Explanatory Memorandum to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025

This Explanatory Memorandum has been prepared by the Health, Social Care and Early Years Group of the Welsh Government and is laid before Senedd Cymru with the above subordinate legislation and in accordance with Standing Order 27.1.

Cabinet Secretary's Declaration

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025. I am satisfied that the benefits justify the costs.

Jeremy Miles MS
Cabinet Secretary for Health and Social Care

23 September 2025

PART 1

Description

1. The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025 ("the amending Regulations") update the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the Principal Regulations"), via the affirmative procedure, to bring into effect changes to duties that exist under the Principal Regulations on NHS responsible bodies.

2. The amending Regulations amend the arrangements responsible bodies are expected to make to respond to and investigate the concerns and communicate the outcome of investigations of concerns notified by persons in respect of services provided by or under arrangements with the National Health Service in Wales, and in relation to components of the redress provisions under the Principal Regulations.

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

3. Due to errors picked up in Regulations laid on 8 July 2025 SL(6)633[1] the Regulations were withdrawn on 11 September 2025 and have been amended and a revised version laid.

Legislative Background

4. The amending Regulations are made under the powers conferred by the following provisions:

- sections 113(2), (3), 115(1), (2), (5), (6), and 195(1) of the Health and Social Care (Community Health and Standards) Act 2003 ("the 2003 Act")[2],
- and sections 1(1) to (4)(a), (5), (6), 2(1), (2), (4), (5), (6)(a), 3(1), (2)(b) to (d), 4(1), (2)(a), 5, 9(1) to (5), (7) and 11(2), (3) of the NHS Redress (Wales) Measure 2008 ("the Measure")[3].

5. Section 195(6) of the 2003 Act provides, by virtue of section 162(1) of, and paragraph 34(1) and (2) of Schedule 11 to, the Government of Wales Act 2006, that the negative resolution procedure will apply to

[1] https://business.senedd.wales/mgIssueHistoryHome.aspx?IId=46250
[2]Health and Social Care (Community Health and Standards) Act 2003 https://www.legislation.gov.uk/ukpga/2003/43/contents
[3]NHS Redress (Wales) Measure 2008 https://www.legislation.gov.uk/mwa/2008/1/contents

Regulations made under sections 113(2), (3), 115(1), (2), (5), (6), and 195(1) of the 2003 Act.

6. Section 11(4) of the Measure provides that the negative resolution procedure will apply to Regulations made under sections 1(1) to (4)(a), (6), 2(1), (2), (4), (5), (6)(a), 4(1), (2)(a), 9(1) to (5), (7) and 11(2), (3) of the Measure.

7. Section 11(6)(c) of the Measure provides that the draft affirmative resolution procedure will apply to Regulations made under sections 1(5), 3, or 5 of the Measure.

8. Under section 40 of the Legislation (Wales) Act 2019, provision subject to the negative procedure may be combined in the same instrument as provision subject to the draft affirmative procedure. As a result, the draft affirmative procedure applies to these Regulations.

Purpose and intended effect of the legislation.

9. The Welsh Ministers established the NHS Redress Scheme under **the Principal Regulations** in exercise of the powers under the following provisions:
   - sections 113(2), (3), (4) (aa) and (b), 115(1), (2), (4) to (6) and 195 of the 2003 Act.
   - sections 187 and 206 of the National Health Service (Wales) Act 2006[4], and
   - sections 1 to 7, 9, 11 and 12 of the Measure.

10. The Principal Regulations have been amended on several occasions, including by the Duty of Candour Procedure (Wales) Regulations 2023[5] and the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023[6].

11. A summary of the amendments made by those instruments which are most relevant as background to these amendments to the Principal Regulations can be found in the associated Explanatory Memorandum[7].

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[4] The National Health Service (Wales) Act 2006 https://www.legislation.gov.uk/ukpga/2006/42/contents
[5] The Duty of Candour Procedure (Wales) Regulations 2023 https://www.legislation.gov.uk/wsi/2023/274/made
[6] The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023 https://senedd.wales/media/2xldqzec/sub-ld15719-e.pdf
[7] 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 https://senedd.wales/media/zbmg2z1h/sub-ld15719-em-e.pdf

12. These amending Regulations include some amendments to Part 7 of the Principal Regulations, which contains provisions detailing how the redress arrangements will operate when a Welsh NHS body enters into arrangements with an NHS body in England, Scotland or Northern Ireland, ensuring consistency with amendments made to Part 6 of the Principal Regulations.

13. The Welsh Government has engaged the two other devolved administrations and UK Government around these regulation changes.

14. The Principal Regulations underpinned the process in Wales formerly known as the Putting Things Right process. However, significant criticism of the name was received through the consultation and all stakeholder engagement, suggesting that whilst the intention was to 'put things right', this did not reflect well for people who had been significantly harmed or were bereaved. Bereaved families described the name as insensitive, leading a substantial number of stakeholders to request a name change.

15. Consequently, the Welsh Government will now refer to this as "Listening to People (LTP) NHS Wales Concerns, Complaints and Redress process" to emphasise the importance of putting people at the centre of the process by listening to them from the start.

16. The aim is to improve the NHS Wales concerns, complaints and redress process by making it more responsive, effective, timelier, and patient-centred.

17. The new of aims of the LTP process will be to:
    - Enhance and improve care delivery through listening and taking action.
    - Promote an open and just culture.
    - Increase transparency and trust.
    - Prevent future harm.
    - Support staff development and learning.
    - Meet legal duties & ethical standards.

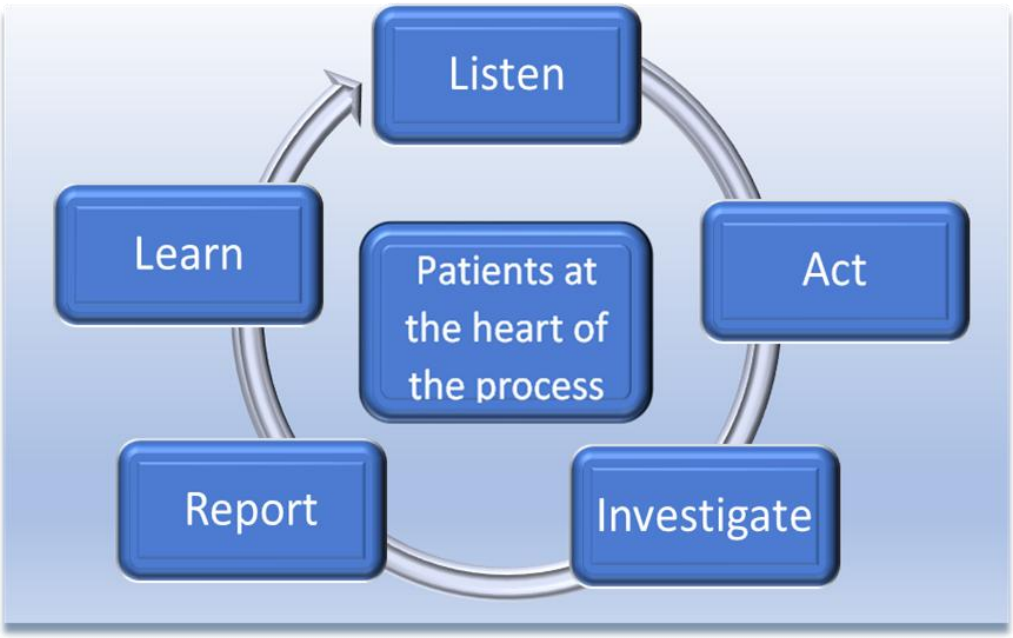
18. Under the revised regulations it is the duty and responsibility of the NHS to listen to, act on, investigate and report back on the concerns that have been raised and to ensure that there are effective actions in place to prevent these concerns from happening again formed from the learning achieved. This is achieved through adherence to the amended Principal Regulations, updated guidance and supporting materials.

19. The amendments made by the amending Regulations intend to ensure that they:

- Place patients at the heart of the process.
- Provide an improved focus on compassionate patient-centred communication.
- Improve the Complaints, Incidents and Redress process to be more inclusive and timelier in response.
- The inclusion of a provision to enable the suspension of the early resolution procedure or an investigation under the Principal Regulations pending the outcome of a safeguarding enquiry, criminal investigation, or criminal proceedings.
- Update record-keeping requirements, including, in relation to certain decisions that independent medical advice is not required in specified circumstances.

20. In addition to the regulation amendments, the programme of work also includes a full rewrite of the guidance to provide a set of standards that outline clearly for those who raise a complaint or are subject to a patient safety incident concern what they can expect from the new process and what they are entitled to under the amended regulations. Additionally, as the guidance is specifically for patients, families and their advocates, the Welsh Government will also issue technical guidance to the NHS.

21. The revised guidance will include the new LTP process to follow a Listen and Act (**stage 1**), Investigate, Report, and Learn (**stage 2**) model. The new guidance will provide clearer information on the redress process and will also provide improvements on what children and young people can expect from the process and how to ensure their voices are heard.



22. ***Figure 1 The amended Listening to People approach***

23. The aim is to ensure there is proportionate investigation when a concern or complaint is raised or an incident has occurred, and that lessons are learned when they have been identified. Information about the issues

and problems should be shared with the patient, and wherever and whenever possible, there should be an immediate correction of things that have gone wrong.

Consultation

24. Prior to the public consultation multiple stakeholder engagement sessions were planned with support from Llais. These and other sessions informed the initial policy concepts and solutions to issues being raised on the current LTP process.

25. The proposed changes were then subject to a 12-week public consultation ending on 6 May 2024 and following requests from stakeholders, was extended to 10 May 2024. The consultation received 213 responses from a wide range of stakeholders, including those working within the NHS, the third sector and members of the public.

26. To provide improved scientific rigour to the data analysis, the qualitative and quantitative analysis was commissioned independently and objectively from the Audit and Assurance Service (NHS Wales Shared Services Partnership).

27. A total of 213 responses were received in response to the consultation, from a population in Wales of 3,132,000[8]. This provided 2,393 narrative responses to be analysed. The analysis of these responses has been conducted with a 95% confidence level, which is a statistical measure that indicates how closely our sample estimates reflect the proportion of agreement in the entire population[9].

28. This information was crucial for making informed decisions from the responses and data analysed. Public support based on the sample size and responses for the policy changes is likely between 74.63% and 85.37%.

29. However, it is important to note that there is a 7% margin of error. This means that the true value could be 7% higher or lower than our estimates. This is a relatively small error rate; good survey design would look to achieve between a 4% and 8% rate. In conclusion, the responses we have received are a strong and accurate representation of the opinion of Welsh citizens and organisations involved in advocacy and care in Wales.

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[8] Population estimates for the UK, England, Wales, Scotland, and Northern Ireland: mid-2022: Population estimates for the UK, England, Wales, Scotland, and Northern Ireland - Office for National Statistics (ons.gov.uk)

[9] The confidence interval is (0.7463) to (0.8537) This interval indicates that you are 95% confident that the true proportion of “yes” responses in the entire population lies between 74.63% and 85.37%.

30. In addition, 133 respondents took the time during the consultation to reflect on and share their often painful and sometimes difficult experiences of raising complaints relating to their care or that of a loved one. There was significant learning and a real demonstration through these shared experiences of just how much change is needed in our complaints system. This in conjunction with the consultation results, stakeholder workshops, the previous review (Evans Review 2014) of PTR, recent inquiries and lessons from Scotland and England have helped form the evidence to reach the conclusions on what we need to change here in Wales.

31. The consultation feedback was clear in that the current process either in its design or its operation is not working for many of those who have reason to raise a complaint.

32. Lengthy delays and protracted investigations are compounded by a confusing system to navigate. Many respondents feel let down and lost in the system and this must change. It is clear that the volume of complaints in the system is a factor and patients and those who raise complaints on behalf of another, cite that their specific concerns raised in the complaint are often not answered fully or clearly or to their satisfaction.

33. The experience of some complainants from the consultation and stakeholder engagement sessions is not of transparency and openness with clear accountability for things that have not gone right but an impression of defensiveness and a lack of honesty and cover up. The consultation responses also highlighted a disconnect between what the regulations require organisations to do, and the resolution requested by the complainant.

34. The summary of responses to the public consultation was published on 4 December 2024[10].

35. The consultation responses have informed the amendments now being made and after the completion of the consultation analysis, several changes were made to the proposed original amendments set out in the consultation.

36. To gain further expert opinion, the Welsh Government formed a Stakeholder Reference Group, made up of NHS leaders, including an Executive Director representative, Heads of Patient Experience, Heads of complaints and redress services and those responsible for learning

[10] Public consultation on the proposed changes to the Putting Things Right Process Response Report Proposed changes to the Putting Things Right process | GOV.WALES

from incidents and complaints representatives from NHS Wales Performance and Improvement, Welsh Risk Pool, the Once for Wales Complaints Management System, Legal and Risk services and Digital Education both from NHS Wales Shared Partnership, Llais and the Public Services Ombudsman for Wales office.

37. This group assisted the Welsh Government by providing expert advice and management data that enabled the Welsh Government to form a clear policy direction and reach decisions when interpreting the consultation responses. The group also assisted by suggesting regulation amendments and revisions to the guidance that support the new process and the amended regulations. The group has been instrumental in providing the vital NHS and Patient perspective.

38. To broaden Welsh Government's understanding of the key issues, the impact of the proposed changes, and the challenges that may be experienced, opinion and advice from other stakeholders and executive peer groups was also sought.

39. **The amending Regulations amend the Principal Regulations as follows:**

40. *Regulation 4 amends regulation 2 of the Principal Regulations (interpretation), inserting new definitions into that provision.*

41. This defines the "Early Resolution Period" and "Early Resolution Procedure". Whilst the Early Resolution Period existed in the former regulations, it was only specifically referred to as an exclusion (regulation 14) and lacked a definition or a specified procedure. In the amending Regulations, the time limit for Early Resolution Period is being extended to 10 working days to enable more cases to be resolved earlier on in the process.

42. *Regulation 5 amends regulation 3 of the Principal Regulations (general principles for the handling and investigation of concerns), including provision for a person who notifies a concern to be kept informed of progress and time frames and about communication requirements.*

43. It was clear from the consultation that those who raise concerns were often not kept informed of progress. The consultation reported repeatedly that time limits were missed, and people's communication requirements were not considered or that their wishes and preferred method of communication were not reliably followed. This is in line with the new accessibility and Welsh Language standards and reducing inequity in access to health care. Additionally, clear feedback through workshops held with Llais demonstrated written communication often featured complex legal and medical terms without any explanation.

44. *Regulation 6 amends regulation 11 of the Principal Regulations (notification of concerns) to remove a cross-reference to a provision which is omitted by these Regulations.*

45. This amendment is connected to the amendments made to regulation 14 of the Principal Regulations by regulation 7 of the amending Regulations (i.e. the omission of regulation 14(1)(f) and insertion of regulation 14(5)).

46. *Regulation 7 amends regulation 14 of the Principal Regulations (matters and concerns excluded from consideration under the arrangements) to add an exclusion from the scope of the Principal Regulations where the Responsible Body considers the concern to be vexatious or frivolous, and to provide that concerns that are resolved through early resolution are excluded from the scope of specified regulations.*

47. NHS stakeholders demonstrated that, whilst rare, there were some examples of vexatious concerns being raised. There were also reports of targeted focus on members of a health board which were concerning. As there is no current provision in the Principal Regulations to allow the exclusion of concerns which the Responsible Body considers is vexatious or frivolous, an amendment is proposed to address this issue. There will be specific guidance to support this aspect, recommending that bodies approach the police or legal teams for advice (as appropriate) where they have concerns around a complainant's behaviour.

48. In addition, the amendments in relation to the Early Resolution procedure required a revision to the exclusion that when that procedure is appropriate and successful at resolving the issue, the Welsh NHS body need not continue to investigate and assess for qualifying liability.

49. *Regulation 8 amends regulation 17 of the Principal Regulations (concerns involving more than one responsible body) to amend the time frames for seeking consent, from a person who notifies a concern, to notify the other responsible bodies involved, and the time frame for giving that notification.*

50. This amendment is to provide 5 working days for responsible bodies to seek consent to the notification of other responsible bodies aligns the Principal Regulations to the Duty of Candour notification period. The amendment in relation to notifying the other responsible bodies not later than 2 working days after receiving that consent ensures consistent language within the Principal Regulations in relation to specifying time frames for clarity.

51. *Regulations 9 and 10 amend regulations 19 (action to be taken where a Local Health Board receives notification of a concern about services provided by a primary care provider) and 20 (action to be taken where a Local Health Board receives notification of a concern from a primary care*

provider) of the Principal Regulations, respectively. The amendments specify the circumstances in which primary care providers are to attempt to resolve a concern through early resolution, and not the Local Health Board.

52. If the person raising the concern is amenable to an Early Resolution being attempted, unless exceptional circumstances apply, this is considered best achieved by the primary care provider responsible for the care (e.g.) the patient's own practice. The data analysis provided through the General Medical Practice Indemnity (GMPI) scheme in Wales, demonstrated that over 95% of concerns raised with GP practices were successfully dealt with in an Early Resolution manner.

53. *Regulation 11 amends regulation 22 of the Principal Regulations (procedure before investigation) to add further matters for the responsible body to offer to discuss with the person notifying the concern, and further requirements where such a discussion takes place including a requirement to maintain records of offers of discussions under that provision.*

54. This regulation outlines the listening discussion providing, for example, an opportunity for the person raising the concern to express their desired outcome, and for the responsible body to seek their consent to attempt the early resolution procedure, where considered appropriate.

55. Additionally, it requires the discussion to be by way of in-person communication (e.g. telephone call, audio- visual communication or a face-to-face meeting). When arranging discussions, when notified of a need for advocacy and support services, the responsible body must take into account the need to ensure that such services are provided at that discussion. The responsible body must document a record of the offer and content of the discussion and its outcome. It was clear from the consultation and stakeholder engagement that people did not feel "listened to" or their concern adequately understood and reported that the focus was not on the answers to their questions or desired outcome.

56. *Regulation 12 inserts regulation 22A into the Principal Regulations, making provision regarding the early resolution period and procedure.*

57. This outlines the "Early Resolution Period" and "Early Resolution Procedure". Whilst the Early Resolution Period existed in the former regulations, it was only specifically referred to as an exclusion (regulation 14) and lacked a definition or a specified procedure.

58. *Regulation 13 inserts regulation 24A into the Principal Regulations, making provision to enable the suspension of the early resolution procedure or investigation pending the outcome of a safeguarding enquiry, criminal investigation, or criminal proceedings.*

59. This new regulation provides for the suspension of the Early Resolution procedure or investigation stage, should there be a safeguarding enquiry, criminal investigation, or proceedings, until after they have concluded or been determined. This is to provide the opportunity to decide whether any action should be taken to safeguard the welfare of a child or an adult at risk. It will also avoid any prejudice of any criminal investigation, criminal proceedings, or prosecution. The option to pause the duty to investigate under the regulations has been missing and now more accurately reflects current safeguarding legislation and practice.

60. *Regulation 14 amends regulation 26 of the Principal Regulations (response to an investigation under regulation 23 where it is decided that there is or there may be a qualifying liability) to amend the time frame for providing interim report, and an investigation report under regulation 31.*

61. Currently under the Principal Regulations, where the responsible body is of the opinion that there is or there may be a qualifying liability, they must provide an interim report within 30 working days of receiving the complaint, but this period may be extended to 6 months or later if exceptional circumstances apply. Additionally, they must provide an investigation report not later than 12 months of receiving the concerns, and this period may also be extended further in exceptional circumstances. The feedback from the consultation and stakeholders was that the 30 working day deadline was infrequently met, and many people's experiences was of a protracted 6- or 12-month period. Therefore, whilst the 30 working day target is retained, the amending Regulations now aim to achieve a timelier conclusion to concerns, by requiring responsible bodies to communicate the likely timeframe, keeping the person updated as to progress, and set a maximum 120 working day turn-around to align the time frame with the National Incident Reporting policy and apply this to complaints and patient safety incidents equally. This is a step change from the initial policy intent.

62. *Regulation 15 amends regulation 29 of the Principal Regulations (redress – financial compensation) to increase the limit for the financial compensation element of redress for the purposes of Part 6.*

63. Currently, the Principal Regulations provide a £25,000 limit for the financial compensation element of redress. Data analysis was completed with reference to the Judicial College's Guidelines on personal injury damages, comparing the damages amounts from 2010 with those of 2024. This showed inflation over time of an average of 45-47%.

64. To ensure that cases intended to be included in the redress scheme were not excluded as they breached the £25K limit for damages, the upper limit is proposed to be increased to £50,000. This also includes a small amount on top of the 45-47% to future-proof against further inflation over the coming years.

65. This proposal was assessed in the public consultation and whilst broadly supported, some caveats were identified as being necessary. These consisted of, for example, the unintentional inclusion of complex cases, protected cases, and those not suitable for the redress scheme. Guidance will provide further advice on the flexibility that exists in the current regulations for responsible bodies to determine which cases a redress offer may be suitable.

66. There is potential for a reduction in litigation cases by increasing the opportunity for their inclusion in the NHS redress scheme.

67. *Regulation 16 amends regulation 31 of the Principal Regulations (investigation report) to include a requirement for a Welsh NHS body (as defined in regulation 2(1) of the Principal Regulations) to offer to discuss an investigation report, where it has provided one, for the purposes of Part 6.*

68. Consultation feedback stated that people seeking redress were often not provided with a detailed report of an investigation that had taken place, nor offered the opportunity to discuss the results of that report, in an in-person communication, with the responsible officer. The amended regulation 31 will now afford this opportunity.

69. *Regulation 17 amends regulation 33 of the Principal Regulations (redress – communication of a decision) reducing the time frame for a Welsh NHS body to communicate a decision for the purposes of Part 6.*

70. Currently, the Principal Regulations provide a 12-month time frame to communicate the decision, with an option to extend this, as necessary. As mentioned in paragraph 60, as the time frame for providing an investigation report is being reduced, an amendment is needed in relation to communication of a decision for consistency (now reduced to a maximum of 120 working days).

71. *Regulation 18 amends regulation 40 of the Principal Regulations (response to an investigation under regulation 39 where a Welsh NHS body is of the opinion that there is, or there may be, a qualifying liability) to amend the time frame for providing interim report, and an investigation report under regulation 46.*

72. As outlined in paragraph 61, it was clear from stakeholder feedback in the consultation, that the time frame for providing the final investigation report was unacceptably long and therefore this has also now been reduced to a maximum of 120 working days. This amendment aligns the revised time frames under Part 7 of the Principal Regulations with the revised time frames under Part 6 discussed above. This brings the deadlines for providing both the interim and final investigation report to 120 working days, as in most cases, there are very few amendments made to the interim report. In addition, this aligns the time frames with the National Incident Reporting policy.

73. *Regulation 19 amends regulation 44 of the Principal Regulations (redress – financial compensation) to increase the limit for the financial compensation element of redress for the purposes of Part 7.*

74. As outlined in paragraph 62 the equivalent provision is being made for the purposes of Part 7.

75. *Regulation 20 amends regulation 46 of the Principal Regulations (investigation report) to include a requirement for a Welsh NHS body to offer to discuss an investigation report, where it has provided one, for the purposes of Part 7.*

76. In the public consultation it was clear that people often received investigation reports and letters that contained complex medical and legal wording and complex reasoning regarding qualifying liability. Feedback received outlined that people struggled to understand the language and found these responses adversarial in nature. Therefore, like the explanation provided in paragraph 67 above relating to Part 6, the equivalent provision is being made for the purposes of Part 7. And an offer to meet to explain the content of the report and answer any questions that will improve understanding, has been included.

77. *Regulation 21 amends regulation 48 of the Principal Regulations (redress – communication of a decision) to reduce the time frame by which a Welsh NHS body must communicate a decision for the purposes of Part 7.*

78. Like the explanation provided in paragraph 69 above, the equivalent provision is being made for the purposes of Part 7.

79. *Regulation 22 amends regulation 50 of the Principal Regulations (monitoring the operation of arrangements for dealing with concerns) to add new record-keeping requirements regarding whether an offer of redress was made, and any determination that independent medical advice is not required in relation to concerns involving the death of, or moderate or severe harm to, a patient.*

80. Throughout the public consultation and in frequent subsequent correspondence received, there is a consistent theme that highlights concerns with the NHS investigating itself, where serious harm has occurred. Many of these call for an independent investigation to be completed to provide assurance of the elimination of bias in investigation findings. The Principal Regulations require responsible bodies to have regard to whether the person investigating the matters raised by the concern requires independent medical or other advice. The PSOW had representation on the Stakeholder Reference Group and provided a suggestion that has been adopted as an amendment. This amendment requires responsible bodies, if they decide that independent medical

advice is not required, to record the reasons why in relation to concerns involving moderate or severe harm or death.

81. *Regulation 23 amends regulation 51 of the Principal Regulations (annual report) to require a Local Health Board to include the annual reports of responsible bodies in its own annual report in specified circumstances.*

82. Currently, the Principal Regulations do not contain a requirement for Local Health Boards to include, within their own annual report, copies of the annual reports of other responsible bodies that have been provided to it. This amendment ensures that all parties share learning and data appropriately.

83. *Regulation 24 contains transitional provision to state that the amending Regulations do not apply to any concern notified in accordance with arrangements in place under the Principal Regulations before the date on which the amending Regulations come into force.*

84. It was felt unreasonable to apply the new time frames and duties contained within the amending Regulations to incidents and complaints already under investigation.

PART 2 – REGULATORY IMPACT ASSESSMENT

Regulatory Impact Assessment (RIA) summary

1. A Regulatory Impact Assessment has been completed for the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025 (“the amending Regulations”) and it follows below.

2. There are no specific provisions in the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (“the Principal Regulations”) or the amending Regulations which charge expenditure on the Welsh Consolidated Fund.

Administration costs

3. Across the implementation of the amending Regulations there are several administrative costs for Welsh Government related to the development and publication of the regulations, guidance, awareness material and training across those duties. There are also opportunity costs for the NHS in releasing staff for training and the initial implementation costs within NHS organisations to adjust to the new processes. The amending Regulations will come into force in April 2026 and there will be implementation / programme costs that continue into the 2026/27 financial year however much of this sit with NHS Wales Performance and Improvement and the NHS in Wales.

Cost Savings

4. The principles of ‘Being open’, are strengthened by the changes to the complaints and incidents process in Wales which focusses on Listening to People who have had a poor experience or have been harmed. Emphasising active listening and learning from individuals' experiences, along with prioritising early resolution and addressing key issues, can lead to enhanced people’s experience, strengthen trust in health care providers as well as an opportunity for significant cost savings. This approach may reduce the number of complaints and litigation, thereby potentially preventing incidents that could result in harm, although this would not be an immediate effect.

5. Creating an open and learning culture in the NHS was as part of a review by West, M and Coia, D (2019)[11]. 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 from implementation between 2017 – 2018 due to higher productivity, reduced back fill costs due to staff suspensions, reduced time to conduct an investigation and reduced legal and termination costs.

6. Attempts to estimate 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 conclusively. However, an assessment of any opportunity to reduce cases of litigation in these changes is included in this RIA.

Compliance Costs:

7. Compliance costs with the Regulations will fall to NHS bodies in the form of opportunity costs to comply with the new 'Listening to People' approach.

8. There is an opportunity cost for NHS bodies to offer an in-person listening discussion aimed at understanding clearly the concern being raised and the desired resolution. This change is more than notification of receipt of their complaint or the incident that has happened as it focusses on active listening as well as providing key information to the person and providing an opportunity to apply an early resolution solution focused approach to resolve the concern. Additionally, where this isn't possible or a realistic endeavour the opportunity to convey a realistic timeframe for the concern to be investigated in a considered and proportionate manner.

9. Estimating the likely impact on NHS bodies is very difficult as there is likely opportunity to move more concerns through the early resolution process and avoid more complex and lengthy investigations which would release resources from investigation teams and management resources. Lengthy and complex investigation processes are not appropriate in all cases or not in line with the person's desired resolution, which are then unnecessarily costly. For the purposes of this impact assessment, the opportunity costs for compliance have been calculated based on the number of reported incidents and complaints. Data used is comprised of NHS management data sources and other published data sets.

[11] West, M., Coia, D., (2019) caring-for-doctors-caring-for-patients_pdf-80706341.pdf (gmc-uk.org)

Benefits:

10. The changes made by the amending Regulations to the Principal Regulations and associated guidance are expected to lead to a range of benefits, although these are challenging to quantify accurately due to a high degree of variability or insufficient available data. The changes being brought in aim to provide an opportunity to move more cases into the early resolution (Listen and Act) stage 1.

11. These are both beneficial to the person and the organisation, providing more timely responsive action and purposeful time to listen to the exact problem and focus on person centred resolution. Where that isn't possible or appropriate based on the nature of the complaint or patient safety incident then the proportionate investigation[12][13][14] will be clear and timely and inclusive of the person raising a concern. Broader and more strategic benefits within the system include overall enhancements in the quality of interactions and responses. By fostering a culture of openness and transparency in health provision, we achieve greater satisfaction when concerns are addressed, or lessons are learned. This approach also places a renewed significant emphasis on preventing future harm supporting the Duty of Candour and NHS Wales Patient Safety strategy.

Assumptions:

12. Throughout the RIA, a wide variety of academic, routine statistical and management 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 estimated based on available data. In several 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.

Options:

Option 1 – Do nothing further. Continue to work with the existing regulations and framework

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[12] Sampson, P. et al. Systems-based models for investigating patient safety incidents BJA Education, Volume 21, Issue 8, 307 - 313

[13] Weaver S, Stewart K, Kay L. Systems-based investigation of patient safety incidents. Future Healthc J. 2021 Tach;8(3):e593-e597. doi: 10.7861/fhj.2021-0147

[14] NHS England (2024) Patient safety incident response framework and supporting guidance https://www.england.nhs.uk/publication/patient-safety-incident-response-framework-and-supporting-guidance/

Option 2 – To amend the guidance and supporting materials only.
Option 3 – Amend both existing regulations, guidance and supporting materials.

Option 1 – Do nothing. Continue to work with the existing regulations and framework

Description:

13. Under this option no refresh or re-design of the Principal Regulations or guidance would occur. This option would involve the continuation of the being open requirements and the investigation of complaints and incidents set out within the Principal Regulations (the process for managing concerns in NHS Wales). The amendments made in 2023 to the Principal Regulations for the introduction of the Duty of Candour would remain unaffected. There would continue to be the challenges in modernising the approach to complaints and patient safety incident investigations in contrary to the Principal Regulations and people's poor experiences of raising a concern, being heard, receiving answers and finding resolution, would most likely would continue. Additionally, there would not be the opportunity to include more cases in the redress scheme, providing potential reductions in the amounts of civil proceedings.

Costs:

14. There would be no additional costs attached to this option. The ongoing litigation provisions for the NHS in Wales under the Legal and Risk Shared services partnership arrangements would be unchanged, and funding already committed to would not see return on investment. Additionally, there is a significant risk of reputational damage within the system and with the public all of whom are looking for and expecting substantial change as evidenced in the consultation responses from stakeholders and the public.

Benefits:

15. Doing nothing further would deliver no additional benefits and the opportunity to build on the work already undertaken would be lost. However, it would reduce the change burden and implementation costs to the NHS and mean no further immediate costs implications for the Welsh Government.

16. In doing nothing the benefits of creating the case for, appetite and momentum for change would fail to be realised. This includes the certainty this would provide to users of NHS services and staff coming

into Wales from other parts of the UK, that NHS bodies would ensure an open, honest and supportive response to complaints and patient safety incident investigations when something goes wrong, people have been harmed or where people report having had a poor experience.

17. This option does therefore not meet the policy intent or previous commitments to refresh and rewrite the Principal Regulations and modernise the arrangements for complaints, incidents and redress in Wales.

Option 2 – To amend the Guidance and supporting materials only.

Description:

18. This would offer the opportunity to improve and modernise the guidance and process but would be limited to the process as ascribed in the Principal Regulations with the added benefits of improving supporting and supporting materials including a more people focused and accessible set of guidance and accessibility compliant materials.

Costs:

19. Welsh NHS bodies, primary care providers, and independent providers should already have arrangements in place to meet the existing requirements under the Principal Regulations that apply to them (for the Putting Things Right process as it was referred to). For Responsible Bodies to understand the changes in the guidance alone will require some impact assessment by organisations however limited that may be due to the lack of regulatory change and ensure that adequate training is provided to their staff to fully understand the changed guidance. Additionally, all sunk costs already committed to the creation of the draft regulation amendments and two years of programme work would be wasted.

20. The additional opportunity costs for NHS organisations and all primary care providers would be the training, some implementation costs and supporting materials costs for Welsh Government and are fully outlined in option 3. In many NHS organisations, change is already underway in preparation for the changes. Effective stakeholder engagement has meant the NHS is fully informed and involved in developing the new ways of working under the proposed amendments and have been piloting and slowly introducing changes to prepare for effective

implementation. There would be some associated costs involved in not taking this forward.

Benefits:

21. This is less costly than option 3, in terms of opportunity costs for Responsible Bodies, as it would not include the increase in cases that can be included in redress or the new listening discussion. It is also less costly for the Welsh Government as it reduces the need for a public awareness campaign and although requires the development of the guidance and materials, reduces the regulatory burden or legislative work involved in the affirmative procedure. It does however miss the opportunity to modernise the regulations governing the process and the improvements in timeliness and change in approach being undertaken in the regulatory reform. The freeing up on policy and stakeholder time on the regulatory changes and their implications, technical briefings and impact assessments and implementation planning would provide reallocation of that resource to develop the guidance and materials. It should be noted however that many of these costs have already been committed and completed or prepared.

Option 3 – Amend both the Principal Regulations and Guidance and Supporting materials.

Description:

22. This option aims to provide a refresh of the Principal Regulations to meet the policy intentions and address the key issues brought out in the public consultation and stakeholder and public engagement. The 2025 Amendments and their effects are explained in greater detail in the Explanatory Memorandum.

23. The 2025 Amendments offer significant improvements to the Principal Regulations. In addition, many of the proposed changes are addressed in the revised guidance. It should be noted that the Principal Regulations include provision requiring that any arrangements set up under the regulations for the handling and investigation of concerns must be such as to ensure that account is taken of any guidance that may be issued from time to time by the Welsh Ministers (regulation 3(1)(k)).

Costs:

24. To successfully implement the reforms into practice there are five key areas where action is required:
    i. public awareness campaign.

ii. Responsible body awareness and training; and
iii. development of guidance and supporting materials.
iv. regulation review, drafting and translation
v. implementation and ongoing operational costs

Awareness, training and support

i. public awareness campaign:

25. The consultation responses to the proposed changes reflected the importance of public information and engagement. It was clear from many workshops and engagement sessions and correspondence that the need for these reforms would be welcomed by the public. A campaign would aim to increase public awareness of the 'Listening to People' process, empowering individuals to ask questions about the care and services they receive, in the knowledge they could expect openness and transparency should they have need to raise concerns or questions where they were unhappy with the experience of care they had received or where harm may have occurred. This links very deliberately directly to the being open framework and the Duty of Candour in Wales.

26. It is envisaged the public awareness campaign would consist of two elements, a publicity campaign and a public information leaflet and materials or digital similar solution. The publicity campaign would likely include public relations, social media and working with relevant bodies.

27. The creation of a public information leaflet would involve the production of a combination of electronic and hard copy material, for displaying in NHS settings, along with an online presence on Health Inspectorate Wales, providers of NHS services, Health in Wales (the official NHS website), and the Llais' (citizen voice body) websites. To achieve this Welsh Government will revise the current Putting Things Right leaflets to incorporate the new changes and develop children and young people's materials as well as explore BSL accessibility material and ensure translation into Welsh and 16 other key languages.

28. 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 2026.

29. Table 1 - Development of public awareness campaign

Activity	Grade	Time	Cost
Publicity campaign	-	-	£11,000
Welsh translation and proof reading	Management Band 2	0.5 days	£200
Design and typesetting(ii)	Management Band 3	5 hrs	£200
Total			£11,400

(i) Similar to the public communication campaign costs associated with the introduction of the special
procedures element of the Public Health (Wales) Act 2017, uprated with inflation.
(ii) Based on the translation, design and typesetting of Putting Things Right leaflet, uprated with inflation for 2025– approximately 600 words.
(iii) Based on the redesign costs of Putting Things Right leaflet in 2017, uprated with inflation, which included the production of easy read and children's versions.
(iv) Based on the cost of dispatching 100,000 Putting Things Right leaflets in 2017, uprated with inflation for 2025.

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

30. The key to encouraging and enabling the changes to be embedded into the fabric of how NHS staff respond to people when a complaint or incident occurs or is raised is through education and training. To support this, a combination of different training and learning is likely to be needed for LHBs, Trusts and Primary Care providers:

31. **Basic all staff awareness training – NHS directly employed:** The Listening to People: the NHS Wales complaints, incidents and redress process awareness video will include a basic level of knowledge and understanding of the initial stages and overall process for all NHS staff and help to create a culture of openness where staff feel able to listen and act when a person raises concerns about the care they have received. This video is 20 minutes long and it is therefore assumed watching it cannot be a part of existing training time and does create opportunity costs for staff time (the opportunity cost associated with staff undertaking the training is included in Table 4 below).

32. Table 2 – Development of training e-learning modules:

Activity	Grade	Time	Cost
Creation of e-learning basic awareness module	Management Band 2	9 days	£2100
Translation of the e-learning material (i)	Management Band 2	9 days	£2100

Creation of e-learning advanced training module	Management Band 2	18 days	£4200
Translation of the e-learning material (i)	Management Band 2	9 days	£2100
			£10,500

(i) Based on an estimate of double the word count of the previous 'Putting Things Right' NHS module (estimated at 18,000 words).

33. 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. Should it be decided an alternative e-learning provider would be more suitable a specification and tendering exercise would need to take place.

34. **Advanced specialist staff, concerns team training**: Building on the general awareness training above, key individuals within each LHB, Trust, SHA and primary care practices will require more in-depth training to build the knowledge and skills required when the new process comes into effect. These will build on understanding the steps involved as well as key skills around compassionate communication and active listening to people who have concerns and empowering staff to take action to resolve issues swiftly as well as the wider options available for modern proportionate investigation methods that can be adopted for patient safety incidents.

35. An education and training resource which is interactive is being prepared for specialist teams and leadership roles building on the Listening to People (LTP) and putting them at the heart of the process approach. This training is estimated to be 60 - 120 mins long and is therefore calculated as an opportunity cost for staff time within the NHS.

36. It is estimated this training would be delivered to approximately 49 individuals (based on five per LHB/ Trust and three for NHS Blood and Transplant), and approximately 262 concerns team individuals, and this training would take approximately two hours to complete per person. As NHS bodies redesign or reallocate their resources, these numbers may change.

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

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

workshops for primary care practice managers/complaints leads are delivered to approximately 1,945 individuals and will take approximately 2 hours to complete per person.

39. **Costs:** Additionally, the expectation is that Welsh Government or NHS premises would be used to deliver the face-to-face training for primary care practice managers/ complaints leads, Legal and Risk Services training, and NHS Boards which would not incur any additional costs. There may, however, be a cost associated with securing venues to deliver this training if suitable cost-free spaces are not available.

40. **Specialised redress teams training:** this training is Principally provided by NWSSP Legal and Risk Team and whilst the content of this training will need to be updated in line with some of the changes in the regulations the impact is not considered to be greater than the original commitment and so whilst a refresh training is likely to be needed it is not considered to be an additional cost to the NHS relative to what is already included in current processes However for transparency the costs have been included for completeness. As NHS bodies redesign or reallocate their resources, these numbers may change

41. There is currently ad hoc specialist training undertaken by redress teams and more senior staff in the NHS which is provided by Legal and Risk Services from the NHS shared service partnership when capacity allows. It is reasonable to plan that there may need to be a refresh of this training, and the materials will need to be updated in line with the new amendments.

42. For any proposed Legal and Risk training it is estimated that each provider of NHS services will require, on average, two days training per year to be provided by an NHS Band 8b solicitor. The opportunity cost for Legal and Risk Services associated with this is estimated to be:

43. Table 3 - Legal and Risk NWSSP – Proposed development and delivery of training

Activity	Training days	Mean hourly rate	27% uplift	Total Annual Cost
Opportunity costs of proposed Legal and Risk Services training	20 days (7-hour day)	£105.00	£28.35	£18,700

44. **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 (both executive and independent 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 people's complaints and patient incidents and that they are using this learning to improve the quality and safety of services. Additionally, for them to gain assurance that the new process is being implemented and followed and adequately monitored.

45. This training would need to be delivered to approximately 246 individuals (based on Board membership in2024/5), and this training would take approximately two hours to complete per person

46. Table 4 – opportunity costs associated with training the NHS

Cohort	**Staff numbers**	**Hours of training per person**	**Mean hourly rate**	**27% uplift representing 'on costs'**	**Estimated opportunity cost**
Basic all staff awareness training - NHS directly employed(ii)	90,948	0.3	£18.64	£5.04	£646,000
Basic all staff awareness training - primary care(ii)	15,329	0.3	£18.64	£5.04	£108,900
Advanced specialist staff awareness training (v)	59	2	£28.21	£7.35	£4,100
Concerns team training(ii)	287	2	£18.64	£5.04	£13,600
Primary care practice managers/complaints leads(iv)	1,945	2	£27.01	£7.29	£133,500
Board level training(vi)	246	2	£66.43	£17.94	£41,600
Proposed Legal and Risk training	1,955	15	£107	£28.89	£3,985,000
Total					£4,932,700

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 shows the mean hourly pay (excluding overtime) for those working in human health was £18.64 in 2024 also includes Llais 100 staff for basic awareness, 10 specialist training and 25 complaints teams.

(iii) The Office for National Statistics Annual Survey of Hours and Earnings shows the mean hourly pay (excluding overtime) for health and social services managers and directors was £28.21 in 2024.

(iv) The Office for National Statistics Annual Survey of Hours and Earnings shows the mean hourly pay (excluding overtime) for those working in health care practice managers 2024 - the data includes dentist and GP practitioners and GP practice staff and community pharmacists and primary care managers.

(v) Based on information received from LHBs and Trusts in relation to the number of staff dealing with concerns, incidents, PALS (Patient Advice and Liaison Service), redress, claims and Ombudsman.

(vi) The Office for National Statistics Annual Survey of Hours and Earnings shows the mean hourly pay (excluding overtime) for chief executives and senior officials was £66.43 in 2024 and includes board members of Llais.

iii. **Development of guidance and supporting materials**.

47. The programme team developed the work associated with the regulatory reform and guidance development using a Stakeholder reference group which comprised of key representatives from NHS organisations and NHS network leads, representatives from NWSSP Legal and Risk solicitors, Public Services Ombudsman for Wales, Llais (the citizen's voice body), NHS Wales Performance and Improvement (NHSP&I formally known as the NHS Wales Executive), Welsh risk pool, the Once for Wales Concerns Management System team and Education and training lead from NWSSP. Additionally, the Executive Directors of Nursing and Patient Experience were represented as the Executive leads for NHS complaints and Incidents in most organisations.

48. The focus of this group was to provide advice and expert opinion and help shape the work undertaken by the programme team. In Quarter 4 of 2024/5 NHS Wales P&I Directors were commissioned to undertake Strategic Oversight Implementation support for the implementation of the new changes and process. This consisted of an executive lead Strategic Oversight Implementation Group (SOIG) and an Operational Lead Implementation Group (OLIG). These groups had clear mandates to ensure that their organisations are ready to fully implement the new regulations and to help shape the training materials needed to deliver to the NHS. The costs associated directly with the groups were included in the NHS Wales Performance and Improvement annual allocation and the SRG was run from within the programme budget.

49. Table 5 – Yearly Welsh Government programme team staff costs 2-year work programme

Role	Annual Cost	Estimated time required	**Cost**
Programme lead - NHS secondee Executive band 1	110,400	0.8 w.t.e	88,400 (i)
Management B1	70,876	0.5 w.t.e	35,500
Management B2	55,881	0.4 w.t.e	22,400
Management B3	45,004	0.4 w.t.e	18,100
Lead Drafting Lawyer	91,860	0.2 w.t.e	18,400
Senior Drafting Lawyer	110,075	0.2 w.t.e	22,100
Total			**204,900**

1. Assuming role would not be filled if not progressed, this is actual costs already incurred.

53. Table 6 - Public Engagement costs:

Event	**Location**	**Costs**
Public Engagement session	South Wales	£100
Public Engagement session	North Wales	£500
Llais run workshops	North and South Wales	Within annual budget allocation
Children in Wales workshop 2024	South Wales but included young people from across Wales	As part of normal annual residential workshop in Llangranogg, Ceredigion- funding for CIW via their annual Grant in Aid.

54. The staff costs to the Welsh Government for developing the guidance are included in the resource at tables 5 and 7.

55. In addition to the guidance for the NHS there is guidance document aimed at patients and their families and the wider public which outlines the process in a more accessible manner. An easy read version and a children and young people version will be created the latter created through a co-design process with Children in Wales.

56. Table 7 – opportunity and sunk costs for the guidance and supporting materials

Activity	**Grade**	**Time**	**Estimated Opportunity Cost**
Main Guidance for the NHS	Management Band 3	**0.5 days**	£100
Design and typesetting(i)	Management Band 3	4 days	£800
Translation and proofreading(i)	Executive Band 2	15 days	£6000
	Management Band 2	7.5 days	£2000

Patient and their family Guidance	Management Band 2	2 days	£500
Design and typesetting(i)	Management Band 3	4 days	£800
Flowcharts x 2	Management Band 2	0.5 day	£200
LTP Patient Leaflets	Management Band 3	1 day	£200
Easy Read version of LTP Patient Leaflets	Management Band 2	1 day	£300
Translation and proofreading(i)	Executive Band 2	10 days	£4200
	Management Band 2	4 days	£1000
Children and Young Peoples Guidance materials	Children In Wales 3 facilitators and psychologist	8 workshops	£22,000
Design and typesetting(i)	Management Band 2	2 days	£500
Translation and proofreading(i)	Executive Band 2	7.5 days	£3000
Translation into 16 common languages	Not able to estimate at this stage	tbc	tbc
Printing of leaflets			£9000
Delivery of leaflets to NHS			£2,100
Total			£45,800

56. There would be no costs associated with the distribution of the guidance as only electronic versions of the guidance would be available. The guidance would be refreshed every five years, with the first cost occurring in 2031, the estimated opportunity cost associated with this refresh are:

57. Table 8 – refresh costs for the guidance in 5 years time

Activity	**Grade**	**Time**	**Estimated Opportunity Cost**
Refreshing guidance	Executive Band 2	10 days	£3,900
Design and typesetting(i)	Management Band 3	7 days	£1400
Translation and proofreading(i)	Management Band 2	7.5 days	£1,800
Total			£7,100

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

58. In addition, the development of a British Sign language video that explains how to raise a complaint with a health board or NHS trust will be developed which is hoped will be universally place on the landing web page for each NHS Responsible Body.

59. Table 9 – British Sign Language estimated costs

Activity	**Development costs**	**Total Cost**
Commissioning of short BSL video to introduce how to raise a complaint in the NHS in Wales	£500 - £1500	Estimated as £1,800 incl VAT

Benefits:

60. The benefits of the amendments to the Principal regulations made by the amending Regulations, aim to provide an opportunity to move more cases into the early resolution (Listen and Act) stage 1, that are both beneficial to the person and the organisation. Whilst this is the costliest option of the three, in terms of opportunity costs for Responsible Bodies and Welsh Government, it produces the widest range of long-term benefits. It requires complex legislative work for legal teams involved in the affirmative procedure, the need for a public awareness campaign in collaboration with NHS bodies and stakeholders, and the development of the guidance and associated materials by policy officials.

61. The regulatory changes and their implications, associated technical briefings, impact assessments and implementation planning, including training costs, will require strategic resource planning and the summary of those monetizable costs are contained within the tables above. The benefits of refreshing the legislation and guidance, will mean that the new Listening to People (LTP) process, will modernise the regulations governing the process and the improvements in timeliness and change in approach for complaints and the investigation of patient safety incidents with a renewed focus on learning from events.

V. Implementation and ongoing operational costs:

62. In addition to the above key areas, where action is required to successfully implement the amending Regulations and the new Listening to People approach there may be other supplementary costs which arise.

63. Where possible, the Listen to People: The NHS Wales Complaints, Incidents and Redress process builds upon the existing systems and processes underpinning the Being Open principles and the Principal

Regulations and Putting Things Right processes, which are already well established within the existing organisational policies and procedures.

64. All providers of NHS services will need to develop an implementation plan to ensure new LTP and the amending Regulations are effectively introduced. This will include a review of policies and procedures to ensure the changes required by the introduction of the amendments are incorporated, reported upon and adopted through organisational governance arrangements – including the arrangements for primary care providers who are providing care on their behalf. It is anticipated that this will fall to primary care managers and corporate concern teams to lead although the early resolution components will fall to the Primary Care practice managers or such staff only in the most. The opportunity cost of this for LHB's and Trust's is estimated to be:

65. Table 10 – opportunity cost for development of an implementation plan

Activity	**Number of organisations**	**Time required**	**Annual rate**	**Estimated opportunity cost**
Develop implementation plan – LHBs & Trusts and Llais	11	3 days	£113,399	£14,400
Develop implementation plan – Primary care practices	1,945	2 days	£110,075	£1,785,000
Total Cost				£1,799,400

(i)Table 10 – EB1 equivalent – annual rate provided by the Central Services & Administration Main Expenditure Group Team based on Average Gross Salary Rates for Non-SCS Pay Bands 2025/6.

Complaints and Patient Safety Incidents

66. Welsh Government receives management information every quarter about the number and nature of concerns received by all health boards, Velindre NHS Trust, Public Health Wales and the Welsh Ambulance Service Trust.

67. Table 11- NHS complaints data for Wales 2022 - 2025

Year	**Total Number of New concerns Reported**	**Early Resolution attempted**	**Referred to PSOW**	**Cases upheld**
2022-23	20,344	Data incomplete	926 (5.22%)	9.59%
2023 -24	19,062	29.77%	987 (5.51%)	12.58%

2024-25	18,334	40.28%	971 (6.14%)	5.1 %

Source: Management data taken from Beacon Dashboard NHS Wales Performance and Improvement 2025

Please note: Management information is raw data which has not been verified and does not meet the standard of a national statistic.

68. For 2024/25 all Wales median for early resolution was 2 working days but the range showed two Responsible Bodies at 5 days and 7 days respectively.

69. The all-Wales Median time for the closure of a concern under the Principal Regulations was 29 working days however there was a greater spread here of 19, 22, 24,27, 29 days and 4 Responsible Bodies were recorded as a median of 30 days.

70. It is an interesting observation to see an increase in the number of concerns that are resolved at the early resolution phase, this will undoubtably reduce the burden on full investigation for those already resolved. The Welsh Government believe by extending the time allowed for early resolution this could result in more cases being resolved early, thus potentially offering a saving on the opportunity costs of the complex investigation stage referred in the new amended guidance as stage 2. This is especially pertinent as the level of staff involved in the oversight and signing off a response tend to be at executive/senior manager or clinical consultant level.

71. There are many patient safety incidents that are detected through the triggering of the Duty of Candour or reported via Datix (the Once for Wales Concerns Management System) by staff or through concerns raised by patients or their families that require proportionate investigations to understand causal factors and the actions required to be taken to mitigate against reoccurrence.

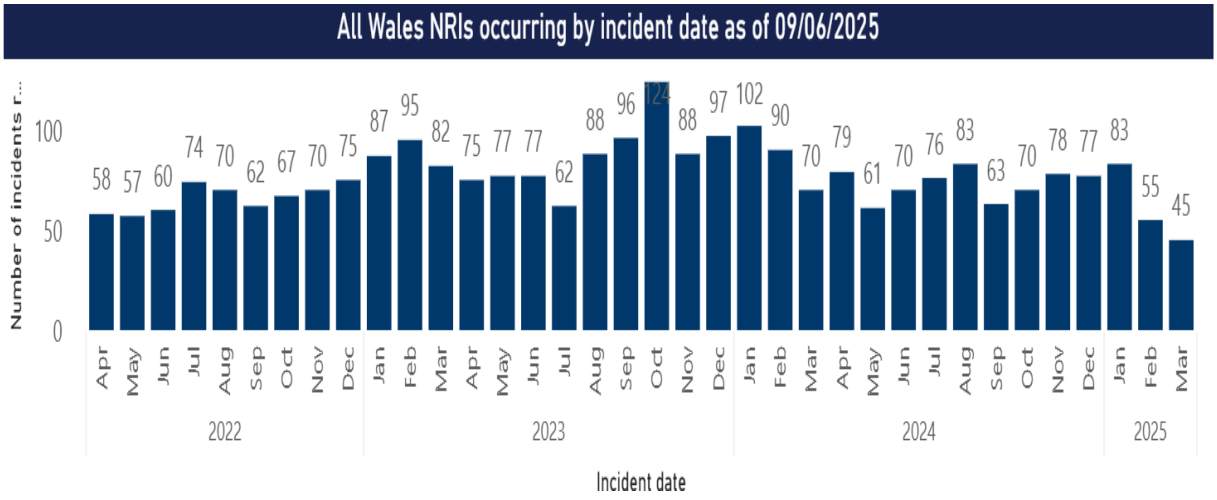
72. However, for those at the lower end of severity there is also an additional opportunity for early resolution to make an impact on the time that would be normally spent on lengthy and detailed investigations. The Welsh Government believes that the utilisation of the early resolution period for complaint and lower to moderate level incidents provides the opportunity to adjust resources to meet any additional time spent in listening to those who are the subject of a patient safety incident or raise a complaint about the care they have received. However, the Welsh Government also considered that for the first two years there may need to be additional resources to implement these adjustments before the overall savings are likely to be realised fully.

73. Additionally, the use of more modern proportionate investigation techniques may also prove to reduce the time spent and overall costs.

This is already in place in some NHS organisations in Wales with early promising results. These would then retain the opportunity to focus on the understanding and sharing of the lessons learnt which avoids future harm to other patients.

74. This process is managed under the National Policy on Patient Safety Incident Reporting & Management[15]

75. Table 12 - All Wales National Reportable Incident data 2022 - 2025



Please note management information is raw data which has not been verified and does not meet the standard of a national statistic.

76. The NRI Data shows total numbers for Wales 2022/23 was 857, for 2023/24 was 1046 and for 2024/25 was 840.

77. Table 13 - Median time to investigate NRI's – source Beacon Dashboard Management information as of 2/5/25

Organisation	Median working days to complete NRI investigations*	Range in working days
NHS Trust/SHA	131	103-180
Local Health Board (LHB)	136	79-170
All Wales median	133	

- *Excludes Pressure ulcers

78. It should be noted that there are high volumes of other clinical incidents that do not meet the threshold for National reportable incidents however require investigation and actions and learning and are subject to the Principal Regulations.

[15] NHS Wales (2024) National Policy on Patient Safety Incident Reporting & Management du.nhs.wales/files/incidents/national-policy-on-patient-safety-incident-reporting-2-0-pdf/

79. The Once for Wales concerns management system will also require some updating and redesign to ensure the amendments are fully incorporated into the digital system. This is also true of Llais' Customer Relationship Management system. Further work will be required to understand the detailed costs for these.

(v) The estimated ongoing costs resulting from the implementation of the amendments to the Principal Regulations and guidance are outlined below.

80. Although difficult to quantify, it is anticipated that the following changes, aimed at giving patients and complainants a stronger voice in the process will lead to more use of the early resolution stage, thus potentially reducing the impact on resources. This trend has already been demonstrated through the increase in early resolution of concerns in the past 12 months. The new amendments also include the following:

- revising the existing mandatory offer of an in-person listening discussion, especially to provide further information to the bereaved.
- allowing more time to attempt early resolution.
- providing updates about progress while the issue is being handled.

81. Under the Duty of Candour Responsible Bodies must already notify the service user or their representative on becoming aware of the incident to inform them what they understood to have happened, explain what 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.

82. The Principal Regulations already include a duty to offer to discuss specified matters with the person who notified the concern (regulation 22(4)) at a time to be agreed with the person, which includes discussion about the type of investigation, any advocacy that may be needed and the length of time of the investigation. The public feedback was that this wasn't always provided and when it was, it did not always leave the person who has raised a concern with the feeling that they had been listened to adequately.

83. It is reasonable to accept that there will be some resource implications from increased content of the listening discussion over the resource requirements when meeting the original legal requirement of offering to discuss the concern and how it was to be investigated. However, this is not thought to be a very large amount in comparison to the existing

processes and so to estimate this the calculations for the Duty of Candour have been used.

84. Opportunity cost for Responsible Bodies to add the additional components of the listening discussion in to the original regulations offer of a discussion when a concern is raised.

85. Table 14 – Estimated additional time for the listening discussion above the discussion already in the Principal Regulations.

Activity	Additional Time required	Uptake on offer	All Wales Concerns Frequency	Hourly rate	Estimated opportunity cost
Opportunity cost – additional communication to service user or representative on top of the original regulation requirement	30 minutes discussion	50 % uptake on offer	8,149.5	£35.83[(i)]	£146,000
	30 minutes discussion	100% uptake on offer	16,299	£35.83	£292,000

Taken from the Duty of Candour RIA analysis the mean hourly pay and on costs for those in management roles in health estimated against 2025 EB2 scale (£91,860 including add on).

86. One of the regulation amendments is to be much clearer on the duty of responsible body to assess the need of advocacy and support at several parts of the concerns process. This emphasis builds on the duty of candour procedure which also placed a similar focus on ensuring that people were supported adequately to ensure they were heard and could participate more actively in the LTP process. This will undoubtedly have an impact on Llais and third sector organisations as the potential demand for advocacy may increase.

87. Currently Llais are involved in 10% of patient safety incident meetings which is reasonably expected to increase with the amendments and combined with the complaints advocacy the organisation will need to carefully assess this through a detailed impact assessment.

88. The policy intention was also to extend the period of time that early resolution can be achieved within in the regulations to maximise the opportunity to answer concerns and questions raised by the bereaved to aim to ensure compassionate and supportive information giving is provided early in the process which the public have reported is significant part of the reason they raised concerns in the first place. It also allows the Responsible Body to swiftly identify early in the process where candour or further investigation is needed for serious concerns about care that may have led to a death. This also aligns to the new statutory role of the medical examiner service raising concerns about

care, voiced by families of those who have died. It also aligns to the national bereavement strategy.

89. The extension in time for early resolution also aims to provide a more realistic period in which staff can act on complaints to reach a resolution or provide accurate information where this is possible to achieve. As the current data demonstrates the NHS is already completing an average of 40% of concerns within the existing 2 working days the extension can only improve this opportunity without adding significant additional burden on resources.

Impact on Litigation:

90. Attempts to estimate what the impact and savings on litigation may be helpful but, due to the challenges with accurate data mean only limited conclusions can be made at this stage. It is assumed however that there will be greater opportunity to use the redress scheme which will result in fewer cases resorting to litigation, by increasing the threshold for redress to £50,000; agreeing the timeframe to resolve a concern or complaint with the complainant; introducing a meeting to discuss the findings of the investigation; improving communication with complainants during the investigation; increasing the fees schedule of fees paid to lawyers handling redress claims, and increasing awareness among claimants that the NHS body pays for the complainant's legal advice and expert medical advice (where applicable).

Redress Cases and Clinical Negligence cases

91. Table 15 - Management Data for Wales Responsible Bodies April 2024 to February 2025

Organisation	**Complaints/Claims/ Redress/ Inquest – 1) Manager (WTE) 2)Administration (WTE)**	**Number of active/open Redress cases within 04/24 – 02/25**	**Number of closed Redress cases within 04/24 – 02/25**	**Number of active Redress cases**	**Number of complaints exceeding Redress value**	**Number of Duty of Candour cases triggered within 04/24 – 02/25**
NHS Trust/SHA	1) 5.2 2) 6.0*	46	26	44	5*[3]	62

Local Health Board (LHB)	1) 20.68 2) 112.73*[1]	448	364*[2]	823*[2]	255	738*[2]
Llais	1) Tbc 2) tbc					

- *Incomplete data from one NHS trust as roles integrated into other quality roles.
- *[1] varying model of roles and structures make comparison difficult many roles integrated into other functions
- *[2]missing data from one LHB.
- *[3] one NHS trust unable to report data with accuracy and returned a nil response

92. Further to the public consultation work undertaken to indicate the intention to simplify the solicitors' fees schedule originally in the 2011 guidance, The Welsh Government intend to increase the fees in the guidance and break them down into two parts.

93. PTR redress process to provide greater access to free legal advice for people raising concerns and complaints.

94. At present, the claimant's legal representative may receive one payment of £1600 for:

- Considering Breach of Duty and investigating causation including the commissioning of up to two expert reports or
- Reviewing the appropriateness of the offer made to the complainant by the NHS body.

95. They may receive a further payment to review any additional report on the condition and prognosis for estimation of damages.

96. The legal representative may receive an additional £868 to advise the complainant where the NHS body admits Qualifying Liability but refuses to offer redress.

97. From the data provided claimant solicitors costs are more than these rates demonstrating that the original rates do not reflect practice.

98. We propose to simplify the current fee system and replace the above with:

- Payment 1: for providing advice on the admission of liability made (£1750)

- Payment 2: for providing advice on the quantum of damages[16] where settlement is reached under the redress arrangements of (£1000)

99. All figures above represent the fees prior to the addition of VAT.

100. As is the case currently, additional payments may be available for instructing additional experts or advising the complainant where the NHS body admits Qualifying Liability but refuses to offer redress.

101. The intention that complex cases or protected cases would not normally fall under the redress arrangements and should therefore continue to be managed through the civil proceedings system until such a time as the proposed Fixed Recoverable Costs Scheme may be extended for Low value Clinical negligence claims by the UK government when this can be reassessed.

Legal Advice costs to Responsible Bodies in the new arrangements

102. **Legal advice from Legal and Risk Services –** The Legal and Risk Services provide chargeable advice to NHS bodies in relation to redress under the principal Regulations. It is estimated that in the first year (2026-27) advice requests relating to the potential additional cases (see table 15 of cases outside of redress limit above) that could be included in the redress pathway would increase the current costs in respect of chargeable advice sought in respect of amendments made to the Principal Regulations matters by 22% and maintained this level 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:

103. Table 16 – costs of obtaining legal advice from NWSSP Legal & Risk Services

	2026-27	2027-28	2028-29	2029-30	2030-31
Cost – legal costs payable to NWSSP Legal & Risk Services for chargeable work relating to advice requests	7,600	7,600	7,600	7,600	7,600

[16] Quantum of damages is a legal term that means the amount of money awarded as compensation for a civil wrong. The underlying principle is that the claimant is entitled to be placed in the position they would have been had the injury not occurred, insofar as money can.

104. A review by Welsh Government officials of settled cases of redress and clinical negligence cases found that in the period of 2020 – 2023 there were 566 redress cases and 431 settled CN cases in NHS Wales. These were broken down as 276 cases where the damages were up to £25,000 and 155 cases where the damages were over £25,000 and up to £50,000.

105. Table 17 - Welsh Risk Pool actual data on settled cases in 2020-23

WRP actual data on settled cases in 2020-23				
	Redress	**Clinical Negligence Reimbursements**		**Comments**
	>£0	>£0 <=£25k	>£25k to £50k	
Numbers of Cases	566	276	155	
Damages total (£)	4,794,607	3,792,583	5,905,930	These are the damages awarded to the claimant directly
Claimant Costs (£)	1,500	8,659,141	6,869,072	These are the costs paid to the claimant solicitors
Defence Costs (£)	359,251	1,124,357	893,835	These are the costs incurred by L&R in court processes

106. If the amendment to regulations 29 (1) and 29 (2) are introduced more cases will be eligible to go through redress and if so, will reduce the claimant costs and the defence costs but will not affect the damages being paid as these are set in accordance with common law and guidance published by the Judicial College.

107. Whilst it is assumed for the purposes of this impact assessment (and to underpin the intent of the policy changes) that more cases would be technically eligible to enter the redress scheme there will always be cases where this would not be appropriate whether that is due to the nature of the case or where a court process would be in the best interests of the claimant or the complexity of the case.

108. For illustration a range of cases migrating to redress have been calculated assuming all cases take up the funded Legal advice based on the new fees schedule.

109. Table 18 - Analysis estimating the impact of inclusion of cases currently outside of the £25,000 threshold in the redress process based on 3 year settled claims data.

If 100% of CN claims moved to redress and all took funded legal	Original redress cases (566 cases)	CN cases £0-25K (276 cases)	CN cases £25 – 50K (155 cases)	Overall maximum impact over 3-year period

advice at the new rates				
£2,741,750	£1,500	£8,659,141	£6,869,072	- £12,787,963
If 60% of CN claims moved to redress and all 60 % took funded legal advice at the new rates	Original redress cases (566 cases)	CN cases £0-25K (276 cases)	CN cases £25 – 50K (155 cases)	Overall maximum impact over 3-year period
£2,267,650 Inc original 566 redress cases	n/a	£3,463,656	£2,747,628	-£7,050,779
If 30% of CN claims moved to redress and all 30% took funded legal advice at the new rates	Original redress cases (566 cases)	CN cases £0-25K (276 cases)	CN cases £25 – 50K (155 cases)	Overall maximum impact over 3-year period
£1,912,075 Inc original 566 redress cases	n/a	£6,061,398 this is 70% of the costs as only 30% transitioned to redress	£4,808,350 this is 70% of the costs as only 30% transitioned to redress	-£2,747,890

110. The numbers of cases represented in this table are not new cases to the NHS as they are currently managed through Legal Services teams in NHS bodies in conjunction with retained external legal firms as well as advice from Legal & Risk Shared Services.

111. Additionally, there may be cost avoidance in defence costs (NWSSP L&R) with cases moving to redress instead of civil litigation currently these for the three 3-year period were £1,224,357 and £893,835 respectively for the £0-25K and £25-50K claims groups. It is difficult to estimate the degree of impact on these.

112. To Note - The assumptions in these calculations are that:

- any CN case would come under redress whereas it is possible that it would be the lower value claims predominantly.
- there could be additional costs in relation to the more complicated CN claims transferring into redress if they are then transferred back to the CN claim route

113. Also, it should be emphasised that:
    - these figures are based on historical claim numbers and cover a 3-year period and are not annual savings; and
    - they may not reflect future claim numbers as there are other initiatives in place aiming at reducing claim numbers not least the early resolution changes and the learning work and the impact of the Duty of candour which is still being fully understood and realised.

- Anecdotal evidence is that more incidents are being reported and investigated having been triggered through the Duty of Candour. This is a very positive and desirable step. The desired result of which is expected to be transition of more cases to redress. It was however, suggested in the Health and Social Care (Quality and Engagement) (Wales) Act 2020 Regulatory impact assessment that it would take 5 years before the true impact on clinical negligence claims was realised.

114. There clearly are opportunities to move more of the complaints into early resolution. Whilst there is a small additional amount of time to listen to the issues the person has; this has been calculated on top of the original offer that exists in the Principal Regulations to discuss the investigation and concern.

115. However, the past 12 months has shown that where early resolution has increased the number of complaints has slightly decreased. Under the Principal Regulations complaints are excluded from the current Putting Things right process if successfully settled in the first two days. There is also data to support that many complaints are investigated and concluded successfully within the time frame of 30 working days.

116. However, as the new amendments allow for alignment with the National Policy on Patient Safety Incident Reporting & Management where 120 working days is set as the maximum number of days to conclude an investigation and provide a final report, so that there is parity between complaints and patient safety investigations where early resolution has not been successful or it was not suitable to attempt.

117. The 30 working days timeframe remains however the desired approach is that where 30 working days is an unrealistic timeframe engagement during the listening discussion enables to the responsible body to identify a more realistic timeframe with the person.

118. The NRI data shows that Wales median is currently at 133 working days. NRI’s are of course not the only type of investigations undertaken and although that data isn’t available to consider the wider opportunity or impact it is reasonable to identify that resources saved elsewhere could be used to support the NRI investigation process and afford an opportunity to make some reductions in median time for completion of them.

119. There may be opportunities to engage more effectively from the outset and by reducing the number of complaint investigation's re-purpose resource into the more complex patient safety incident investigations.

120. One of the regulation amendments is to be much clearer on the duty of responsible body to assess the need of advocacy and support at several parts of the concerns process. This emphasis builds on the duty of candour procedure which also placed a similar focus on ensuring that people were supported adequately to ensure they were heard and could participate more actively in the LTP process. This will undoubtedly have an impact on Llais and third sector organisations as the potential demand for advocacy may increase.

121. Currently Llais are involved in 10% of patient safety incident meetings which is reasonably expected to increase with the proposed amendments.

122. Careful planning by Responsible Bodies on how they realign their resources to meet the additional time at the early stages of the process will be needed and consideration will need to be given to how to fund the possible 22% increase in redress that may come from the overall reduction in litigation bill costs by implementing this and the new solicitors fee's schedule which is aligned to the UK Government consultation on the fixed recoverable costs scheme for low value clinical negligence claims proposals.

123. Table 19 - Overall sunk and opportunity costs for Welsh Government and the NHS for 7 years

	2024-5	2025-6	2026-7	2027-8	2028-9	2029-30	2030-1
WG							
Programme staff costs (i)	204,900	89,200					
Stakeholder Engagement	£600						
Training Materials		£10,500					
BSL product			£1800				
Public awareness campaign		£11,400					
Guidance & supporting materials		£45,800					£7,100
Total	£205,500	£156,900	£1,800				£7,100

NHS Bodies (opportunity costs)							
Implementation planning		£1,799,400					
Training time (ii)		£1,233,200	£3,699,500	£493,040	£493,040	£493,040	£493,040
Proposed training L&R NWSSP		£18,700					
Increased Legal advice			7,600	7,600	7,600	7,600	7,600
Total		£3,051,300	£3,707,100	£500,640	£500,640	£500,640	£500,640

(i) Programme runs April 2023 until October 2025. NHS secondee costs (April 2023 until June 2025).

(ii) Training time is calculated as part effect in 2025/6 and ¾ of training occurring in 2026/7 and assumes a 10% turnover necessitating new training.

124. Table 20 - Analysis of resource (time spent on complaints responses) and saving opportunities.

Metric	Value	Working Days
Complaints reduced in the last year	From 19062 to 18334 = 728	21,840 working days
NRI Data for Wales 2022/23	857 (ii and iii)	11,2267 - 113981
NRI Data for Wales 2023/24	1046 (ii and iii)	137026 -139118
NRI Data for Wales 2024/25	840 (ii and iii)	11,0040 – 11,1720
Reduction in NRI's	206 (ii and iii)	26,986 - 27,398
5% improvement in complaints	917 complaints,	27,510 working days saved
10% improvement in complaints	1833 complaints,	54,999 working days saved

Management information is raw data which has not been verified and does not meet the standard of a national statistic.

125. Table 21 – Time commitment of the listening discussion with variable uptake

Uptake of discussion in time	50 % uptake with a 5% improvement	4,354 hours
Uptake of discussion in time	75% uptake with a 5% improvement	6531 hours
Uptake of discussion in time	100% with a 5% improvement	8709 hours
Uptake of discussion in time	50% uptake with (10% improvement)	4125 hours
Uptake of discussion in time	75% uptake with (10% improvement)	6189 hours

Uptake of discussion in time	100% uptake with (10% improvement)	8250 hours

(i) Calculated as 30 working days median time for a completed response multiplied by the number of complaints reduced. The true figure will be a representative portion of this.

(ii) NHS Trust/SHA median time for NRI completed investigation 131 working days

(iii) LHB median time for NRI completed investigation 133 working days

126. It is recognised that the inclusion of working days here are not intended to be a direct comparator to the additional time for the listening discussion as not all the working days will be spent on each individual case. However, it but it seems reasonable to assume that there will be direct working time efficiencies created by the overall reduction in complaints or incident investigations which have the potential to be used organisationally to offset the additional time for the listening discussion or other amendments that impact on resources.

Competition assessment

127. The Principal Regulations already placed a requirement for claimant solicitors to be suitably qualified specialists in clinical negligence field and membership of the Law society's specialist panel or the action against medical accidents clinical negligence panel. These requirements remain unchanged.

128. The proposed increased fee schedule is aligned to the public consultation by UK government where the questions about suitable dispensations was consulted upon and was the subject of The Welsh Government's public consultation on adjusting the Fee's Schedule in 2024. We do not consider it therefore necessary to undertake a competition assessment for these Regulations since they will not affect the business sector in any new significant way.

Post-implementation review

129. The Regulations provide for two types of monitoring and learning – monitoring the process, which will be done via statistical returns and annual reports; and learning from concerns, which requires organisations to demonstrate that they have proactively used the outcome of investigations to learn lessons and built them into service improvements. The Director General will issue guidance to the NHS in terms of what is to be l expected by way of information.

Summaries of the Integrated Impact assessments:

130. The Integrated Impact Assessment consolidates several key assessments to ensure that new regulations are developed and implemented with a comprehensive understanding of their effects:

131. **Children's Rights Impact Assessment**: The assessment concludes that the needs of children have been thoroughly considered within the LTP process. This consideration was ensured through focus group sessions, conducted by Children in Wales. These sessions provided valuable insights and feedback on the revised process, ensuring that the perspectives and rights of children were adequately addressed. By incorporating these inputs, the LTP process aims to be more inclusive and responsive to the unique needs and rights of children, thereby promoting their well-being and ensuring that their voices are heard in matters that affect them.

132. **Equality Impact Assessment**: The LTP process represents a significant step forward in making the NHS Wales complaints system more accessible, inclusive, and responsive. While it does not impact existing equality duties or negatively affect any protected characteristics or groups, it is expected to positively influence the ability of individuals from various backgrounds, to raise concerns and complaints effectively. This approach aligns with the commitment to high-quality, person-centred care.

133. **Data Protection Impact Assessment**: A data screening tool indicated that a full assessment was not required. However, an article 36 notification form has been submitted to the Information Commissioner's Office.

134. **Justice Impact Assessment:** The Justice Impact Assessment indicated that a full Justice Service Impact identification was not required. In the Justice Impact assessment there is reference to a 5-year review of the impact of the regulation changes and The Welsh Government will plan to review the impact at that point. It is not envisaged the LTP process itself will have an impact on the justice system.

135. The LTP process will not create patient safety incidents as these should already be reported by NHS bodies, but it will require NHS bodies to be open and honest when dealing with complaints or incident investigations. It is anticipated that in the long term, learning from patient safety incidents will reduce the number of cases, which will lead to fewer complaints and litigation from service users. There is also a potential

reduction in cases entering the civil proceedings pathway if the increase to the damage's threshold is amended as planned.

136. The LTP process does not appear to affect the work of the judiciary, or the administration of the courts system and the tribunal system, as they do not involve any changes to the criminal law (such as new criminal offences or penalties), rights of appeal, or the operation of the judicial system.

Duty of Quality Assessment

The Welsh Ministers' Duty of Quality in section 1A of the NHS (Wales) Act 2006, inserted by the Health and Social Care (Quality and Engagement) (Wales) Act 2020, requires us to evidence that we make policies and decisions with a view to securing improvement in the quality of health services in line with the following criteria:

Safe – amendments to the Principal Regulations and guidance aims to improve patients' experience through openness and transparency and learning applied for the future prevention of harm from incidents.

Timely – the proposals aim to increase the use of Early Resolution and extend the timeframe for Early Resolution which will result in a timelier resolution of concerns.

Effective – the LTP process aims to promote learning from concerns and complaints, whilst also improving a person's experience as they go through the process. The learning is expected to improve the safety and quality of services, therefore making them more effective.

Efficient – the proposals would make the LTP process more efficient, by aiming to increase the use of Early Resolution, thus avoiding distressing delays in resolving a concern or complaint. Increasing the threshold for damages for cases in the LTP redress process from £25,000 to £50,000 will mean more cases can go through the LTP redress process rather than resorting to costly litigation.

Equitable – the proposals to raise patients' awareness that persons notifying concerns can have free advocacy and expert advice, and to increase the fees offered to lawyers, will increase access to expert representation.

Person-centred – amending the regulations and updating the guidance will improve clarity and understanding for service users and practitioners. Improved understanding and an increased awareness of the free legal and expert advice will provide more support for complainants.

Leadership – there will be improved governance and accountability through clearer guidance; modernising our redress arrangements; setting standards

for including and valuing our patients and their families in the management of concerns and complaints with healthcare, and by holding organisations to account for their practice on openness and transparency.

Culture and valuing people – the proposals to improve the guidance and the materials on staff training will equip staff with the skills they need when dealing with concerns and complaints.

Information – the proposals to improve the guidance and materials for staff training, and by prescribing expectations for meetings with patients at the start and end of the complaints process, will provide direct feedback to NHS staff, thus increasing their understanding of patients' concerns and complaints.

Learning, improvement, and research – the proposals will increase NHS staff's understanding of patients' concerns and complaints. Increased use of the Early Resolution process will reduce the number of claims relating to clinical negligence cases.

Whole-systems perspective – the proposals aim to enable concerns and complaints to be settled more quickly and efficiently, without affecting patients' access to justice. They also seek to free up the significant cost pressure posed by the often-unplanned costs of clinical negligence cases. This will afford NHS organisations to reinvest the money in other priority areas, for example, front-line care and services.

Workforce – strengthening the guidance and redress arrangements (especially the proposal to improve the guidance and materials for staff training) will support the workforce managing these processes. Undertaking the learning from these incidents by NHS staff will improve their practice, enabling them to grow professionally and leading to a better-trained and better-informed workforce.