of Candour

Regulatory Impact Assessment Data

Update 24th February 2023

The Welsh Risk Pool obtained data on behalf of Welsh Government to identify the proportion of reported incidents that could have triggered the Duty of Candour if it was in force.

The Welsh Risk Pool contacted CEOs to make the request for anonymised data from the Datix Cymru system.

Data was requested in respect of incidents reports between 01/04/22 and 31/01/23 and only incidents where the person affected was a patient or service user were requested. This time period was selected because this relates to when all organisations have incident data in the Datix Cymru systems in NHS Wales.

The OfWCMS Central Team provided support by creating a standard listing report to extract the required data for each organisation's system

The OfWCMS Central Team also provided support to cleanse the data

Data was obtained from twelve Health Bodies. All organisations provided data following the request made to CEOs and further enquiries.

The health bodies which provided data are:

- ABUHB
- BCUHB
- CTMUHB
- CVUHB
- DHCW
- HDUHB
- HEIW
- PHW
- PTHB
- SBUHB
- VUNHST
- WAST

Data analysis:

A total of **122,626 Incidents** were **reported** across the eleven health bodies between 01/04/22 and 31/01/23 where the person affected was a patient or service user.

Of these, 5021 (**4.09%**) related to an incident that **occurred more than 90 days prior** to the reported date. It is normal practice for incidents to be reported as soon as the issue is identified (known as the date of knowledge) and this appears to be a reasonable proportion of historic incidents, providing assurance that he data source is valid.

During a cleansing review, 6185 (**5.04%**) appeared to have been **closed without a confirmation of the harm grading** and will be returned to the health body for action.

75447 (**61.53%**) of the reported incidents were **closed between 01/04/22 and 31/01/23**. Data from these incidents can be relied upon as the recorded harm grading has been validated following review or investigation.

Of the closed incidents:

268 were graded following investigation as involving catastrophic harm

261 were graded following investigation as involving severe harm

5410 were graded following investigation as involving moderate harm

42109 were graded following investigation as involving low harm

27398 were graded following investigation as involving no harm

This means that 5939 (268+261+5410) (**7.87% of closed incidents**) were graded as involving **catastrophic, severe or moderate harm** and are likely to have triggered the Duty of Candour if it had been in force at the time.

Of the closed incidents to top five occurring incident types are:

Pressure Damage, Moisture Damage (27.70%)

Accident, Injury (19.46%)

Behaviour (including violence and aggression) (9.34%)

Medication, IV Fluids (6.22%)

Access, Admission (5.97%)

Infection Prevention and Control (5.09%)

Treatment, Procedure (4.96%)

Assessment, Investigation, Diagnosis (4.84%)

Maternity adverse occurrence (3.54%)

Communication (1.99%)

Appendix B

List of abbreviations

2000 Act - Care Standards Act 2000

2006 Act - National Health Service (Wales) Act 2006.

2011 Regulations - National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

2014 Act – Social Services and Well-being (Wales) Act 2014

2016 Act - Regulation and Inspection of Social Care (Wales) Act 2016

2017 Regulations - The Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017

AfC – Agenda for Change (the NHS terms & conditions of employment including pay scales)

CEO – Chief Executive Officer

CIW – Care Inspectorate Wales

CRIA – Children's Rights Impact Assessment

EB1 - Executive Band 1

EB2 – Executive Band 2

EIA – Equalities Impact Assessment

FTE – Full Time Equivalent

GOWA – Government of Wales Act 2006

GP/s – General Practitioner/s

GPC – General Practitioners Committee

H&SS – Health and Social Services

HCP – Health Care Professional

HEIW – Health Education Improvement Wales

HIA – Health Impact Assessment

HIW – Health Inspectorate Wales

HR – Human Resources

ICT – Information and Communications Technology

IM – Independent Member

IT – Information Technology

JIA – Justice Impact Assessment

LA – Local Authority

LHB/s – University or Teaching Health Board/s

MB1 - Management Band 1

MB2 – Management Band 2

MB3 – Management Band 3

NHS – National Health Service

NHS Bodies (Quality) – Local Health Boards (LHBs), NHS Trusts, Special Health Authorities (not including cross-border special health authorities)

NHS Bodies (Candour) – LHBs, Trusts, Special Health Authorities (including cross-border Special Health Authorities in relation to their Welsh functions) and primary care providers in Wales in respect of the NHS services they provide

NRLS – National Reporting and Learning System

OECD – Organisation for Economic Co-operation and Development

PAYE – Pay As You Earn

PIA – Privacy Impact Assessment

PTR – Putting Things Right

PSBs – Public Services Boards

PSOW – Public Services Ombudsman for Wales

RIA – Regulatory Impact Assessment

RISCA – Regulations and Inspection of Social Care (Wales) Act 2016

RPIA – Rural Proofing Impact Assessment

SCS – Senior Civil Service

SHAs – Special Health Authorities

tHB – Teaching Health Board

VAT – Value Added Tax

WG – Welsh Government

WLIA – Welsh Language Impact Assessment

WM/s – Welsh Minister/s

WTE – Whole Time Equivalent