



Llywodraeth Cymru
Welsh Government

HEALTH AND SOCIAL CARE (QUALITY AND ENGAGEMENT) (WALES) BILL

Explanatory Memorandum
incorporating the
Regulatory Impact Assessment and
Explanatory Notes

June 2019

Health and Social Care (Quality and Engagement) (Wales) Bill

Explanatory Memorandum to Health and Social Care (Quality and Engagement) (Wales) Bill

This Explanatory Memorandum has been prepared by the Health and Social Services Department of the Welsh Government and is laid before the National Assembly for Wales.

Member's Declaration

In my view the provisions of the Health and Social Care (Quality and Engagement) (Wales) Bill introduced by me on the 17th June 2019, would be within the legislative competence of the National Assembly for Wales.

Vaughan Gething AM

Minister for Health and Social Services
Assembly Member in charge of the Bill

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List of Abbreviations

2000 Act - Care Standards Act 2000

2003 Act - Health and Social Care (Community Health and Standards) Act 2003

2006 Act - National Health Service (Wales) Act 2006

2010 Regulations - The Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010

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

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

2015 Act - the Well-being of Future Generations (Wales) Act 2015

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

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

ABMUHB - Abertawe Bro Morgannwg University Health Board

AGW - Auditor General for Wales

AQS - Annual Quality Statements

the Bill – the Health and Social Care (Quality and Engagement) (Wales) Bill

the Body - the new Citizen Voice Body for Health and Social Care in Wales

CEO - Chief Executive Officer

CHCs - Community Health Councils

CIW - Care Inspectorate Wales

CRIA - Children's Rights Impact Assessment

CRM - Customer Relationship Management

EB1 - Executive Band 1

EB2 - Executive Band 2

EIA - Equalities Impact Assessment

FTE - Full Time Equivalent

GoWA 2006 - Government of Wales Act 2006

GP/s - General Practitioner/s

GPC - General Practitioners Committee

H&SS - Health and Social Services

HEIW - Health Education Improvement Wales

HIA - Health Impact Assessment

HIW - Health Inspectorate Wales

HR - Human Resources

ICT - Information and Communications Technology

IM - Independent Member

IT - Information Technology

JIA - Justice Impact Assessment

LA - Local Authority

LHB/s - University or Teaching Health Board/s

MB1 - Management Band 1

MB2 - Management Band 2

MB3 - Management Band 3

MBE - Member of the British Empire

NAW - National Assembly for Wales

NHS - National Health Service

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

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

NPV - Net Present Value

NRLS - National Reporting and Learning System

OCPA - Office of the Commissioner for Public Appointments

OECD - Organisation for Economic Co-operation and Development

PAYE - Pay As You Earn

PCC - Patient and Client Council

PIA - Privacy Impact Assessment

PTR - Putting Things Right

PSBs - Public Services Boards

PV - Present Value

PwC - PriceWaterhouseCooper

RIA - Regulatory Impact Assessment

RPBs - Regional Partnership Boards

RPIA - Rural Proofing Impact Assessment

SCS - Senior Civil Service

SHC - Scottish Health Council

SHAs - Special Health Authorities

tHB - Teaching Health Board

VAT - Value Added Tax

WG - Welsh Government

WGSB - Welsh Government Sponsored Body

WLIA - Welsh Language Impact Assessment

WM/s - Welsh Minister/s

WTE - Whole Time Equivalent

PART 1 – EXPLANATORY MEMORANDUM

1. Description

1. The Health and Social Care (Quality and Engagement) (Wales) Bill ('the Bill') uses legislation as a mechanism for improving and protecting the health, care and well-being of the current and future population of Wales. It contains provisions in respect of health and social care policy.
2. The Bill builds on the assets we have in Wales to strengthen and future proof our health and social care services for the future; facilitating a stronger citizen voice, improving the accountability of services to deliver improved experience and quality of care for people in Wales and contributing to a healthy and prosperous country. Taken together the provisions are intended to have a cumulative positive benefit for the population of Wales and to put in place conditions which are conducive to improving health and well-being.
3. In summary the Bill proposes to introduce changes that will:
 - place quality considerations at the heart of all that NHS bodies in Wales and the Welsh Ministers (in relation to their health functions) do through a specific duty, building upon the Well-being of Future Generations (Wales) Act 2015 ("the 2015 Act")¹ and the Social Services and Well-being (Wales) Act 2014 ("the 2014 Act")². In relation to the duty of quality NHS bodies are defined as Local Health Boards (LHBs), NHS Trusts, Special Health Authorities (not including cross-border special health authorities);
 - place a duty of candour on all NHS bodies at an organisational level, requiring them to be open and honest when things go wrong. In relation to the duty of candour NHS bodies are defined as LHBs, Trusts, Special Health Authorities (including NHS Blood and Transplant in relation to its Welsh functions) and primary care providers in Wales in respect of the NHS services they provide;
 - strengthen the voice of citizens across health and social services, further connecting people with the organisations that provide them with services; and
 - strengthen the governance arrangements for NHS Trusts.
4. The Bill will also provide the Welsh Ministers with regulation-making powers to:
 - set out a procedure to be followed by an NHS body when the duty of candour has been triggered (section 4);

¹ **Well-being of Future Generations (Wales) Act 2015.** London: HMSO.

² **Social Services and Well-being (Wales) Act 2014.** London: HMSO

- make regulations containing supplementary, incidental or consequential provision, and/or transitory, transitional or saving provision, to bring into force or give full effect to the provisions of the Act if the Welsh Ministers consider it necessary or expedient (section 26(1); and
- make commencement orders specifying that provisions in the Act shall come into force on a specified date (section 27).

2. Legislative Competence

5. The National Assembly for Wales ('the Assembly') has the legislative competence to make the provisions in the Health and Social Care (Quality and Engagement) (Wales) Bill ("the Bill") pursuant to Part 4 of the *Government of Wales Act 2006* ("GoWA 2006") as amended by the *Wales Act 2017*.

3. Purpose and intended effect of the legislation

Policy background

6. Quality is at the heart of every aspect of the approach to health care in Wales. It is highlighted in the core values that underpin the NHS in Wales, originally set out in Together for Health in 2011³. The values are:
 - **putting quality and safety above all else:** providing high value evidence based care for our patients at all times;
 - **integrating improvement** into everyday working and eliminating harm, variation and waste;
 - **focusing on prevention, health improvement and inequality** as key to sustainable development, wellness and well-being for future generations of the people of Wales;
 - **working in true partnerships** with partners and organisations and with our staff; and
 - **investing in our staff** through training and development, enabling them to influence decisions and providing them with the tools, systems and environment to work safely and effectively.
7. This approach was reinforced in the Parliamentary Review of Health and Social Care in Wales in 2018⁴ (“the Parliamentary Review”), which recommended that moving forward the vision for health and care in Wales should aim to deliver against the four mutually supportive goals of the “Quadruple Aim”, which are to continually:
 - improve population health and well-being through a focus on prevention;
 - improve the experience and quality of care for individuals and families;
 - enrich the well-being, capability and engagement of the health and social care workforce; and
 - increase the value achieved from funding of health and care through improvement, innovation, use of best practice, and eliminating waste.
8. The Review also highlighted the need for a system where care and support should be person centred and seamless; without artificial barriers between physical and mental health, primary and secondary care, or health and social care. It describes the need for a system where NHS bodies are not just there to manage or deliver care but to improve it every day. This

³Welsh Government. Together for Health - A 5-year vision for the NHS in Wales [Internet]. 2011. Available from: <https://gweddiill.gov.wales/docs/dhss/publications/111101togetheren.pdf>

⁴Parliamentary Review representatives. The Parliamentary Review of Health and Social Care in Wales [Internet]. 2018. Available from: <https://gov.wales/sites/default/files/publications/2018-01/Review-health-social-care-report-final.pdf>

means constant and serious attention to three aspects of a quality system - quality planning, improvement and control. It highlighted that we need a health and care system that is always learning and where the voice of the citizen is clearly heard. It drew attention to the evidence that, if NHS Boards focus on these three aspects, the outcomes for service users are better.

9. In response, the Welsh Government's plan A Healthier Wales: our Plan for Health and Social Care⁵ ("A Healthier Wales") outlines how quality will be key to making the health and social care system in Wales both fit for the future and one which achieves value. It outlines our expectation that, going forward, health and social care services are brought together so they are designed and delivered around the needs and preferences of individuals. It emphasises the importance of continuous engagement with citizens which allows people to contribute their knowledge, experiences and preferences.
10. The provisions in the Bill aim to help realise these ambitions in a number of inter-connected ways by placing improvement in quality as the central concept underpinning the provisions within the Bill: duty of quality, citizen voice, duty of candour and the opportunity for NHS Trusts to have a Vice Chair. Quality should be viewed as more than just meeting service standards; it is a system-wide way of working to enable safe, effective, person-centred, timely, efficient and equitable services in the context of promoting a learning culture.
11. The internationally accepted definition, put forward by the then Institute of Medicine⁶, outlines six domains of health care quality as systems which are:
 - **Safe:** Avoiding harm to patients from the care that is intended to help them.
 - **Effective:** Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively).
 - **Patient-centred:** Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
 - **Timely:** Reducing waits and sometimes harmful delays for both those who receive and those who give care.
 - **Efficient:** Avoiding waste, including waste of equipment, supplies, ideas, and energy.
 - **Equitable:** Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

⁵ Welsh Government. A Healthier Wales: our Plan for Health and Social Care [Internet] 2018. Available from: <https://gweddill.gov.wales/docs/dhss/publications/180608healthier-wales-mainen.pdf>

⁶AHRQ (2016). *The Six Domains of Health Care Quality* | Agency for Healthcare Research & Quality. [online] Ahrq.gov. Available at: <https://www.ahrq.gov/professionals/quality-patient-safety/talkingquality/create/sixdomains.html> [Accessed 28 Nov. 2018].

Therefore the elements of the Bill all contribute to this overarching aim.

12. Reframing the **duty of quality**⁷ to require NHS bodies and the Welsh Ministers to exercise their functions with a view to securing improvements in the quality of services they provide will shift the focus of decision making and represent a further step on the journey towards ever-higher standards of person-centred health services in Wales.
13. Placing a **duty of candour** on NHS bodies will improve service user experience, communication and engagement between the NHS and its service users. It will build on the work that has already been undertaken to ensure NHS bodies in Wales are open and honest when things go wrong, and support the drive towards a system that is always learning and improving and has the trust and confidence of patients and service users.
14. The creation of the **new Citizen Voice Body for Health and Social Care in Wales** ("the Body") will underline our commitment to driving forward the integration of health and social services by establishing, for the first time in Wales, a single body that will represent the voice of citizens in relation to both health and social services matters.
15. The creation of a power for the Welsh Ministers to **appoint a Vice Chair on NHS Trust Boards** will ensure consistency across LHBs and Trusts, and strengthen leadership and governance arrangements.
16. The rationale for introducing legislation, what we are setting out to do and how the legislation will help to deliver our objectives, are set out in more detail below for each of these areas.

DUTY OF QUALITY

Background

17. Within the NHS in Wales, the drive to improve quality has been ongoing for over 20 years. The introduction of clinical governance in 1998⁸ provided a framework at national and organisational level for ensuring improvement and high standards of care, with more openness and transparency about performance, and promoting active patient engagement and involvement. This important milestone set the foundations on which all subsequent initiatives have been built.
18. Since that time, we have sought to embed quality throughout the Welsh NHS, from board level to frontline staff. Quality is seen as the golden thread that must run through all aspects of service planning and provision and be explicit within organisations' integrated medium term plans. The use of

⁷ **Health and Social Care (Community Health and Standards) Act 2003**. London: HMSO

⁸ Welsh Office. Quality Care and Clinical Excellence. London: Welsh Office, 1998.

specific tools and processes such as clinical audit, mortality reviews, patient feedback and patient safety incident reporting are key elements of necessary quality assurance mechanisms to identify areas for learning and improvement. This together with clear lines of accountability and corporate responsibility are designed to contribute to a safer, higher quality service. Inspection, improvement reviews and investigation into serious service failures are also now an established part of driving quality improvement within the NHS.

19. Additionally, there is a wide range of key expectations, contained in policy, guidance and legislative measures, underpinning the Wales approach to quality and quality improvement in service delivery and planning.
20. In social care the Regulation and Inspection of Social Care (Wales) Act 2016⁹ ("the 2016 Act") sets the statutory framework for the regulation and inspection of social care services and reforms the regulation of the social care workforce in Wales. It establishes a new regulatory framework with an emphasis on quality and improvement. The Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017¹⁰ ("2017 Regulations") developed under the 2016 Act⁹ include requirements for monitoring, reviewing and improving the quality of the regulated service.

Why change is needed

21. NHS bodies have been under a duty to make arrangements for the purpose of improving the quality of health care since 2003, under section 45(1) of the Health and Social Care (Community Health and Standards) Act 2003⁷ ("the 2003 Act"). Although the 2003 Act⁷ requires NHS bodies to make arrangements to monitor and improve the quality of health care, it has largely been interpreted as requiring NHS bodies to have quality assurance (control) arrangements in place to monitor and improve the quality of healthcare provided rather than a comprehensive focus on the three aspects of a quality system as described by the parliamentary review⁴: quality planning, improvement and control to ensure a focus on quality services at a wider population level.
22. The duty of quality set out in the 2003 Act⁷ has succeeded in providing some focus on improvement in quality and the development of an infrastructure to provide assurance that improvement is taking place. This includes Quality and Safety Committees at every LHB and Trust with direct links to the Board, as well as robust arrangements for the reporting, investigation and learning from patient safety incidents and concerns.

⁹ **Regulation and Inspection of Social Care (Wales) Act** 2016. London: HMSO

¹⁰ The Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations (SI 2017/1264). Available from:
<http://www.legislation.gov.uk/wsi/2017/1264/made>

23. The duty has also, to an extent, helped foster a more positive culture of quality; something which the OECD Review of 2016¹¹ noted was “at the heart of the Welsh health system” and paved the way for more openness, honesty and transparency. However, the report by the OECD commented that some years after their establishment LHBs were “showing less innovation and fewer radical approaches to system change and quality improvement than might have been expected”.
24. The duty of quality in the 2003 Act⁷ has tended to have been interpreted in a narrow way, focussing on improvements in quality for individuals and the implementation of service standards. Consequently, as set out below, we wish to take the opportunity to take the next step by replacing this duty and enacting a broader duty of quality, more in keeping with how we now want NHS bodies to work, which will strengthen actions and decision making to drive improvements in quality.
25. Additionally, the Welsh Ministers have responsibility for oversight of the NHS in Wales and many of the policies that are developed by the Welsh Ministers, whether legislative or otherwise, have an impact on how NHS bodies in Wales operate. However the 2003 Act⁷ does not place a duty of quality on the Welsh Ministers in the exercise of their health related functions. This is considered to be a gap in the current duty which needs to be addressed.
26. Finally, the duty of quality in the 2003 Act⁷ lacks any reporting mechanisms. Reporting mechanisms are beneficial as they allow bodies that are subject to the duty of quality to demonstrate how their functions have been exercised to secure improvement in the quality of services provided. Additionally, reporting also provides a mechanism for holding bodies to account as it is a transparent way of demonstrating how the duty has been complied with.

Policy Objectives

27. Our objective is to achieve a system wide approach to quality in the health service to secure improvement and shift the focus away from the narrower interpretation of quality which has a particular focus on quality assurance.
28. The objective is for the new, broader duty to require NHS bodies (as defined in paragraph 12) to exercise their functions in a way that requires them to consider how they can improve quality on an on-going basis. The aim is that improving quality and therefore outcomes for service users will become an embedded and integral part of the decision making process.
29. Additionally, given the breadth and significance of the Welsh Ministers’ health related functions, our objective is to ensure that decisions taken by

¹¹OECD. OECD Reviews of Health Care Quality: United Kingdom 2016 [Internet]. Paris: OECD Publishing; 2016. Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/oecd-reviews-of-health-care-quality-united-kingdom-2016_9789264239487-en

the Welsh Ministers support and contribute to this system wide approach to quality, by placing the Welsh Ministers under a corresponding duty of quality to that of NHS bodies.

30. To reflect the importance that we place on the new, broader duty, and our wish to further strengthen and embed quality at the heart of decision making for health services the duty will be given added prominence by its inclusion in the NHS (Wales) Act 2006 ("2006 Act")¹² which is where the key duties that are placed on the NHS in Wales are located.

Purpose of the Legislation

31. The purpose of the Bill's provisions in relation to a duty of quality is to reframe and broaden the current duty of quality within the 2003 Act⁷ to ensure quality becomes a system-wide way of working and that focus is placed on outcomes. The new duty will reframe the concept of "quality" to ensure that it is used in its broader definition, not limited to the quality of services provided to an individual nor to service standards. The Bill will ensure the Welsh Ministers (in relation to their health functions) and NHS bodies exercise all their functions with a view to securing improvement in the quality of health services.
32. The Bill will achieve this change by repealing section 45(1) of the 2003 Act⁷ which requires NHS bodies to establish and maintain arrangements for the purpose of monitoring and improving the quality of health services provided. The Bill will place a revised duty upfront in Parts 1 and 2 of the 2006 Act¹².
33. To address the policy objectives the intention is to place a general duty on:
- (a) the Welsh Ministers to exercise their functions in relation to the health service with a view to securing improvement in the quality of health services; and
 - (b) LHBs, Trusts and Wales-only SHAs to exercise their functions with a view to securing improvement in the quality of health services provided.
34. Quality under the duty is defined as including, but not limited to, quality in terms of the effectiveness and safety of health services, and the quality of the experience of users of health services. Health services are defined as services provided or secured in accordance with the 2006 Act¹².
35. For NHS bodies, the duty to exercise their functions with a view to securing improvements in the quality of services applies to the exercise of all of their functions, not just their clinical functions. It was considered important to ensure this was the case as the exercise of non-clinical functions (such as the provision of IT services) can have a significant impact on the quality of services provided.

¹² National Health Service (Wales) Act 2006. London: HMSO

36. The Bill makes consequential amendments to section 47 of the 2003 Act⁷ to ensure that NHS bodies will still be under a duty to take into account the health and care standards published by the Welsh Ministers under this section when discharging the new duty of quality.
37. Both the Welsh Ministers and NHS bodies will also be placed under a duty to report on an annual basis on the steps they have taken to comply with the duty. This must include an assessment of the extent of any improvement in outcomes achieved during the reporting period. This allows the actions the Welsh Ministers and NHS bodies have taken to improve outcomes to be monitored and for there to be transparency on the steps that have been taken to improve quality.
38. The duty will apply to the following in Wales:
- the Welsh Ministers
 - LHBs;
 - NHS Trusts; and
 - SHAs that operate on a Wales only basis.

How the legislation enables sectors to operate more efficiently

39. The policy intent behind the duty, in essence, is when the Welsh Ministers and NHS bodies plan or make decisions, or do anything else in relation to the health service that they actively consider how they can improve service quality, as defined above. The aim is to secure improvement in outcomes.
40. The reporting requirement will require the Welsh Ministers (in relation to their health related functions) and NHS bodies to assess the improvement in outcomes achieved during the reporting year, thereby demonstrating how they are improving the quality of health services in Wales. Consequently, the requirement to report annually will make explicit how the delivery of the duty has led to improvements in quality, providing a baseline to measure future improvement, and adding to the openness and transparency of the system. This approach supports the five ways of working as set out within the 2015 Act¹, by encouraging long-term thinking and integrated and collaborative action that works to achieve the well-being goal of a healthier Wales⁵.

Risk if legislation is not made

41. The new duty of quality requires NHS bodies and the Welsh Ministers to think and act differently by applying the concept of “quality”, not just to services being provided but to the whole process and across all functions within the context of the well-being and health needs of their populations. The immediate risks of not bringing forward the legislation would include significantly obstructing the prevention agenda, reinforcing existing barriers to planning for future population need, and limit the spread of best practice.

42. While there has been significant progress in driving up the quality of care, moving the focus away from the narrow interpretation of quality requires a step-change that will not be achieved by working within the existing legislative framework, and using existing tools to provide further guidance to the NHS on quality. The current framework has led the NHS towards this way of thinking, and without a legislative change the desired effect of achieving a system wide approach to quality is unlikely.
43. Put simply, continuing with the status quo creates a risk that “quality” continues to be a term applied as a method of assurance within local services and not a principle which supports system-wide improvement.
44. Additionally, there would be no statutory duty of quality placed on the Welsh Ministers, which is a significant omission from the current duty given the extent of the Welsh Ministers’ health related functions, and no reporting duty which again is something lacking from the current duty that we wish to take the opportunity to address.

DUTY OF CANDOUR

Background

45. All health and social care providers have a shared goal to deliver high quality care. There is evidence that increased openness, transparency and candour are associated with the delivery of higher quality health and social care^{13 14}. Organisations with open and transparent cultures are more likely to spend time learning from incidents, rather than trying to hide or be overly defensive about issues, and they are more likely to have processes and systems in place to support staff when things go wrong.
46. Known barriers to disclosure include fear, a culture of secrecy and/or blame, a lack of confidence in communication skills, fears that people will be upset and doubt that disclosure is effective in improving culture. Disclosure is also inhibited by professional or institutional repercussions, legal liability, blame, lack of accountability and negative family reactions. Factors that facilitate disclosure are an emphasis on accountability, honesty, restitution, trust and reduced risks of claims.
47. In social care, a duty of candour already exists for providers and responsible individuals of regulated services. The 2017 Regulations¹⁰ deal with the duty of candour in regulations 13 and 83 and require service providers and

¹³ World Health Organization, Organisation for Economic Co-operation and Development, and The World Bank. Delivering quality health services: a global imperative for universal health coverage. [Internet]. Geneva; 2018. Available from:

<https://apps.who.int/iris/bitstream/handle/10665/272465/9789241513906-eng.pdf?ua=1>

¹⁴ Department of Health and Social Care and The Rt Hon Jeremy Hunt MP. Good care costs less [Internet]. GOV.UK. 2014 [cited 1 April 2019]. Available from: <https://www.gov.uk/government/speeches/good-care-costs-less>

responsible individuals to act in an open and transparent way. The statutory guidance issued under section 29 of the 2016 Act⁹ sets out how the requirements may be complied with.

48. The statutory guidance sets out that providers should promote a culture of candour and must have policies and procedures in place to support a culture of openness and transparency, ensuring that staff are aware of them and follow them. The 2017 Regulations¹⁰ also include requirements which support the duty such as requiring providers of regulated services to ensure there are systems in place to:

- record incidents and complaints and concerns,
- keep records of incidents, complaints and concerns, and
- keep records of incidents that would be classed as harm events.

49. Additionally, the 2017 Regulations¹⁰ require the designated responsible individual for the service to make provision for the quality of care and support to be reviewed as often as required but at least every six months and to report to the service provider. This requirement supports a culture of continuous improvement and includes an analysis of the aggregated data on incidents, notifiable incidents, safeguarding matters, whistleblowing, concerns and complaints.

Why change is needed

50. In Wales, there have been calls to introduce a duty of candour^{15 16 17 18} at an organisational level on health care services, separate from and building on the non-statutory duties of candour that apply to a range of healthcare professionals as part of their professional regulation.

51. An independent investigation commissioned by the First Minister into the circumstances of the death of Robert Powell¹⁹, made a number of

¹⁵Kennedy, I and others. The Bristol Royal infirmary inquiry. Learning from Bristol - The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 [Internet]. Crown; 2001. Available from:

https://webarchive.nationalarchives.gov.uk/20090811143822/http://www.bristol-inquiry.org.uk/final_report/the_report.pdf

¹⁶Donaldson, L. Making Amends - A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS [Internet]. Department of Health Publications; 2003. Available from:

https://webarchive.nationalarchives.gov.uk/20120809195448/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4060945.pdf

¹⁷Francis, R and others. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry [Internet]. Staffordshire NHS Foundation Trust; 2013. Available from:

<https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry>

¹⁸4. Evans, K. "Using the Gift of Complaints" - A REVIEW OF CONCERNS (COMPLAINTS) HANDLING IN NHS WALES [Internet]. 2014. Available from:

<https://gweddill.gov.wales/docs/dhss/publications/140702complaintsen.pdf>

¹⁹Jones, N. THE ROBERT POWELL INVESTIGATION - A REPORT TO THE WELSH MINISTERS [Internet]. 2012. Available from:

recommendations relating to candour under the theme of "better communication and involvement with patients and their families" when things go wrong.

52. The Francis report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry¹⁷ included recommendations in support of an essential aim to ensure openness, transparency and candour throughout the health system about matters of concern. It was recommended that every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public. Organisational and personal interests must never be allowed to outweigh that duty to be honest, open and truthful.
53. The Inquiry recommended that where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or any lawfully entitled personal representative or other authorised person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information.
54. An independent review of the NHS Wales' Putting Things Right process²⁰, carried out by Mr. Keith Evans¹⁸, made a specific recommendation, recommendation 49, for a new "legal duty of candour". Additionally Ruth Marks' review of Healthcare Inspectorate Wales²¹ published in November 2014 also called for an explicit duty of candour to be introduced in Wales.
55. Finally, there have also been wider calls for a stronger legal duty of candour to be introduced for the NHS in Wales in light of such duties being introduced in other parts of the UK: for NHS England it is set out at Regulation 20 of the Health and Social Care Act 2008²² (Regulated Activities), Regulations 2014, and in Scotland, a duty of candour procedure is set out in Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016²³.
56. The 2016 Welsh Labour Manifesto²⁴ promised a consultation on a potential statutory duty of candour to further promote a culture of openness and

<https://webarchive.nationalarchives.gov.uk/20121105061144/http://wales.gov.uk/topics/health/publications/health/reports/powell/:jsessionid=7715EFC40A4DCD5B5DD28E35A550C584?status=gxbqamrvi&lang=en>

²⁰ Information about Putting Things Right [Internet]. Putting things right. 2018 [cited 4 April 2019]. Available from: <http://www.wales.nhs.uk/sites3/page.cfm?orgid=932&pid=50738>

²¹ Marks, R. An Independent Review of the work of Healthcare Inspectorate Wales. The way ahead: to become an inspection and improvement body [Internet]. 2014. Available from: http://www.powysthb.wales.nhs.uk/sitesplus/documents/1145/Board_Item_5.1a_Independent%20Review%20of%20HIW_Appendix%201_EXECUTIVE%20SUMMARY.pdf

²² The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (SI 2008/2936). Available from:

<https://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/20>

²³ **Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016**. London: HMSO

²⁴ Welsh Labour Party. Together for Wales - Welsh Labour Manifesto [Internet]. 2016. Available from:

transparency in our health and care system. This was delivered through the publication of the White Paper *Services Fit for the Future* in June 2017²⁵.

57. However, when considering the introduction of a new duty on health services, it is important to recognise that various steps have already been taken with the aim of developing a “culture of openness” in the NHS. These include the introduction of new arrangements for handling complaints in the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011²⁶, better reporting and investigation of serious incidents, reviews of all deaths in hospitals and the publication of Annual Quality Statements by LHBs, NHS Trusts and the Welsh Government. Additionally, as in England and Scotland, we have also sought to learn lessons from real cases where harm has been caused and from the recommendations of various reports and reviews.
58. It is therefore apparent that a great deal of work has been done to develop and support a culture of openness within the NHS in Wales. This work has placed health organisations in a favourable position to implement a more formal duty of candour, which is felt to be the next logical step in the series of measures already undertaken to improve quality and openness.

Policy Objectives

59. Inevitably in complex and multi-faceted services, sometimes things go wrong. When they do, the way in which organisations deal with these situations becomes very important and can make a huge difference to people’s experience and to their on-going relationship with their care provider. This is of vital importance in a health care setting where patients often have ongoing relationships with their health care providers. In general, patients and service users want to be told honestly what happened and be reassured that everything is being done to learn from what went wrong. Being defensive, “closing ranks” or trying to deflect the issue are the exact opposite to the behaviours expected.
60. Our policy objective is to ensure that whether a person receives care from the NHS, from a regulated provider of social care services or from a regulated independent health care provider, that person can be assured that should something go wrong with their care or treatment they will be dealt with in an open and honest way. The Bill provides the platform to achieve this for NHS bodies.

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

²⁵Services fit for the future [Internet]. Welsh Government services and information. 2017 [cited 2 April 2019]. Available from: <https://gov.wales/services-fit-future>

²⁶The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (SI 2011/704). Available from: <http://www.legislation.gov.uk/wsi/2011/704/contents/made>

Purpose of the Legislation

61. The primary purpose of the Bill's provisions is to help achieve a system wide approach to being open and honest when things go wrong. It will achieve this by requiring NHS bodies (as defined at paragraph 12) to follow a process when:
- i. a service user to whom health care is being or has been provided has suffered an adverse outcome; and
 - ii. the provision of health care was or may have been a factor in the service user suffering that outcome.
62. A service user is treated as having suffered an adverse outcome if the service user experiences, or if the circumstances are such that the service user could experience, any unexpected or unintended harm that is more than minimal. It is the intention to set out in statutory guidance what "more than minimal harm" means. It is intended to establish a working group, which will include clinicians, to develop the guidance so that it is clear to providers and service users what level of harm must be suffered before the duty of candour is triggered. The guidance will be developed having regard to existing definitions of harm, such as those used in the National Reporting and Learning System which is the existing system for reporting adverse patient safety incidents in the NHS. For the purpose of the duty of candour, harm includes psychological harm.
63. The duty is triggered where the provision of the health care was or may have been a factor in the service user suffering the outcome. The outcome must therefore relate to the provision of the care by the NHS body rather than being solely attributable to the person's illness or underlying condition. It need not, therefore, be certain that the health care caused the harm; it is sufficient that the health care may have been a factor. This means that the application of the duty does not indicate that the NHS body has acted negligently.
64. The provisions will place a duty on NHS bodies at an organisational level, and not onto individual health care staff.
65. The Bill provides the Welsh Ministers must set out in regulations the procedure that must be followed by a NHS body when the duty of candour is triggered. The procedure must contain the provision set out at section 4 of the Bill. The regulations will therefore include a duty upon the NHS body to:
- i. notify the service user (or someone acting on their behalf) as soon as they become aware the duty of candour has been triggered. The notification procedure will be detailed in the regulations;
 - ii. inform the service user (or a person acting on their behalf) of the person who has been nominated as the point of contact at the body for any queries the service user may have about the duty of candour procedure; and

- iii. provide information to the service user, or someone acting on the service user's behalf of any further enquiries to be carried out in relation to the circumstances that gave rise to the triggering of the duty;
 - iv. provide an apology;
 - v. keep records; and
 - vi. provide support, in accordance with the regulations, to the service user.
66. The Bill also provides for NHS bodies to report annually on whether the duty of candour has come into effect in relation to the body during the reporting year (each financial year). When reporting, NHS bodies will be required to specify if the duty of candour has come into effect in the reporting year and, if it has:
- i. how often the duty of candour has come into effect during the reporting year;
 - ii. give a brief description of the circumstances in which the duty came into effect; and
 - iii. specify any steps taken by the body with a view to preventing similar circumstances from arising in future.

But the report must not identify any person to whom health care is being or has been provided by or on behalf of the NHS body, or anyone acting on behalf of a person of that type.

67. Reports on candour must be published as soon as practicable after the end of the financial year. The Bill provides that primary care providers must send their candour reports to the LHB with whom they have entered into arrangements for the provision of NHS services. LHBs must publish a summary of those reports as part of the candour report on services they provide directly. Trusts and SHAs must also publish their reports.
68. Compliance with the duty will form part of the matters considered by Healthcare Inspectorate Wales when inspecting and reviewing the NHS. The annual reporting requirements will also provide information to the public and the Welsh Government about the duty which will help to make the process transparent.
69. Section 11(3) of the Bill defines what is meant by the term "NHS body". The duty will apply to the following NHS bodies in Wales:
- LHBs;
 - primary care providers (GPs, dentists, pharmacists and optometrists) in respect of the NHS services they provide under an arrangement with a LHB;
 - NHS Trusts; and
 - SHAs including (NHS Blood and Transplant in relation to the functions they exercise in relation to Wales).

70. Section 1 as read with section 11 of the Bill clarifies which organisation will be responsible for complying with the duty of candour in situations where services are provided by one body on behalf of another. In summary:

- (i) an NHS body (as defined in section 11(3) of the Bill) is responsible for complying with the duty of candour in relation to all health care which it actually provides. Therefore, for example, where a LHB enters into arrangements with a primary care provider for the provision of NHS services, it is the primary care provider that is subject to the duty. Similarly, if a LHB enters into arrangements with a Trust for the provision of services it is the Trust that is subject to the duty;
- (ii) if an NHS body (as defined in section 11(3)) enters into an arrangement for the provision of services with someone other than another NHS body, the duty to comply with the duty of candour rests with the NHS body. Therefore, for example, if a LHB entered into an arrangement with an independent provider for the provision of services, the duty would remain with the LHB.

The duty of candour only applies where the health care is delivered in Wales as part of an NHS service. If, for example, a LHB enters into arrangements with an English provider for the provision of health care services, it is the English duty of candour under the Health and Social Care Act 2008²² that will apply in relation to that care should anything go wrong.

It is intended that the duty applying to NHS organisations will be in line with arrangements planned for regulated independent healthcare via regulations to be made under powers contained in the Care Standards Act 2000²⁷ (“the 2000 Act”). There is also an existing duty requiring the providers of social care to be open and honest.

It is important to note the fact the duty of candour has come into effect does not mean that the care or treatment received by a service user has been negligent. In addition, section 2 of the Compensation Act 2006²⁸ makes clear that an apology, offer of treatment or other redress shall not of itself amount to an admission of negligence or breach of statutory duty.

How the legislation enables sectors to operate more efficiently

71. As discussed earlier, a duty of candour can result in better quality healthcare provision and service user experiences, which in turn impacts favourably on cost savings and efficiency^{13, 14, 29}. The evidence shows, being open and honest provides opportunities for both the reporting body and other providers

²⁷ **Care Standards Act 2000**. London: HMSO.

²⁸ **Compensation Act 2000**. London: HMSO

²⁹ Economics, F. Exploring the costs of unsafe care in the NHS. London: Department of Health; 2014.

to learn from what happened; contributes to generating the cumulative data required to drive improvement; and encourages decisions about services to be based on what matters most – the outcome for current and future patients.

72. Adopting a service wide approach that ensures NHS bodies, regulated social care providers and regulated providers of independent health services are subject to a duty of candour supports the move to an integrated approach to service delivery across health and social care. It will encourage the system to behave culturally as one, and will promote a culture of openness, and learning, increasing the trust of service users.
73. Specifically, the duty will support NHS bodies to build on the work that has already been started as part of the Putting Things Right²⁰ process to embed candid behaviour by making openness and transparency with people in relation to their care and treatment a normal part of the culture across these bodies in Wales.
74. Requiring bodies to report on an annual basis will make explicit the delivery of the duty by encouraging organisational reflection and learning; promoting a culture of openness and transparency in the system, which will in turn promote patient trust in the health service; and provide a baseline to help identify where services need support to improve with a view to avoiding future incidents.
75. Separately, in order to provide a system-wide approach, it is also our intention to place a duty of candour on regulated independent health providers. This will be done through provisions in regulations made under the 2000 Act²⁷ **Error! Bookmark not defined..**

Risk if legislation is not made

76. The main risk related to not imposing a duty of candour on NHS bodies in Wales is that this may operate to impede the disclosure of harm, as noted in the known barriers set out in the policy background.
77. For health providers, an approach which does not encourage openness and honesty (candour) may:
- lead to risk-averse decision-making with care and treatment;
 - create a tendency to classify events in ways which avoid the need for notification;
 - actively seek a policy or culture of secrecy;
 - create a culture of fear of action by the regulator or damaging public confidence in services;
 - lead to low staff engagement and retention;
 - lead to low public confidence in NHS healthcare services; and
 - lead to a missed opportunity to support continuous improvement in the provision of quality healthcare services.

78. Therefore, not imposing the duty risks instances of harm not being disclosed to anyone outside the body where the harm occurred, lessons not being learned, and the events which led to the incident occurring again in the same or a different setting.
79. Additionally, a further risk if the proposals are not taken forward is the continued disparity in the rights afforded to citizens accessing health and social care services in Wales when something goes wrong with their care or treatment.
80. Should the legislation not be made, an NHS Wales service user would not benefit from the duty of candour, which would put him or her at a material disadvantage to a user of regulated social care services in Wales should something go wrong with their treatment. NHS Wales service users would also have fewer rights when compared to a patient receiving NHS care in England or Scotland. Northern Ireland is currently undertaking a call for evidence on the introduction of a duty of candour.

CITIZEN VOICE BODY

Background

81. Setting out a pathway towards positive system change, 'A Healthier Wales'⁵ discusses the adoption of the Quadruple Aim, a key recommendation of the Parliamentary Review⁴ which is described as driving the development of many high performing international health and social care systems. One of the four strands, interpreted for our context in Wales, is enhancing engagement and shared-decision making with people to improve health and well-being outcomes.
82. There is a growing body of evidence that people should be at the heart of the health and care system, and that the starting point of any decision should be what is best for the person as a whole:

*Davies, 2012*³⁰, stated that:

"Analysing the real life experiences of people in your care helps to determine what individuals want and expect from their care. Patients are not outsiders to the healthcare system. In many ways, they are the only true 'insiders'. They are the ones who experience healthcare most personally – the reliability of the system and effectiveness of treatment can literally be a matter of life or death to a patient."

³⁰Davies, J. Person Driven Care - A study of The Esther Network in Sweden and the lessons that can be applied to enable NHS Wales to become a patient-centred healthcare system [Internet]. 1000 Lives; 2012. Available from: [http://www.1000livesplus.wales.nhs.uk/sitesplus/documents/1011/Person%20Driven%20Care%203%20May%20\(Final\).pdf](http://www.1000livesplus.wales.nhs.uk/sitesplus/documents/1011/Person%20Driven%20Care%203%20May%20(Final).pdf)

The Institute of Medicine³¹ includes ‘person-centred’ care as one of the six domains which constitute quality in healthcare”. Person-centred - care that is respectful of and responsive to individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions.”

‘*The Quality Improvement Guide*’, by 1000 Lives³², states that:

“Evidence shows that person-centred care can lead to improved quality, reduced waste, a better experience of care, and better use of resources.”

83. This supports the commitment made in *A Healthier Wales*⁵ to link health and social care services so they are designed and delivered around the needs and preferences of individuals.

Why Change is Needed

84. The Interim Parliamentary Review published in July 2017³³ reported the panel heard repeated calls for a better conversation with the public about their role in their own health and well being, their expectations of services, and the rights and responsibilities they will have in the future. It called for stronger arrangements for public engagement. It cited Community Health Councils (“CHCs”) in healthcare as an example of arrangements that could go further in terms of representing the public voice.
85. The Parliamentary Review was published in January 2018⁴. One of the key recommendations was for the seamless integration of health and social care services alongside more integrated citizen engagement. Under recommendation 4, “Put the People in Control”, the Review commented that there “needs to be a much stronger effort to find out what users think of the care that they have received, and the outcomes, and that this information is regularly incorporated into the management of care at a local and national level”.
86. The drive towards closer integration of health and social services with improved public engagement, is also reflected in the aims of *A Healthier Wales*⁵ which sets out the goal of ensuring citizens are placed at the heart of a whole system approach to health and social care services in Wales and stresses the importance of listening to all voices through a process of continuing engagement.

Current arrangements

³¹ Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Washington, D.C: National Academy Press; 2003.

³² 1000 lives. The Quality Improvement Guide - The Improving Quality Together Edition [Internet]. 1000 lives; 2013. Available from: <http://www.1000livesplus.wales.nhs.uk/sitesplus/documents/1011/Quality%20Improvement%20Guide%20-%203rd%20edition%20%28IQT%29%20WEB.pdf>

³³ Parliamentary Review representatives. Parliamentary Review of Health and Social Care in Wales - Interim Report [Internet]. 2017. Available from: <https://gov.wales/sites/default/files/publications/2017-07/170714-review-interim-report-en.pdf>

87. In relation to social services, the current arrangements/provisions of the 2014 Act² ensures that local authorities and health boards jointly assess the needs of the people in their area and set out in area plans how they will meet those needs. Regional Partnership Boards (“RPBs”) are responsible for taking forward this work and driving the integration of health and social care. There is also a requirement for citizen and carer representatives on each RPB. To support citizen engagement, citizen panels operate under the RPBs.
88. In relation to health, CHCs represent the patient voice in the health service in their local area. There are seven CHCs whose areas align with LHB boundaries. There is also a Board of CHCs in Wales that has a number of functions, including advising and assisting CHCs with respect to the performance of their functions and setting standards for CHCs. Although CHCs have undertaken valuable work since they were established, there are a number of significant drawbacks with the current CHC model.
89. Firstly, their functions are limited by the 2006 Act¹² to matters related to the NHS. Their principal function is “to represent the interests in the health service of the public in its district”. Regulations³⁴ confer additional functions on CHCs, such as scrutinising the operation of the health service in their district, providing complaints advice and assistance to adults who wish to make a complaint about NHS services and a power to enter and inspect premises where NHS services are provided. However, they are unable to represent the voice of citizens in relation to social services.
90. Secondly, CHCs are not established as legal bodies in their own right. They are “unincorporated associations”. Consequently, CHCs and the CHC Board are hosted by Powys Teaching Health Board which means all CHC staff are NHS employees and all contracts are entered into by the NHS on behalf of CHCs. They are also dependent on the Welsh Government to enter into arrangements for their accommodation. This means that complex accountability arrangements are currently needed in order to ensure the operational independence of CHCs.
91. When the CHCs were established, over 40 years ago, it was considered acceptable for them to be established as unincorporated associations; dependent upon a “host” body to be able to operate. However, given the desire to place the citizen voice in a more central role in decision making it is considered a body representing the interests of the public needs to be independent and should not be hosted by a NHS body (or any other public body) as the potential for conflicts of interest are too high. Consequently, when viewed in light of current expectations it is considered an unincorporated association model is no longer appropriate.

³⁴ The Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010 (SI 2010/28 (W.37), as amended by SI 2015/509 (W.). Available from: <http://www.legislation.gov.uk/wsi/2015/509/made>

Review of current arrangements

92. There have been a number of reports and reviews into CHCs and how best the citizen voice may be represented more widely in Wales in relation to health. The reports contain recommendations which are equally applicable to representing the citizen voice in social services. We have taken the recommendations in these various reports and reviews into consideration when considering the functions that the Citizen Voice Body should exercise, and briefly summarise the key recommendations below.
93. Commissioned by the Welsh Government, the Longley Review³⁵ evaluated CHCs following reforms that had been made in 2010. The Review made a number of recommendations for short, medium and long term improvements. It identified areas of strength, such as independent complaints advocacy services and effective relationships between CHCs and health bodies, and areas of “persistent weaknesses”; namely consistency of performance across individual CHCs, diversity of membership, public knowledge and understanding of CHCs.
94. The Review also recognised that CHCs had then been in existence, in their current format, for almost 40 years and that in order to deliver a truly “world class” service more fundamental reform of the role and functions of CHCs might be required. It set out some potential options for wider reform, which included establishing one national CHC for Wales with local committees to represent the citizen voice at a local level. This is similar, in terms of proposed structure, to the proposal in the Bill for a national Citizen Voice Body with a local presence.
95. Following the *Longley Review*, Ruth Marks MBE carried out a review of Healthcare Inspectorate Wales (“HIW”) in 2014²¹. Whilst primarily focusing on HIW, the review considered the role and functions of CHCs. It acknowledged their importance in promoting and protecting the interests of patients and in providing advocacy services to patients who wished to complain about NHS services. However, it also acknowledged that CHCs needed to have a higher public profile “*as too many people do not know of their existence*”, and needed to “*offer much more advice and support to people who have concerns and wish to make complaints about their health care*”.
96. More recently, the OECD review of 2016¹¹ considered the role and functions performed by CHCs in Wales. They confirmed that CHCs should focus their activities on representing the patient voice. They concluded that the potential for CHCs to engage with local communities and advocate for patients around their concerns was key, but “*the value added by some of the CHCs*

³⁵ Longley, M and others. MOVING TOWARDS WORLD CLASS? A Review of Community Health Councils in Wales [Internet]. 2012. Available from: http://wihsc.southwales.ac.uk/media/files/documents/2012-10-24/Review_of_CHCs_-_Final_report.pdf

other functions, notably inspections and on-site scrutiny of health care was less clear”.

The Report indicated CHCs would be more effective and efficient if they were to focus their activities on reflecting the patient voice and engaging with other scrutiny bodies in Wales, notably HIW, to make sure that patient concerns are heard and followed through.

97. The legal framework establishing the CHCs limits their functions to health rather than health and social services and the absence of a national body has placed restrictions on their ability to work effectively across LHB boundaries. While some changes could be made to the current structures, or a new body created to mirror the CHCs functions in social services, this would not deliver an integrated approach across the system.
98. Our review of the literature summarised above and the recommendations of the *Parliamentary Review*⁴ and *A Healthier Wales*⁵, clearly demonstrates there is widespread agreement as to the value and necessity of both (1) strengthening the citizen voice in modern social services and health care systems; and (2) closer integration of the two systems. We consider the optimum vehicle for delivering this strengthened, more integrated, citizen voice, is an independent national body, with a strong local network informing it and an efficient, effective IT infrastructure which will facilitate extending the reach of the body to the largest possible number of citizens.

Policy Objectives

99. Strengthening the voice of the citizen helps to deliver on our vision for ‘A Healthier Wales’⁵ where the voices of citizens are continuously engaged and listened to.
100. The policy aims are therefore to:
- a. strengthen the citizen voice in Wales in matters related to both health and social services, ensuring that citizens have an effective mechanism for ensuring that their views on, for example, their need for and experience of these services is heard;
 - b. ensure the body has a higher public profile than the current CHCs and has the IT infrastructure that will enable it to reach far larger numbers of citizens to obtain information from all sectors of Welsh society to ensure it captures a truly representative citizen voice;
 - c. ensure that individuals are supported with advice and assistance when bringing forward a complaint in relation to their care; and
 - d. create synergy across the health and social services system in using the service user experience to drive forward improvement.
101. To achieve this objective, Wales needs a body that is able to effectively represent the views of individual citizens and demographic groups both at a

local and national level, engaging with LHBs, Trusts, SHAs, local authorities, RPBs, Public Service Boards³⁶, Social Care Wales³⁷ and other bodies, such as the inspectorates^{38, 39, 40}, who are responsible for delivering and improving health and social services.

102. It is considered that, when gathering information about the user experience, the new body may uncover information that it is relevant for the inspectorates to consider. Similarly, the inspectorates may discover information or hear views from service users during the course of inspections that may be of interest to the body and inform their programme of work. In particular, it is considered that the new body could have a role in gathering key, systematic data for the user experience framework and this could also possibly inform reviews by the inspectorates.
103. This body will have to use the full suite of engagement tools that will be at its disposal to ensure that it reaches large numbers of people to seek their views about health and social services matters. These tools could include online tools such as polls and consultations; engaging with the large number of third sector organisations that also have interests in this area and face to face meetings with citizens. It will also need to be responsive to the future needs of the population and the changing face of health and social services. In the same way that quality cannot be defined by existing services, the representation offered by this body cannot be tied to a set geographic footprint or rigid organisational structure. It must be able to work effectively across sectors, settings and health board and local authority areas; enabling it to maintain accessibility at the local level, whilst retaining the ability to respond to local and regional needs, and have real influence on national policy.

Purpose of the Legislation

104. The Bill's provisions establish the Citizen Voice Body for Health and Social Care, which will:
- a. establish a single, independent body representing the interests of the public in health and social services which reflects the inter-dependency of these services. CHCs deal with health only. The need for this was recognised in the Longley Review³⁵ and the Parliamentary Review⁴;

³⁶ Public Services Boards [Internet]. Gov.Wales Welsh Government services and information. 2019 [cited 2 April 2019]. Available from: <https://gov.wales/public-services-boards>

³⁷ About [Internet]. Social Care Wales. 2019 [cited 2 April 2019]. Available from: <https://socialcare.wales/about>

³⁸ 6. About us [Internet]. Care Inspectorate Wales. 2019 [cited 2 April 2019]. Available from: <https://careinspectorate.wales/about-us>

³⁹ About us [Internet]. Healthcare Inspectorate Wales. 2019 [cited 2 April 2019]. Available from: <http://hiw.org.uk/about/?lang=en>

⁴⁰ About Us [Internet]. Health Education and Improvement Wales. 2019 [cited 2 April 2019]. Available from: <https://heiw.nhs.wales/about-us1/about-us/?CFID=8b709f4b-fbd2-415f-9308-ed2e67f8090c&CFTOKEN=0>

- b. have the ability to provide complaints advice and assistance in relation to NHS complaints and complaints relating to social services where services are not already in place;
- c. be a single corporate body. This will ensure consistency in the arrangements and services provided across Wales; give more central control than that of the current CHC Board; facilitate cross-boundary working; and, unlike CHC's, enable the Body to employ staff and enter into contracts which will give it more independence and remove some of the practical complexities that currently exist; and
- d. have "teeth" so that public bodies responsible for providing and securing the provision of health and social services have a duty to have regard to representations made by the Body.

105. The Bill will achieve these changes by abolishing CHCs, established under section 182 of the 2006 Act¹², and the Board of CHCs, established under paragraph 4 of Schedule 10 of that Act.

106. The Bill establishes the Body which will exercise the following functions:

- a. to represent the interests of the public in respect of health services and social services by seeking the views of the public about these services. Health services is broadly defined as services provided under or by virtue of the 2006 Act¹² for or in connection with (i) the prevention, diagnosis or treatment of illness or (ii) the promotion and protection of public health. Social services are similarly broadly defined by reference to local authorities' social services functions as set out in section 143 of the 2014 Act².
- b. to promote public awareness of its functions, publish a statement of policy setting out how it proposes to do this and how it intends to seek the views of members of the public. This will facilitate greater engagement of the public with the Body. In order to represent the interests of the public it will be essential the Body has a strategy to maximise its engagement with members of the public, using all resources that are available to it. It is our hope that this will enable the Body to reach large numbers of the public with online polls, discussion groups and consultations. This is seen as key to enabling the Body to reach greater numbers and more diverse groups of people. The Body will need to engage not only with current service users, but past users, prospective service users, family members of service users etc. in order to ensure that when they seek views they are as representative as possible.
- c. to make representations to LHBs, Trusts, Welsh SHAs and LAs about any matter it considers is relevant to the provision of health services or social services. This is a very broad power and means, for example, the Body could make representations to LHBs and Trusts about matters relating to changes in NHS services and could also make

representations to local authorities in relation to proposed change in social services. It could also make representations relating to service users' experience of health or social services generally or about service users' experience of particular health or social services or aspects of such services.

- d. the power to provide advice and assistance with complaints relating to health and social services. The Citizen Voice Body will be able to provide assistance to such extent as it considers necessary to meet reasonable requirements to individuals making or intending to make the following kinds of complaint:
 - i. NHS complaints – the Body will provide advice and assistance in respect of complaints made under an NHS complaints procedure..
 - ii. social services complaints – the Body will provide assistance with a complaint to a local authority about social services provided or arranged by the local authority (apart from a group of complaints made by children and young persons where local authorities are already under a duty to arrange assistance (see further information below);
 - iii. complaints to a regulated social care provider⁴¹; this enables the Citizen Voice Body to assist persons who wish to make a complaint directly to a provider of a regulated service as defined in section 2 of the 2016 Act⁹. Currently, this means the Body could assist with a complaint made directly to a care home, a provider of secure accommodation, a residential family service centre, an adoption service, a fostering service, an adult placement service, an advocacy service or a domiciliary support service (as defined in Schedule 1 and in regulations made under *section 2 of the 2016 Act*⁹).
 - iv. complaints to the Public Services Ombudsman for Wales about health services, social services, care home providers or domiciliary care providers.

107. The Body will not provide complaints advice and assistance to children and young people in relation to social services complaints as they have existing statutory rights to assistance from the local authority under the 2014 Act.² It is not, therefore, intended to duplicate the provision already provided by local authorities.

108. Both the Longley and Marks Reviews noted there was a lack of awareness amongst the public of the role of the CHCs. This is a serious impediment to the Body's principal function of gathering the views of citizens. As set out above, in order to resolve this issue, the Bill places the Body under a duty

⁴¹ Within the meaning of section 2 of the Regulation and Inspection of Social Care (Wales) Act 2016

to promote awareness of its functions and prepare and publish a statement of policy setting out how it proposes to promote awareness of its functions and how it will seek the views of the public. The Body will be able to use all modern methods of engagement, in particular online tools such as online consultations, polls, discussion groups and deliberative polling. Alongside more traditional engagement methods such as face to face meetings and cross-sector working this should ensure the Body reaches citizens in far greater numbers, which is a key goal of these reforms, to maximise the authenticity of the citizen voice.

109. The Bill places a duty on LHBs, Trusts, Welsh SHAs and LAs to have regard to representations that are made to them by the Citizen Voice Body about health and social services matters, respectively. This means that when exercising a function to which the representation relates the Body must take the representations into account and be able to demonstrate it has done so.
110. LHBs, Trusts, Welsh SHAs and local authorities are under a duty to promote the work of the Body to persons who use services that are provided by them or on their behalf. This means, for example, that a LHB would be under a duty to promote the activities of the Body to persons to whom it directly provides services, for example in a secondary care setting, and also to users of primary care services that it arranges with GPs, dentists, pharmacists and opticians. This is essential in order to help to raise the awareness of the Body and the functions that it performs amongst members of the public. This again will help to address criticisms that have been levelled at CHCs for not having a high enough public profile.
111. LHBs, Trusts, Welsh SHAs and LAs are also under a duty to provide the Body with any information it may reasonably require to enable it to carry out its functions. This means, for example, that where changes in health services are proposed, the Body would be able to request information relating to the planning and operation of services and proposals for change. However, LHBs, Trusts, Welsh SHAs and LAs cannot be required to disclose information if doing so would be unlawful.
112. Paragraph 11 of Schedule 1 to the Bill permits the Body to “do anything which is calculated to facilitate, or which is conducive or incidental to, the exercise of its functions”. This enables the Body to recruit volunteer members to assist it in the performance of its functions, outside of the public appointments process. It is envisaged that empowering the Body to recruit its own volunteers will result in a more diverse and sustainable volunteer base to assist the Body in the performance of its functions.
113. The Body will be a body corporate with the ability to recruit and employ staff and enter into contracts for accommodation and services. The Board will have a chair and at least 7 but no more than 9 members who will be appointed by the Welsh Ministers. It will receive its funding from the Welsh Ministers and so will be a Welsh Government Sponsored Body (the same model of establishment as, for example, Social Care Wales³⁷). This is a

positive move away from the current unincorporated association model used to establish the CHCs and will mean that the complex accountability arrangements that are currently required to ensure the operational independence of the CHCs will not be required for the new Body.

114. The Bill establishes the Body as a national body. It may establish committees and sub committees but the Bill does not prescribe a local or regional structure. It will be for the Body to determine the structure that it will need to enable it to perform its functions on a national, regional and local basis. It is anticipated that to do this it will, in all likelihood, align along Regional Partnership Board lines.

How the legislation enables sectors to operate more efficiently

115. Establishing a new independent Citizen Voice Body covering both health and social services means that a cohesive approach to representing the citizen voice across health and social services can be adopted which is consistent with the recommendations arising out of the *Parliamentary Review*⁴ and our vision for more integrated health and social care services articulated in *A Healthier Wales*⁵.
116. The new body will have the ability to provide the citizens' perspective to discussions and decisions made by public bodies in relation to health and social services allowing for informed decision making. It is anticipated that service user feedback will be positively received by LHBs, Trusts, Welsh SHAs and LAs and used to improve the services provided to the citizen. The value of citizen engagement is recognised by all Welsh public bodies, and all of the literature reviewed at paragraphs 92 to 98 recognises its importance.
117. It is also anticipated that the Body will engage with other groups, organisations and bodies that have an interest in the views of citizens in relation to health and social services matters. In particular there would seem to be a clear link between the work of the Body and the citizen panels established by RPBs and third sector organisations that have an interest in health and social services that are delivered to people in Wales.
118. The creation of the new Body has also provided an opportunity to consider whether there is any duplication of functions inherent in the current arrangements. CHCs currently have the power to "inspect" premises where NHS care is provided. This power pre-dates the creation of HIW.
119. The Body will not have the power of inspection as it is generally agreed that the inspection of service provision should rest with HIW (in relation to health services) and Care Inspectorate Wales³⁸ ("CIW") in relation to social care services. Both are professional inspectorates whose inspectors and associated staff are trained to undertake the role and have the relevant professional qualifications where appropriate.
120. This approach, with clearly defined functions between these bodies means that the Body is free to concentrate on its core function of representing the views of the public in health and social services matters. It also accords with the view expressed in the OECD Review that the value added by the CHC inspection function was unclear.
121. We anticipate that the Body will enter into MOUs with HIW and CIW which will describe how they will work together. Even though these bodies exercise different functions, their functions are, in many ways, complementary and there will be many instances where it will be beneficial for them to work together and to share information. For example, the Body may repeatedly hear from service users that there are shortcomings in

treatment on a particular ward, this is information that the Body may wish to share with HIW (to inform its programme of inspection) as well as with the organisation concerned.

122. The Citizen Voice Body will also have the ability to represent persons who wish to bring a complaint about NHS services and social services (with the exception of children who have existing statutory rights under the 2014 Act²). Enabling the Body to deal with complaints about both health and social services is beneficial to the individual making it easier to navigate the complaints' system, improving their experience and delivering organisational efficiencies.
123. As a consequence, the legislation will strengthen the current arrangements for obtaining the views of the citizen in relation to health and social services for the benefit of people in Wales by ensuring a whole system approach; creating harmonisation and coherence across the health and social services system.

Risk if legislation is not made

124. The CHCs were established to function as part of the health service as it existed more than 40 years ago. The health and social services system has changed and continues to change. If the legislation to replace the CHCs with a new body is not delivered, the functions of the CHCs and the CHC Board will continue to reflect an outdated model of the health service and become increasingly less effective and sustainable. The literature referenced above has made it clear that there are shortcomings in the existing CHC model, consequently it is considered that replacing it with a new Body that can exercise functions across health and social care is essential.
125. Unless the legislation is brought forward, CHCs will continue to be restricted to exercising functions in relation to health services. An opportunity will be lost to create a new body which can exercise functions across health and social services which reflects the direction of travel for more closely integrated health and social services. The current status of CHCs as an organisation that has to be "hosted" by an NHS body, unable to employ staff or enter into contracts in its own right, would also continue. This is considered to be undesirable in policy terms as it a body that represents the voice of patients should not continue to be hosted by a NHS body. The creation of the new Citizen Voice Body as a corporate entity will allow it to adapt the way it recruits volunteer members. Without this change, the opportunity to strengthen the sustainability and diversity of the volunteer membership will be lost.
126. As the health and social care services continue to evolve into person centred seamless services, key decisions will need to be made locally, regionally and nationally which will set the course for the next 40 years. Failing to properly empower the citizen to influence this direction of travel will risk decisions being made for the wrong reasons; decisions being made

which harm the health and well-being of groups of the population and decisions being made which focus on the wrong outcome measures because the decision makers did not have an effective mechanism to ask the citizen what outcomes mattered to them. The risk is that we would, therefore, fail to meet the ambitions set out in A Healthier Wales⁵ on patient voice, as highlighted in paragraph 99.

VICE CHAIRS OF NHS TRUST

Background

127. At present the constitutional and membership arrangements provided for in relation to Trusts and LHBs are not consistent and this has potential to hamper efforts to embed consistent approaches to leadership, quality, and governance.
128. In relation to LHBs, Schedule 2 to the 2006 Act¹² provides that Vice Chairs can be appointed to the Board where the Welsh Ministers consider it appropriate. Model Standing Orders refer⁴² to the role of Vice Chairs and set out a corporate role across the breadth of the Board's responsibilities (Section B1.1.6 and 1.4.7) and a specific brief for oversight and scrutiny of the LHB's performance in the planning, delivery and evaluation of primary care, community health and mental health services (Section 1.4.9).
129. In relation to NHS Trusts however, there is no equivalent power for the Welsh Ministers to appoint a Vice Chair. The same arrangements exist across all three NHS Trusts in Wales.
130. There is, however, nothing in law to prevent a NHS Trust from appointing a Vice Chair from amongst its statutory membership although this role would be in addition to the original appointment.

Why Change is needed

131. In recent years, the role and function of the Vice Chair has been viewed by Trust Boards and the Welsh Ministers as a valuable role and a necessary requirement for NHS Trusts. Changes in the external environment mean that Vice Chairs are being called on routinely to participate in collaborative and partnership based activities on an all-Wales basis. This was highlighted by the service responses received at Green Paper⁴³ and White Paper consultations²⁵. The Vice Chairs are also being asked more often to deputise for the Chair, whose role has similarly expanded, as the Trusts

⁴²Welsh Government. Model Standing Orders: Reservation and Delegation of Powers for Local Health Boards. [Internet]. Welsh Government; 2014. Available from: <http://www.wales.nhs.uk/sitesplus/documents/1064/LHB%20Model%20Standing%20Orders%20Reservation%20and%20Delegation%20of%20Powers%20%28March%202014%29.pdf>

⁴³Welsh Government. Green Paper: Our Health, Our Health Service [Internet]. Welsh Government; 2015. Available from: <https://gov.wales/green-paper-our-health-our-health-service>

have become more integrated within the wider NHS. Therefore, provision to enable the statutory appointment of a Vice Chair to ensure continuity of service and consistency across all NHS Wales organisations would be welcomed.

Policy Objectives

132. The policy seeks to improve the quality and governance arrangements within NHS Trusts by introducing a formal Vice Chair role for each Trust. This will standardise and clarify the roles and responsibilities of Chair and Vice Chair arrangements throughout Wales; strengthening leadership and therefore continuing a commitment to improvement in quality service standards and patient experience.

Purpose of the Legislation

133. The purpose of the Bill's provisions is to ensure consistency and continuity of quality services across all NHS Wales LHBs and Trusts by ensuring each Chair is supported in their role by a Vice Chair.
134. To achieve this, the Bill proposes to amend Part 1 of Schedule 3 of the 2006 Act¹² to provide that the Welsh Ministers may appoint a vice chairs to an NHS Trust, thereby ensuring consistency with LHBs in relation to that role.

How the legislation enables sectors to operate more efficiently

135. Vice Chairs will give NHS Trust boards the ability to operate more effectively, efficiently and consistently throughout Wales. The Vice Chair will share responsibilities with the Chairs. This clarity will improve the governance arrangements for Trusts, leading to efficiencies in leadership which will cascade throughout the Trusts' structures, and impact positively on service quality standards and improve patient experience.

Risk if legislation is not made

136. Trusts are currently attempting to appoint a Vice Chair, but whilst working within the existing statutory framework this creates inequities, including an increase in time commitments for those taking on the role, with local approaches developing regarding remuneration for that additional responsibility and time commitment. By providing for a specific Vice Chair statutory role, these inequities can be removed.
137. Additionally, creating a position which requires a greater time commitment may widen the application pool and draw interest from candidates with a different and more appropriate skill set. The current method is reliant on the existing Independent Members having:

- a) the available time to fulfil the role; and
- b) the appropriate skills to operate at the level of a Vice Chair and deputy to the Chair.

By doing nothing these inequities would continue and may hold potential for negatively impacting on the individual undertaking the role and restrict their ability to undertake the role to its full potential.

Implementation and Delivery

Improving outcomes for disadvantaged or excluded sections of society

138. The Equality Act (2010)⁴⁴ requires public organisations and bodies to actively consider the impact of the decisions they make on the need to eliminate discrimination and advance equality of opportunity. It also requires LHBs, Trusts and local authorities to consider how they can positively contribute to a fairer society through promoting equality in their day to day activities.
139. The purpose of the four areas of the Bill (introducing a Duty of Candour, Duty of Quality, the creation of a Citizen Voice Body and a statutory power for the Welsh Ministers to appoint Vice-Chairs for NHS Trusts) is to ensure that providers of health and social services in Wales deliver a constantly improving high quality of care, honest and learning when something goes wrong, which is responsive to the needs of the whole population of Wales and open and based on robust quality and governance arrangements within NHS Trusts.

Quality

140. By applying “quality” as a system wide principle, the Bill requires organisations to actively consider how the quality of service provision can be improved whenever they act or make a decision. Making this consideration mandatory will improve the decision making processes of bodies, which will improve the quality of services across Wales, and result in the improvement of quality outcomes for all sections of society.

Candour

141. The Bill will introduce a duty of candour, at an organisational level, on NHS bodies in Wales. The duty will complement the existing duty of candour that already applies to providers of regulated social care services and the duty that we intend to impose on regulated independent health care providers in regulations made under the 2000 Act²⁷. Ensuring a duty of candour applies across all NHS bodies, regulated social care providers and regulated

⁴⁴ **Equality Act** 2010. London: HMSO

providers of independent health care services will make it easier for disadvantaged or excluded sections of society to know what rights they have when something goes wrong.

- 142. Requiring health and social care providers to proactively inform patients and families when something has gone wrong will also help improve the relationship between the patient and the professional, leading to maintained trust in the services.
- 143. This will contribute to a system wide approach to candour for all sections of society.

Citizen Voice

- 144. The new body will have the overarching function of representing the interests of all people to whom health and social services are being or may be provided locally, regionally and/or nationally across Wales.
- 145. The body will be able to directly recruit volunteers and our expectation is that it would actively seek to encourage volunteers from all sectors of society to contribute to a diverse volunteer base that is representative of the users of health and social care services in Wales.
- 146. A move away from the rigid membership structure of CHCs based largely around the public appointments process offers an opportunity to involve people in the work of the body who might have found such a lengthy and formal application process off putting. Allowing direct recruitment of volunteers will encourage the growth of a more diverse volunteer base. The body will also have an active role in providing complaints advice and assistance to those who wish to make a complaint about NHS or social services they have received including those who might otherwise struggle to raise a complaint effectively.
- 147. The body will have the power to make representations to LHBs, Trusts, Welsh SHAs and LAs about matters connected to health services and social services with the goal of improving the health and well-being of the population which will help ensure those outcomes which are most important for the population are brought to the attention of the bodies responsible for the delivery of our health and social services.

Vice Chair

- 148. A Vice Chair will provide further leadership capacity to support and contribute to the wider board's approach to equality and improving outcomes for disadvantaged or excluded sections of society.

4. Consultation

149. The Welsh Government's proposals for the Health and Social Care (Quality and Engagement) (Wales) Bill were first consulted on as part of the Green Paper: Our Health, Our Health Service⁴³, between July and November 2015. The Green Paper explored whether legislation could help efforts to further improve the health service in Wales. To do this, the paper asked people to share their views on a number of topical issues which relate to the quality of health services and its governance and functions, including:

- how services work together to meet the local population's needs, and how the public can become involved more effectively in planning NHS services and how changes in services should be taken forward;
- how quality is the first priority for everyone working in the NHS, and how quality should be reflected in the way services are planned as well as delivered;
- the use of common standards, across all healthcare service providers, including NHS, independent and voluntary sectors;
- how to improve transparency and honesty about performance in the Welsh NHS, including how concerns are handled, the importance of being open and honest when things go wrong and could there be improvements in the joint investigation of complaints across health and social care;
- how the NHS can share patient information more effectively, to provide joined-up services and the best quality of care for individuals; and
- the arrangements in place for external assurance of health services, including a single inspectorate for health and social care. It also considers whether CHCs need to change to more effectively represent patients and the public.

150. Overall, 170 written responses to the Green Paper were received⁴³. A report summarising the outcome of the consultation was published in February 2016⁴⁵.

151. After reflecting on the responses, the Government identified a number of proposals to be included in the White Paper: Services Fit for the Future, Quality and Governance in Health and Care in Wales, which was published for consultation between 28 June and 29 September 2017. A consultation

⁴⁵ Welsh Government. Consultation – summary of responses - Our Health, Our Health Services Green Paper [Internet]. Welsh Government; 2016. Available from: <https://gov.wales/sites/default/files/consultations/2018-01/160222greenpapersummaryresponsesen.pdf>

summary report was published in February 2018⁴⁶.

152. At the time of consultation, the Welsh Government were seeking views to determine if legislation was required in several distinct areas, including:

- Board Membership and Composition;
- Board Secretaries;
- Duty of Quality;
- Duty of Candour;
- Setting and Meeting Common Standards;
- Joint Investigation of Health and Social Care Complaints;
- Representing the Citizen in Health and Social Care;
- Co-producing Plans and Services with Citizens; and
- Inspection and Regulation.

153. A total of 336 responses to the White Paper were received²⁵. During the consultation, the CHCs issued their own proforma relating to the citizen voice proposals. The Welsh Government received 1328 of these completed proforma responses, signed by members of the public, and these were considered as part of the analysis of the consultation responses.

154. Additionally, the Welsh Government presented at a number of stakeholder meetings before and during the consultation period, and held a number of events between 18 and 28 September at various venues across Wales which attracted approximately 100 people in total. These events were attended by a number of groups who are traditionally under-represented in consultations including people with learning disabilities and their carers, young people, older people, and BAME participants.

155. The analysis of the responses indicated joint working between organisations was considered essential in order to promote well-being, to identify people's needs, and when planning and providing quality services to a robust and consistent standard. Detailed analysis indicated responses to the Duty of Candour, Duty of Quality and NHS Vice chairs were generally in favour of the proposals. However, many responses for the citizen voice body proposals were multi-thematic, even within the single topic of the need for citizen voice representation, and did not always deliver a consistent message.

156. In the area of co-producing plans and services with citizens and joint investigation of health and social care complaints, further work has determined that proposals can be delivered under existing powers. However due to the complexity of the issues around inspection and regulation, further work is required before legislative proposals can be developed. It is

⁴⁶ Welsh Government. Consultation – summary of responses - Services Fit for the Future [Internet]. Welsh Government; 2018. Available from: <https://gov.wales/sites/default/files/consultations/2018-02/180226summary-of-responses.pdf>

therefore expected that a future Bill will be introduced to address these issues.

157. Before introducing the current Bill into the National Assembly for Wales, the Welsh Government has engaged with a range of stakeholders to explain the proposals in more detail, to hear the views of those most likely to be impacted by the changes and to understand the impacts.
158. Due to the extensive consultation already undertaken in relation to the proposals in the Bill, including through the White Paper²⁵ and various stakeholder engagement sessions, no additional consultation on a draft Bill has been undertaken in advance of introduction to the National Assembly for Wales.

5. Power to make subordinate legislation

159. The Bill contains provisions to make subordinate legislation and issue determinations. Table 5.1 (subordinate legislation) and Table 5.2 (directions, codes and guidance) set out in relation to these:

- (i) the person upon whom, or the body upon which, the power is conferred;
- (ii) the form in which the power is to be exercised;
- (iii) the appropriateness of the delegated power; and
- (iv) the applied procedure; that is, whether it is “affirmative”, “negative”, or “no procedure”, together with reasons why it is considered appropriate.

160. The Welsh Government will consult on the content of the subordinate legislation where it is considered appropriate to do so. The precise nature of consultation will be decided when the proposals have been formalised.

Table 5.1: Summary of powers to make subordinate legislation in the provisions of the Health and Social Care (Quality and Engagement) (Wales) Bill

Section	Power conferred on	Form	Appropriateness of delegated power	Procedure	Reason for procedure
4	the Welsh Ministers	Regulations	The detail of the procedure is suitable for regulations as this will enable the candour procedure to be kept in line with the procedure relating to complaints which is set out in	Negative	The regulations will set out a technical procedure to be followed.

Section	Power conferred on	Form	Appropriateness of delegated power	Procedure	Reason for procedure
			regulations (the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 – it is intended that the candour procedure and the complaints procedure work together so that there is no duplication. Putting the detail of the procedure in regulations means that primary legislation would not required should the procedure need to be amended in future to take account of this. Placing the procedure in regulations will also ensure that the procedure can be reviewed and changed in light of experience and feedback from stakeholders if necessary.		
26	the Welsh Ministers	Regulations	Appropriate for regulations to ensure that where amendments to other legislation are found to be necessary, to give full effect to this Bill, further primary legislation is not required.	Affirmative	Regulations could potentially amend primary legislation.
27	the Welsh Ministers	Order	Suitable for commencement by order as coming into force needs to be timed to ensure delivery arrangements are in place.	Negative	This is a commencement order to set a coming into force date for provisions already agreed in the Bill.

Table 5.2: Summary of powers to make directions and to issue codes and guidance in the provisions of the Health and Social Care (Quality and Engagement) (Wales) Bill

Section	Power conferred on	Form	Appropriateness of delegated power	Procedure	Reason for procedure
10	the Welsh Ministers	Statutory guidance	Suitable for guidance as arrangements need to be flexible to respond to future changes in professional practice.	No procedure	

PART 2 – REGULATORY IMPACT ASSESSMENT

6. Regulatory Impact Assessment (RIA) summary

161. A Regulatory Impact Assessment has been completed for the Bill and it follows below.
162. There are no specific provisions in the Bill which charge expenditure on the Welsh Consolidated Fund.
163. The following table presents a summary of the costs and benefits for the Bill as a whole. The table has been designed to present the information required under Standing Order 26.6 (viii) and (ix).

<i>Health and Social Care (Quality and Engagement) (Wales) Bill</i>		
Preferred option: The preferred option is to introduce a Bill that creates new duties of quality (page 67) and candour (page 89), replaces CHCs with a new Citizen Voice Body (page 112), and creates a power for a statutory position of Vice Chair for NHS Trusts (page 117).		
Stage: Introduction	Appraisal period: 2020-21 to 2025-26	Price base year: 2019/20
Total Cost Total: £11,001,500 - £11,467,700 Present value: £10,182,100 - £10,596,100	Total Benefits 0 Total: £0 Present value: £0	Net Present Value (NPV): £-10,182,100 - £-10,596,100

Administrative cost

Costs: Across the Bill's various provisions, there are a number of administrative costs for the Welsh Government, in relation to the duties of quality and candour these relate to the development and publication of guidance, awareness material and training across those duties. There are also opportunity costs for the NHS in releasing staff for training. There are ongoing administrative and operational costs associated with running the new Citizen Voice Body, as well as significant transitional costs relating to establishing the new body. These costs are contained within Tables 1-10, 14-24, 34, 38 and 42.

Transitional: £7,315,500	Recurrent: £3,228,700 - £3,694,900	Total: £10,544,200 - 11,010,400	PV: £9,775,100 - £10,189,100
<p>Cost-savings: A key area of cost-savings estimated in the RIAs relates to the abolition of the CHCs. Additionally, evidence shows poor quality health care services are more expensive, therefore the duty of quality and the duty of candour will help bodies improve quality via learning and improvement. Additionally, being open, which is associated by introducing the duty of candour, may result in savings as litigation against incidents that result in harm may be further avoided. These cost savings have not been quantified and are therefore unknown. The quantified cost-savings relate to LAs and voluntary organisations no longer having to appoint CHC volunteer members.</p>			
Transitional: £0	Recurrent: £27,500	Total: £27,500	PV: £23,800
Net administrative cost: £10,516,700 – 10,982,900			

Compliance costs

Compliance costs with the Bill will fall to NHS bodies in the form of opportunity costs to comply with the duty of candour. There is an opportunity cost for NHS bodies to notify the service user (or someone acting on their behalf) as soon as they become aware the duty of candour has been triggered. Compliance costs associated with reporting on the duties of quality and candour are deemed cost neutral. These costs are contained within Tables 23 and 24.

Transitional: £0	Recurrent: £484,800	Total: £484,800	PV: £430,800
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Other costs

The costs identified in the RIAs all fall into the category of either administrative or compliance costs – outlined above.

Transitional: £0	Recurrent: £0	Total: £0	PV: £0
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Unquantified costs and disbenefits

There are unquantifiable opportunity costs related to potential judicial reviews associated with the duty of quality (paragraph 218), the potential support primary care providers may require from an LHB (paragraphs 320-321), and to local authorities responding to representations from the new Citizen Voice Body (paragraphs 413-416) .

Benefits

The Bill is expected to lead to a range of benefits, although these cannot be quantified due to a high degree of variability or a lack of available data. For example, there will be benefits from improving quality and having a stronger citizen voice across health and social care.

Total: £0

PV: £0

Key evidence, assumptions and uncertainties

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

7. Options

164. The assessment of costs and benefits is centred on the six year period 2020-21 to 2025-26. If passed the Bill is expected to receive Royal Assent in the summer of 2020. A six year appraisal period has been chosen, since the costs and benefits of the Bill are expected to reach a steady state quickly. Costs have been rounded to the nearest £100, some table totals may not sum due to this rounding.
165. The RIA presents a best estimate of the costs and benefits of the Bill based upon the available evidence. The analysis has been informed by engagement with key stakeholders including the LHBs and LAs. Nevertheless, it has been necessary to make a series of assumptions in order to complete the calculations. Any assumptions made are explained in the narrative.

DUTY OF QUALITY

OPTIONS

166. Two options have been identified and explored:

Option 1: Do Nothing - Continue to work within the existing legislative framework; and

Option 2: Create a new overarching duty of quality on the Welsh Ministers and NHS bodies (Local Health Boards, Trusts, and Special Health Authorities (established by the Welsh Ministers)), to exercise their functions in relation to the health service with a view to securing improvement in the quality of services.

OPTION 1: DO NOTHING - CONTINUE TO WORKING WITHIN THE EXISTING LEGISLATIVE FRAMEWORK

Description

167. This option would involve continuing to rely on existing frameworks, policies and measures to drive forward innovation and quality improvement, underpinning section 45(1) of the 2003 Act ⁷.

Costs

168. Although no legislative framework changes are proposed by this option, there are potential impacts and costs associated with retaining the status quo. Evidence shows poor quality health services are more expensive; with the definition of quality including (but not being limited to) the effectiveness of services; the safety of services; and the experience undergone by service users.
169. The 1000 Lives programme³² in their 2012 report, entitled '*Improving Quality Reduces Costs – Quality as the Business Strategy*', stated:

“Placing quality at the heart of the business strategy for NHS Wales will result in improved health outcomes for the people of Wales, and a better return on investment in our health services. The equation of quality care with higher costs is a fallacy and an undue focus on cost cutting will not deliver the changes required.

The impact of poor quality healthcare can be measured through the broken and damaged lives of those failed by the health services, but it is also seen in spiralling costs, overspends, wasted resources and poor investment.

There is evidence that poor quality increases costs through harm, waste and variation. A collaborative approach between clinical decision makers, managers and finance teams is required to ensure that resources are used most effectively to deliver the highest quality of care.”

170. Research undertaken by the Health Foundation⁴⁷ in 2009, entitled ‘Does improving quality save money? A review of evidence of which improvements to quality reduce costs to health service providers’, provides further evidence that poor quality in healthcare has cost impacts:

“Costs of poor quality.

The research reviewed shows that poor quality is common and costly. There is evidence of the high financial and human cost of poor quality in the harm caused by healthcare, and by sub-optimal care in the overuse, misuse and underuse of treatments. It has been estimated that the costs to the UK NHS of hospital-acquired infections are £1.0bn a year (Mayor 2000), and adverse drug events are estimated to be between £0.5bn (Pirmohamed et al 2004) and £1.9bn (Compass 2008). Patients with chronic diseases do not always receive optimal care and the cost of avoidable emergency admissions is high.”

171. Finally, the King’s Fund Report ‘Improving quality in the English NHS’, February 2016⁴⁸, makes the case for quality improvement to be at the heart of how the NHS responds to its current pressures and how it delivers the transformational changes in care that are needed to ensure it is sustainable.

172. The evidence above suggests there is a cost associated with not maximising opportunities to improve quality if we continue with this option, however the exact financial burden the NHS would continue to face is difficult to assess and provide an estimate across the whole system.

⁴⁷ Øvretveit, J. Does improving quality save money? A review of evidence of which [Internet]. The Health Foundation; 2009. Available from: https://www.health.org.uk/sites/default/files/DoesImprovingQualitySaveMoney_Evidence.pdf

⁴⁸ Ham, C and others. Improving quality in the English NHS [Internet]. London: The Kings Fund; 2016. Available from: https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/Improving-quality-Kings-Fund-February-2016.pdf

Benefits

173. The evidence demonstrates working within the existing legislative framework, and using existing tools to provide further guidance to the NHS, does not have the desired effect of achieving a system wide approach to quality. Therefore, there is a risk associated with this option, as it would miss the opportunity to instil quality as a principle which operates on a system-wide, population basis to drive forward service sustainability and improvements in services - undermining the effects of the other provisions set out in the Bill and the delivery of 'A Healthier Wales'⁵.
174. However doing nothing may provide a minor benefit in comparison to Option 2, in the form of certainty for NHS bodies in that the status quo will be maintained.

OPTION 2: CREATE A NEW OVERARCHING DUTY OF QUALITY ON THE WELSH MINISTERS AND NHS BODIES (LOCAL HEALTH BOARDS, TRUSTS, AND SPECIAL HEALTH AUTHORITIES (ESTABLISHED BY THE WELSH MINISTERS)), TO EXERCISE THEIR FUNCTIONS IN RELATION TO THE HEALTH SERVICE WITH A VIEW TO SECURING IMPROVEMENT IN THE QUALITY OF SERVICES.

Description

175. This option would place an overarching duty on the Welsh Ministers and NHS bodies (LHBs, Welsh NHS Trusts and Welsh SHAs to exercise their functions relating to the health service with a view to securing improvement in the quality of services in the broadest sense.
176. The duty will sit in the National Health Service (Wales) Act 2006. It will replace the obligations set out in section 45(1) of the 2003 Act⁷. The duty is broader in scope and different in nature to the 2003 Act⁷. It will reframe 'quality' to ensure it is used in its broader definition; not limited to the quality of services provided to an individual or to service standards, and require the Welsh Ministers and NHS bodies to exercise all of their functions with a view to securing improvement in the quality of health services.
177. Therefore the new duty will require the bodies to exercise their functions in a particular way and consider how they can improve quality on an ongoing basis when they exercise all of their functions. Improving quality will have to become embedded and an integral part of their decision-making.
178. Additionally, the duty would strengthen the governance arrangements by requiring the Welsh Ministers and NHS bodies to publish a report annually on the steps they have taken to comply with the duty and assess the extent of any improvement in outcomes.
179. The new duty is not intended to deliver a particular outcome or to ensure a particular level of service is attained; the intent of this option is that when the Welsh Ministers and NHS bodies make decisions about the health service, they must actively consider whether the decision will improve service quality and secure improvement in outcomes, including:

- the effectiveness of the services;
- the safety of the services; and
- the experience undergone by service users.

Costs

Awareness and training:

180. Moving the Welsh Government (including the Welsh Ministers) and NHS bodies to a position where they are more routinely and actively focusing on quality and continuous improvement is likely to involve a combination of leadership, cultural and behavioural changes. It is anticipated training will be required to embed these new ways of working at all levels. Therefore to successfully implement the duty there are four key areas where action is required:

- Digital awareness campaign;
- Organisational awareness training;
- Enhanced leadership training; and
- Supporting resources.

181. Description - the four areas are outlined in turn below:

- Digital awareness campaign:

182. A campaign would aim to increase NHS staff awareness of the duty of quality, highlighting how NHS bodies will be exercising their functions in a particular way as to renew focus on improving the quality of services and what this means for staff.

183. It is envisaged an internal communication campaign which would consist of a variety digital tools, supported by a digital information leaflet. The campaign would engage staff via existing NHS channels, and be displayed in NHS offices and staff areas.

- Organisational awareness and training:

184. To embed a basic level of knowledge and understanding of the duty of quality for all staff, and to create a culture where staff take decisions with a view to securing improvement in the quality of services, a basic level of awareness training will be required. It is anticipated the training will help consider what amendments are needed to current working practices to ensure quality and continuous improvement are a fundamental consideration.

185. We anticipate this training will be delivered to all Welsh Government health and social services staff within the Health and Social Services Group and NHS staff.

186. For NHS staff, it is expected this training can be delivered via an update to the relevant e-learning modules on the NHS training portal, such as the 'Improving Quality Together' module (accessible to all NHS staff). We anticipate this e-learning module can then be modified for Welsh Government staff and hosted on the Welsh Government intranet.

iii. Enhanced leadership training:

187. To support the required focus on quality at all levels within organisations; to encourage and support staff in delivering against the duty; to provide the leadership to achieve the cultural and behavioural changes needed to implement the duty; and to ensure compliance with duty; enhanced training will be required for the Welsh Ministers responsible for Health (the Minister for Health and Social Services and the Deputy Minister for Health and Social Services), senior civil servants within the Welsh Government's Health and Social Services Group and Board members of NHS bodies.

188. It is envisaged this training would be delivered face to face.

iv. Supporting resources:

189. To support the ongoing implementation of the duty, the Welsh Government will create online resources similar to that used for the 2015 Act⁴⁹ such as range of case studies⁴⁹ providing examples of how organisations have applied the principles of quality to secure improvement, supported by guidance for organisations.

190. Costs – the four areas are costed in turn below:

191. The costs, unless indicated otherwise, are anticipated to be incurred in 2020-21. Time, where stated, refers to the number of working days.

192. Due to the specialist nature of this work, unless stated otherwise, it is anticipated 0.5 WTE secondee from the NHS will be required to develop the content of the public awareness campaign, the all staff e-learning module, the enhanced leadership training material and the supporting resources. Additionally the secondee will be required to deliver the enhanced leadership training. This work is anticipated to take no longer than 12 months, and be delivered by a member of staff at an appropriate level - estimated to be at a grade equivalent to a Welsh Government Executive Band 2 (EB2). The cost to Welsh Government of the NHS secondee is approximately:

Table 1 - NHS secondee

Costs for EB2 equivalent NHS secondee		
EB2 Annual Average Cost	Estimated time required	Cost

⁴⁹ Welsh Government Case studies [Internet]. Gov.Wales Welsh Government services and information. 2019 [cited 2 April 2019]. Available from: <https://gweddill.gov.wales/topics/people-and-communities/people/future-generations-act/case-studies/?lang=en>

£76,300*	0.5	£38,200
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*provided by the Welsh Government Central Services & Administration Main Expenditure Group Team based on Average Gross Salary Rates for Non-SCS Pay Bands 2018/19.

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

i. Digital awareness campaign:

Table 2 – development of a digital leaflet

Activity	Grade	Time	Cost
Opportunity cost - Translation and proofreading information leaflet ⁽ⁱ⁾	Management Band 2	0.5	£100
Opportunity cost - Design and typesetting information leaflet ⁽ⁱ⁾	Management Band 3	4hrs	£100
Total			£200

⁽ⁱ⁾ Based on the translation, design and typesetting of Putting Things Right leaflet²⁰ – approximately 600 words.

194. The staff costs to the Welsh Government for developing the public awareness campaign are included in the resource at table 1.

ii. Organisational awareness and training:

Table 3 - development of awareness and training materials

Activity	Grade	Time	Cost
Opportunity cost - Translation of the NHS e-learning module ⁽ⁱ⁾	Management Band 2	8 days	£1,400
Opportunity cost - Translation of the Welsh Government e-learning module ⁽ⁱⁱ⁾	Management Band 2	4 days	£700
Total			£2,100

⁽ⁱ⁾ Based on the current word length of the current 'Improving Quality Together' NHS module (estimated at 16,000 words).

⁽ⁱⁱ⁾ Based on modifying part of the above module (estimated at 8,000 words).

195. NHS Wales Shared Services Partnership has confirmed uploading and hosting the e-learning module online for NHS staff 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.

196. The staff costs to the Welsh Government for developing the organisational awareness and training are included in the resource at table 1.

iii. Enhanced leadership training:

197. For the enhanced leadership training, where required a simultaneous interpreter will be supplied by Welsh Government. The opportunity cost of this, along with translation of the training material is estimated below:

Table 4 – development of enhanced leadership training

Activity	Grade	Time	Cost
Opportunity cost - Translation of the training material ⁽ⁱ⁾	Management Band 2	0.5 days	£100
Opportunity cost - Interpreter for Welsh Ministers enhanced leadership training (one session)	2 x Management Band 2	0.5 day per MB2 ⁽ⁱⁱ⁾	£200
Opportunity cost - Interpreter for Welsh Government enhanced leadership training (two sessions)	2 x Management Band	1 day per MB2 ⁽ⁱⁱ⁾	£400
Opportunity cost - Interpreter for NHS bodies enhanced leadership training (12 sessions – a separate session for each NHS body)	2 x Management Band 2	6 days per MB2 ⁽ⁱⁱ⁾	£ 2,400
Venue costs			£ 100
Total			£ 3,200

⁽ⁱ⁾ Based on training being provided via a presentation at a maximum of 1,000 words

⁽ⁱⁱ⁾ Based on the duration of each training session (two hours), the preparation, set-up and dismantlement of equipment, reading of papers prior to the session, and travel.

198. Our expectation is that NHS and Welsh Government premises would be used to deliver the face to face training, 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 space is not available. Based on the cost of hiring a venue, used by Welsh Government to interview perspective members to the CHCs in February 2018, this cost is estimated to be £100.
199. The staff costs to the Welsh Government for developing and delivering the enhanced leadership training are included in the resource at table 1.

iv. Supporting resources:

200. **Case studies:** It is estimated approximately 10 case studies will be developed, which will be no more than 15,000 words in total. The estimated opportunity cost associated with the development of the case studies are:

Table 5 - development of case studies

Activity	Grade	Time	Cost
Opportunity cost - Translation and proofreading	Management Band 2	9 days	£1,600
Opportunity cost - Design and typesetting	Management Band 3	2 days	£300
Total			£1,900

201. There would be no costs associated with the distribution of the case studies as only electronic versions would be available on the Welsh Government website.

202. The case studies would be refreshed every five years to reflect local good practice, with the first cost occurring in 2025-26, the estimated opportunity cost associated with this refresh are:

Table 6 - refreshing case studies

Activity	Grade	Time	Cost
Opportunity cost - Refreshing guidance	Executive Band 2	10 days	£2,900
Opportunity cost - Translation and proofreading ⁽ⁱ⁾	Management Band 2	4.5 days	£800
Opportunity cost - Design and typesetting ⁽ⁱ⁾	Management Band 3	1 day	£100
Total			£3,800

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

203. **Guidance:** It is estimated the guidance will be no more than 25,000 words. The estimated opportunity cost associated with the development of the case studies are:

Table 7 - development of guidance

Activity	Grade	Time	Cost
Opportunity cost - Translation and proofreading	Management Band 2	15 days	£2,600
Opportunity cost - Design and typesetting	Management Band 3	4 days	£500
Total			£3,100

204. There would be no costs associated with the distribution of the guidance as only electronic versions would be available on the Welsh Government website.

205. The guidance would be refreshed every five years, with the first cost occurring in 2025-26, the estimated opportunity cost associated with this refresh are:

Table 8 - refreshing guidance

Activity	Grade	Time	Cost
Opportunity cost - Refreshing guidance	Executive Band 2	10 days	£2,900
Opportunity cost - Translation and proofreading ⁽ⁱ⁾	Management Band 2	7.5 days	£1,300
Opportunity cost - Design and typesetting ⁽ⁱ⁾	Management Band 3	2 days	£300
Total			£4,500

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

206. The staff costs to the Welsh Government for developing the supporting resources in 2020-21 are included in the resource at table 1.

Opportunity cost of training:

207. Separately, to the above development costs, there are opportunity costs associated with each element of delivery. The estimated opportunity costs associated with staff delivering or receiving the training have been calculated based on the number of staff-hours spent on the training, multiplied by the average cost per hour of those taking part. This does not take into account that it is intended this training will be developed from or to replace existing training, and therefore a portion of the staff time costed in the table would be incurred undertaking the existing training if this approach was not taken forward.
208. The opportunity costs estimated below are based on the following assumptions:
209. **Awareness training - WG staff in the H&SS Group:** It is estimated this training would need to be delivered to approximately 449 (staff paid via the Health and Social Services payroll in December 2018 - not including those in Knowledge and Analytical Services and Children and Family Court Advisory and Support Service) individuals and the e-learning module would take approximately 30 minutes to complete per person.
210. **Awareness training - NHS staff:** It is estimated this training would need to be delivered to approximately 91,200 individuals⁵⁰ (staff directly employed by the NHS in Wales at 30 Sept 2017 plus staff employed by HEIW in April 2019) and the e-learning module would take approximately 30 minutes to complete per person.
211. **Enhanced leadership training - Welsh Ministers:** It is estimated this training would need to be delivered to two individuals (the Minister for Health and Social Services and the Deputy Minister for Health and Social Services – as at February 2019) and the training would take approximately two hours to complete per person.
212. **Enhanced leadership training – Senior Civil Servants WG H&SS Group:** It is estimated this training would need to be delivered to 35 individuals (senior civil servants paid via the Health and Social Services payroll in December 2018 - not including those in Knowledge and Analytical Services and Children and Family Court Advisory and Support Service.) and the training would take approximately two hours to complete per person.
213. **Enhanced leadership training – Board Level:** This training would need to be delivered to approximately 218 individuals (based on Board membership at January 2019), and this training would take approximately two hours to complete per person.

⁵⁰ Figures provided by Welsh Government Knowledge and Analytical Services

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

Table 9 – opportunity costs of training

Cohort	Staff numbers	Hours of training per person	Mean hourly rate	27% uplift representing 'on costs' ⁽ⁱ⁾	Estimated opportunity cost
Awareness training - WG staff in the H&SS Group	449	0.5	£18.45 ⁽ⁱⁱ⁾	£4.98	£6,000
Awareness training - NHS staff	91,157	0.5	£16.59 ⁽ⁱⁱⁱ⁾	£4.48	£960,300
Enhanced leadership training - Welsh Ministers	2	2	£43.24 ^(iv)	£11.67	£200
Enhanced leadership training – Senior Civil Servants WG H&SS Group	35 ^(vii)	2	£46.75 ^(v)	£12.62	£4,200
Enhanced leadership training - Board level training	218	2	£57.68 ^(vi)	£15.57	£31,900
Total					£1,002,600

(i) As advised by Welsh Government Health and Social Services Finance a percentage uplift of 27% has been included to include on costs.

(ii) As advised by Welsh Government Health and Social Services Finance, this has been calculated using an average annual gross salary of £51,180, minus a notional 27% representing on costs to allow comparison.

(iii) 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 £16.59 in 2018.

(iv) The determination on Members' Pay and Allowances⁵¹ shows for 2017-18 the total salary for a Minister (£102,100) and Deputy Minister (£86,785) is averaged at £94,442.50.

(v) As advised by Welsh Government Health and Social Services Finance, Senior civil servants paid via the Health and Social Services payroll in December 2018 - not including those in Knowledge and Analytical Services and Children and Family Court Advisory and Support Service.

(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 £57.68 in 2018.

Operational costs:

215. The implications for changes to working practices within Welsh Government (acting on behalf of the Welsh Ministers) and NHS bodies will depend upon the strategies they develop to meet the objectives they set in response to the legislation. Decisions taken by organisations in both settings and achieving the duty include the exercise of discretion - allowing the decision makers within the bodies to make a choice about what course of action will best enable the body fulfil its legal duty. The Bill provides a defined framework for how to determine these actions but it is ultimately the responsibility, and indeed choice of the organisations as to what actions to take, but bodies will be expected to justify these actions through their reporting arrangements. Since these decisions have yet to be made and the associated responses have yet to be developed and implemented, it is difficult to estimate the operational costs for Welsh Government and NHS bodies at this stage as the range of potential actions and outcomes is simply too broad. It is for the organisations themselves to find the best sustainable solutions in the context in which they operate. These costs are therefore unknown at this stage.

216. This assumption is supported by the work completed for the Regulatory Impact Assessment for the 2015 Act¹, which introduced a duty that achieves a similar change to operational practices to that desired by the proposed duty of quality. PwC were commissioned to assess the administrative impact of the 2015 Act on the public bodies subject to the Bill. They concluded:

“whilst identifying the need for cultural change within organisations, improved leadership and better partnership-working....were unable to provide a quantified assessment of the costs involved.”⁵²

Legal costs:

217. By introducing a duty of quality on the Welsh Ministers and NHS bodies, it could be suggested this option creates a further “hook” for legal challenges to decisions on the grounds they do not comply with the duty. For example, an individual affected by a decision to move a service from hospital A to hospital B may potentially seek a judicial review of that decision by claiming the decision maker failed to take proper account of a duty to have regard to the quality of services.

⁵¹ National Assembly for Wales. Determination on Members' Pay - Remuneration Board of the National Assembly for Wales [Internet]. National Assembly for Wales; 2017. Available from: http://www.assembly.wales/Job%20Documents/Cams/Determination/Determination_Sep_17_EN.pdf

⁵² Welsh Government - Future Generations Bill: Administrative Impact Appraisal. (2014). PWC.

218. While failure to comply with the duty can be challenged in the courts it is considered unlikely the duty will amount to an entitlement to an individual receiving a particular service. For example, it was determined in the case of *R (Dyer) v Welsh Ministers* [2015] EWHC 3712 the statutory regime (the National Health Service (Wales) Act 2006)⁵³ was not suitable to create an individual entitlement to service provision and that no public law duties had been breached in relation to collating data as to service provision or in making service provision decisions. Therefore, while the potential costs associated with possible challenges by judicial reviews could be significant if they were to materialise, the likelihood of this is considered to be minimal. These costs are unquantifiable as even if a judicial review challenge were to be brought, the costs of judicial reviews vary significantly and therefore this cost is unknown at this stage.

Reporting annually:

219. The duty will require the Welsh Ministers and NHS bodies to publish separate reports annually on the steps they have taken to comply with the duty and assess the extent of any improvement in outcomes. Currently NHS bodies produce Annual Quality Statements (AQS)⁵⁴ providing an overview of the work they have undertaken to improve the quality of healthcare. These are published and submitted to Welsh Government who in turn produces the “All Wales AQS”⁵⁵ – currently prepared and published by Director General for Health and Social Services/ NHS Wales Chief Executive. The all Wales report provides a national picture of quality in the NHS.

220. It is proposed the current requirements for the publication of the AQS are built upon and used as the basis for the annual reports required by the duty.

221. For Welsh Government, the duty strengthens the current AQS process by requiring an All Wales AQS to be produced by the Welsh Ministers for publication and laying before the Assembly. The Welsh Government will continue to consider the annual reports produced by NHS bodies and produce a single ‘All Wales’ report, which will also include detail of the actions taken by the Welsh Ministers to comply with the duty. The duty will therefore build on the existing All Wales AQS.

222. There will be an opportunity cost with the time of Welsh Ministers in considering the content of the reports, any supporting briefing and possibly responding to Assembly questions on the annual report in the Assembly. It is not possible to quantify this time as it will depend on the nature of the reports content and any high profile incidents or concerning trends which can be expected to

⁵³ *R (Dyer) v Welsh Ministers* [2015] EWHC 3712 (Admin), [2015] MHLO 109 - Mental Health Law Online [Internet]. Mentalhealthlaw.co.uk. 2017 [cited 2 April 2019]. Available from: [http://www.mentalhealthlaw.co.uk/R_\(Dyer\)_v_Welsh_Ministers_\(2015\)_EWHC_3712_\(Admin\),_\(2015\)_MHLO_109](http://www.mentalhealthlaw.co.uk/R_(Dyer)_v_Welsh_Ministers_(2015)_EWHC_3712_(Admin),_(2015)_MHLO_109)

⁵⁴ Welsh Government. The Annual Quality Statement - Delivering high quality health services to the people of Wales. [Internet]. Welsh Government; 2016. Available from: <https://gweddill.gov.wales/docs/dhss/publications/170407aqs-reporten.pdf>

⁵⁵ NHS Wales [Internet]. Gov.Wales Welsh Government services and information. 2018 [cited 2 April 2019]. Available from: <https://gweddill.gov.wales/topics/health/nhswales/?skip=1&lang=en>

generate questions and added scrutiny. This cost is therefore unknown at this stage.

223. Additionally, there will be an opportunity cost to the Welsh Government based on the amount of staff time required each year to collect, prepare, publish and brief Ministers on the additional information required for the All Wales AQS on the duty. This cost would occur annually and is estimated to be:

Table 10 – All Wales AQS

Activity	Grade	Time	Total
Compile, draft and clear the additional content for the report	Management Band 2	3	£500
	Management Band 1	3	£700
	Executive Band 2	2	£600
Translate the additional content	Management Band 2	0.5	£100
Total			£1,900

224. Since the report will be published electronically only, there will be no printing costs.

225. For NHS bodies, it is intended the requirement to report annually on the duty will build on the existing AQS process. It is therefore not anticipated the Bill will place an additional burden on NHS bodies as the duty simply changes the focus of the information gathered and published i.e. quality is considered in a much broader sense demonstrating how decisions taken improve service quality and secure improvement in outcomes. Therefore there is no cost for NHS bodies associated with this option as it is anticipated the requirement to report annually can be delivered within the resources currently used for the existing AQS process.

Forums for discussion:

226. In terms of implementing the duty, it is considered there will no additional cost for the Welsh Ministers or NHS bodies. The new duty will require the Welsh Ministers and NHS bodies to exercise their existing functions in a particular way and consider how they can improve quality on an ongoing basis when they exercise all of their functions; improving quality will have to become a part of their decision-making. This will also influence the way in which integrated medium term plans are framed.

227. It is not anticipated the duty will change existing governance and decision making systems which already operate; but it will ensure any decisions and the nature of conversations held within these systems to one which focuses on quality and improvement. This will also influence the way in which their integrated medium term plans are framed. To achieve this it is not expected the duty will require the establishment of any additional forums to enable collaboration. It is considered that

existing well established channels such as Public Service Boards³⁶, established under the 2015 Act¹, the NHS Wales National Quality and Safety Forum⁵⁶ the Welsh NHS Confederation⁵⁷ and the RPBs⁵⁸ will be used to help achieve the collaborative approach necessary to discharge a bodies' functions under the duty. The duty is simply intended to ensure any decisions and the nature of conversations held within these systems focus on quality improvement.

Summary of costs:

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

Table 11 – Cost to Welsh Ministers

	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
Opportunity cost - enhanced leadership training (Table 9)	£200	£ -	£ -	£ -	£ -	£ -

Table 12 – Cost to Welsh Government

	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
NHS Seconded (Table 1)	£38,200	£ -	£ -	£ -	£ -	£ -
Development of digital awareness campaign (Table 2)	£200	£ -	£ -	£ -	£ -	£ -
Development of awareness and training materials: (Table 3)	£2,100	£ -	£ -	£ -	£ -	£ -
Development of enhanced leadership training (Table 4)	£3,200	£ -	£ -	£ -	£ -	£ -
Development of case studies (Table 5)	£1,900	£ -	£ -	£ -	£ -	£ -
Refreshing case studies (Table 6)	£ -	£ -	£ -	£ -	£ -	£3,800

⁵⁶ Welsh Government (Health and Social Services Group) and NHS Wales. NATIONAL QUALITY & SAFETY FORUM - Terms of Reference [Internet]. Welsh Government (Health and Social Services Group) and NHS Wales; 2015. Available from: <http://www.wales.nhs.uk/sitesplus/documents/862/Item22NationalQuality%26SafetyForumTermsOfReference16July2015.pdf>

⁵⁷ 6. Welsh NHS Confederation [Internet]. NHS Confederation. 2019 [cited 2 April 2019]. Available from: <https://www.nhsconfed.org/regions-and-eu/welsh-nhs-confederation>.

⁵⁸ Regional Partnership Boards | Information and Learning Hub [Internet]. Social Care Wales. 2017 [cited 2 April 2019]. Available from: <https://socialcare.wales/hub/sswbact-regional-partnership-boards>

Development of guidance (Table 7)	£3,100	£ -	£ -	£ -	£ -	£
Refreshing guidance (Table 8)	£ -	£ -	£ -	£ -	£ -	£4,500
Opportunity cost of training - WG staff in the H&SS Group (Table 9)	£6,000	£ -	£ -	£ -	£ -	£ -
Opportunity cost of training - Senior Civil Servants WG H&SS Group (Table 9)	£4,200	£ -	£ -	£ -	£ -	£ -
All Wales AQS (Table 10)	£600	£1,900	£1,900	£1,900	£1,900	£1,900
Total	£59,500	£1,900	£1,900	£1,900	£1,900	£10,200

Table 13 – Cost to NHS bodies

	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
Opportunity cost - awareness training (Table 9)	£960,300	£ -	£ -	£ -	£ -	£ -
Opportunity cost - enhanced leadership training (Table 9)	£31,900	£ -	£ -	£ -	£ -	£ -
Total	£992,200	£ -	£ -	£ -	£ -	£ -

Benefits

Welsh Government and NHS bodies:

229. There is a policy desire to enhance the existing duty of quality that currently sits in section 45(1) of the 2003 Act⁷. The duty, when compared to the 2003 Act⁷, is stronger and enhanced in addition to duty being placed on NHS bodies it will also apply to the Welsh Ministers when exercising functions related to health. By placing the duty in primary legislation (a full legislative duty) provides quality with the force required to bring about the change needed. This method also reflects the approach taken in other countries.

230. Placing the proposed duty in part 1 of the 2006 Act¹² will increase the prominence of the duty and will strengthen and enhance the section 45(1) duty by:

- ensuring quality improvements are not limited to the quality of services provided to an individual or to service standards, and instead requiring the Welsh Ministers and NHS bodies, when seeking to improve quality, to focus on the outcomes achieved;
- placing the core duty onto the Welsh Ministers when exercising functions related to health (in addition to current duty on NHS bodies);
- requiring the Welsh Ministers and NHS bodies to produce an annual report demonstrating how they have improved outcomes; and

- d. by being placed in a prominent position in the NHS Wales Act – underlining the policy desire to ensure quality is “at the heart of the health service”.

231. Increasing the prominence of duty of quality will place it at the heart of future thinking around health services. It will require the Welsh Ministers and NHS bodies to make decisions on the principles of securing improvement of certain outcomes – including effectiveness, safety and the users’ experience. This will ensure quality becomes a fundamental principle against which the Welsh Ministers and NHS bodies will assess against before making decisions regarding health services.

232. The Welsh Ministers and NHS bodies will be held accountable via the production of annual reports on the steps they have taken to comply with the duty and assess the extent of any improvement in outcomes. This approach will essentially require the Welsh Ministers and NHS bodies to keep the exercise of the new duty under review and ensure there is independent scrutiny of their assessment. This approach will ensure the annual quality report is in line with, and part of, the current annual financial/governance reporting requirements in respect of the NHS giving an overall picture of services across Wales. This is in line with current Welsh Government expectations on NHS bodies.

233. Separately, the NHS has adopted the internationally accepted definition put forward by the then Institute of Medicine⁵⁹ which outlines six domains of health care quality. However, to unlock the potential of this model, it is often necessary to look beyond organisational boundaries and work collaboratively with others to achieve the right outcomes for the population served. It has proved difficult for health boards in Wales to achieve this, with constraints in their establishment orders potentially restricting them from finding new and innovative solutions (on a local, regional or national basis) which would provide greater benefits to their populations. This view is supported by an OECD report¹¹ which commented that some years after their establishment LHBs were:

“showing less innovation, and fewer radical approaches to system change and quality improvement that might have been expected”.

234. Additionally, the 2015-16 Welsh Government’s Chief Medical Officer report⁶⁰ made a case for greater collaboration between NHS bodies, other public sector partners and those communities so services influence the whole life course, improving outcomes, health and well-being, reducing health inequalities and ultimately reducing demand on statutory services. Therefore it can be argued health boards should not continue to provide the same services, in the same way, achieving the same effect as their neighbours. Instead health boards should look on how they can tackle issues in a much wider context i.e. look beyond organisational boundaries and work collaboratively with others to achieve the right outcomes for their populations.

⁵⁹ Six Domains of Health Care Quality [Internet]. Agency for Healthcare Research & Quality. 2015 [cited 2 April 2019]. Available from: <https://www.ahrq.gov/talkingquality/measures/six-domains.html>

⁶⁰ Welsh Government. Rebalancing healthcare - Working in partnership to reduce social inequity [Internet]. Welsh Government; 2016. Available from: <https://gov.wales/docs/dhss/publications/161110cmoreport16en.pdf>

235. The current duty of quality within the 2003 Act⁷ does not support the above approach and therefore the proposed duty, via the necessary strengthened approach to collaboration, will assist NHS bodies achieve the changes necessary to realise the benefits. As a result, the duty will also further support NHS bodies discharge their functions under two landmark Welsh laws – the 2014 Act² and the 2015 Act¹, which require NHS bodies to work together with other public bodies for the long-term benefit of the people of Wales. The later has required a change from the traditional way of working, delivering against service based targets, to one that focuses on the five ways of working:

- Long term: balancing short-term needs with planning for the long-term;
- Prevention: acting to prevent problems occurring or getting worse;
- Integration: considering how a body's actions could deliver against well-being goals and how they could impact on the objectives of other public bodies;
- Collaboration: how working with others could help a body to meet its well-being objectives; and
- Involvement: involving people with an interest in achieving the body's goals, and ensuring those people reflect the diversity of the area which the body serves.

NHS bodies:

236. The sustainability of the health services depends on, amongst other things, the need for NHS bodies to think much more broadly and perhaps even to rebalance the health services they provide.

237. The Institute for Healthcare Improvement in its paper entitled a '*Framework for Effective Board Governance of Health System Quality*' considered the relationship between improved quality outcomes with both better hospital management practices and increased board attention to quality. Their analysis found⁶¹:

"greater board engagement is correlated with better quality outcomes...board and management prioritization of quality speaks to a leadership commitment that impacts the culture and strategic priorities of the organization."

238. Decisions should therefore not just focus on the quality of care an individual receives as they access a service, but to determine, in collaboration with cross sector partners, how every decision could impact all current and future service users, and improve the wider social determinants of health. Therefore, a proposed duty of quality would ensure decisions are made in this broader quality context, considering the effectiveness of the interventions in improving quality.

⁶¹ Institute for Healthcare Improvement. Framework for Effective Board Governance of Health System Quality [Internet]. Institute for Healthcare Improvement; 2018. Available from: <http://www.ihl.org/resources/Pages/IHIWhitePapers/Framework-Effective-Board-Governance-Health-System-Quality.aspx>

239. By requiring NHS bodies to consider the wider implications of their decisions to improve their population outcomes, the proposed duty would ensure LHBs were required to work with their neighbours and cross sector partners to reduce unwarranted variation and health inequality; encouraging the sharing of resources and expertise which will in turn unlock opportunities to improve the effectiveness, safety and quality of services.

240. Introducing a duty of quality also sits comfortably alongside the concepts of 'Prudent Healthcare' and 'Value Based Health Care'; which seek to reduce harm and to target resources in the most appropriate way with the aim of improving the effects of treatment (outcomes) and reducing variation in care. Much work is already underway in the Welsh NHS to look at unwarranted variation and outcome measures and this will support the delivery of the proposed duty.

Healthcare professionals:

241. There is already a culture amongst healthcare professionals that encourages and promotes quality improvement. This is supported though professional duties which, for example, require doctors to take part in systems of quality assurance and improvement⁶², and requires nurses and midwives to act to ensure the quality of care or service they provide is maintained and improved⁶³.

242. The proposed duty of quality will support this existing culture by requiring organisations to act in the same manner; for example, making decisions to improve quality on a wider organisational basis. This in turn will mean organisations and services will be a more attractive place to work for health professionals as staff would be being encouraged to suggest and supported in implementing ideas to improve the quality of care provided at an organisational level. This will ultimately improve job satisfaction, motivate staff and lead to a more sustainable workforce – a strand of the 'Quadruple Aim' (described as driving the development of many high performing international health and social care systems within the Welsh Government's '*A Healthier Wales: our Plan for Health and Social Care*'⁶⁵).

Public:

243. Although Welsh Ministers already operate in an open and transparent manner, with the majority of the Assembly's committees and plenary sessions being available for public viewing and the publishing of decision reports which summarise the decisions made by the Welsh Ministers, the requirement to lay the annual quality report before the Assembly will add to this transparency – providing further evidence of how decisions made by the Welsh Ministers in relation to the health service ultimately improve quality for service users.

⁶² General Medical Council. Good medical practice [Internet]. General Medical Council; 2013. Available from: https://www.gmc-uk.org/-/media/documents/good-medical-practice---english-1215_pdf-51527435.pdf

⁶³ Nursing and Midwifery Council. The code: Professional standards of practice and behavior for nurses, midwives and nursing associates [Internet]. Nursing and Midwifery Council; 2018. Available from: <https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf>

SUMMARY AND PREFERRED OPTION

244. **Option 1** proposes no change to the current legislative framework, with any improvement of service delivery being driven via policy tools such as guidance and regulations. The last 20 years have demonstrated this approach is not effective at changing organisational behaviour and there is no reason to believe continuing in this way would support the adoption of the broader definition of quality required to deliver efficient and effective health services in the future. Accepting this option would fail to capitalise on the need to change and the opportunity to build on the work already undertaken in this space would be lost. Given the evidence this option fails to deliver against the policy objectives.
245. **Option 2** creates a duty on the Welsh Ministers and NHS bodies to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care.
246. It strengthens and enhances the current duty in 2003 Act⁷ by placing a duty of quality for the first time onto the Welsh Ministers (in addition to NHS bodies). It also allows for the Welsh Ministers (in relation to their functions for the health service) and NHS bodies to be held to account for improved outcomes via the publication of a report annually on the steps they have taken to comply with the duty and assess the extent of any improvement in outcomes.
247. Quality will be placed in a prominent position in the NHS Wales Act, underlining the policy desire to ensure quality is at the heart of the health service and it is the driving characteristic that draws together the other changes included in the Bill.
248. The option builds upon existing governance and reporting processes and systems so as to minimise any potential burden and costs. Additionally, there is the possibility of savings arising from this option when compared to the potential cost of poor quality described in **Option 1**; however any exact savings are difficult to quantify.
249. This option fully meets the policy objectives and is the preferred option.

DUTY OF CANDOUR

OPTIONS

250. Two options have been identified and explored:

Option 1: Do nothing;

Option 2: Create a statutory duty of candour applicable to NHS bodies (LHBs, Trusts, Welsh SHAs (including NHS Blood and Transplant in relation to its Welsh functions) and primary care providers in Wales in respect of the NHS services they provide).

OPTION 1: DO NOTHING

Description

251. Under this option no statutory duty of candour would apply to NHS providers. This option would involve the continuation of the being open requirements set out within the existing NHS Putting Things Right process²⁰ (the process for managing concerns in NHS Wales) and the non-statutory duties of candour which apply to a range of healthcare professionals as part of their professional registrations which support openness and transparency when things go wrong.

Costs

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

Benefits

253. Doing nothing would deliver no additional benefits and the opportunity to build on the work already undertaken would be lost. For regulated social care settings, a 'duty of candour' already exists under the 2016 Act⁹, therefore this option would not create a unified health and social care system-wide approach to candour. For NHS bodies it would fail to address the barriers which currently exist in the system⁶⁴ which prevent candour. Separately, there is an expectation from health professionals and the public following the 2016 Welsh Labour Manifesto commitment²⁴ which stated Wales will bring its arrangements into line with other parts of the UK^{22,23}. In doing nothing we would fail to capture the benefits of creating the duty, including the certainty this would provide to users of NHS services and staff coming into Wales from other parts of the UK in that NHS bodies would ensure an open, honest and supportive response when something goes wrong.

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

⁶⁴Waring, J. Beyond blame: cultural barriers to medical incident reporting. Social Science & Medicine [Internet]. 2005;60(9):1927-1935. Available from: <https://www.sciencedirect.com/science/article/pii/S0277953604004666>

OPTION 2: CREATE A STATUTORY DUTY OF CANDOUR – APPLICABLE TO NHS BODIES (LOCAL HEALTH BOARDS, TRUSTS, AND WELSH SPECIAL HEALTH AUTHORITIES (INCLUDING NHS BLOOD AND TRANSPLANT IN RELATION TO ITS WELSH FUNCTIONS) AND PRIMARY CARE PROVIDERS IN WALES IN RESPECT OF THE NHS SERVICES THEY PROVIDE

Description

255. This option would create a statutory duty of candour on providers of NHS services to provide information and support to service users when a patient safety incident occurs resulting in an adverse outcome. The duty will apply to NHS bodies.
256. The duty of candour will apply where a service user to whom health care has been provided has suffered an adverse outcome which has or could result in more than minimal harm and the provision of health care was or may have been a factor.
257. When the duty applies, providers of NHS services will be required to follow a procedure which is set out in regulations. The procedure will require the provider to notify the service user or their representative on becoming aware of the incident to inform them what they understood to have happened, explain what will happen next, provide an apology and offer support.
258. NHS bodies will be required to report annually on the duty. The report will be required to set out whether the duty of candour has applied during the year, how often, briefly describe the circumstances of each case and describe the steps taken by the provider with a view to preventing similar circumstances from arising in the future.

Costs:

259. LHBS, Trusts and primary care providers should already have some arrangements in place in order to meet the existing requirements of Being Open principles⁶⁵ within Putting Things Right²⁰. The resources required by a provider to implement the duty are therefore likely to vary depending on the maturity of their existing arrangements. However all providers will need to ensure their staff are aware of, and where appropriate trained to discharge the new duty. Policies and procedures will also need to be revised. It will also be essential to make the public aware of what they can expect should something go wrong.
260. For SHAs the costs are expected to be negligible as the duty only applies in situations where health care is being or has been provided. Consequently the costs for SHAs relate only to the opportunity cost of undertaking a limited programme of

⁶⁵ National Patient Safety Agency. Being Open [Internet]. 2009. Available from: <https://www.hsj.co.uk/download?ac=1293677>

training (referenced at paragraphs 297 and 298). Welsh Government will work with the SHAs to whom the duty applies to ensure the guidance, and its application to them, is understood in relation to the small number of instances that it is likely to apply. Costs described below therefore mainly relate to implementation of the duty for LHBs, Trusts and Primary Care providers:

Awareness, training and support

261. To successfully implement the duty there are three key areas where action is required:

- i. public awareness campaign;
- ii. organisational awareness and training; and
- iii. development of statutory guidance.

Description - the three areas are outlined in turn below:

i. Public awareness campaign:

262. The consultation responses to the White Paper reflected the importance of a public information campaign²⁵. A campaign would aim to increase public awareness of the duty of candour, empowering individuals to ask questions about the care and services they receive, in the knowledge they could expect openness and transparency should they suffer an adverse outcome that may result in harm.

263. It is envisaged the public awareness campaign would consist of two elements, a publicity campaign and a public information leaflet.

264. The publicity campaign would likely include public relations, social media and working with relevant bodies. 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 HIW's³⁹, providers of NHS services, Health in Wales⁶⁶ (the official NHS website), and the proposed new citizen voice body's websites. To achieve this Welsh Government would look to revise the current Putting Things Right leaflets²⁰ to incorporate the duty of candour.

ii. Organisational awareness and training:

265. The key to encouraging and enabling candour is education and training⁶⁷. Therefore moving providers of NHS services further forward to a position where

⁶⁶ Health in Wales [Internet]. NHS Wales. 2019 [cited 3 April 2019]. Available from: <http://www.wales.nhs.uk/>

⁶⁷ Professional standards agency. Telling patients the truth when something goes wrong - Evaluating the progress of professional regulators in embedding professionals' duty to be candid to patients [Internet]. Professional standards agency; 2019. Available from: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/telling-patients-the-truth-when-something-goes-wrong---how-have-professional-regulators-encouraged-professionals-to-be-candid-to-patients.pdf?sfvrsn=100f7520_6

they are routinely and responsively open and transparent with a service user or their representative when something has gone wrong is likely to involve a combination of leadership, communication and awareness training and development. To support this, a combination of different training and learning is likely to be needed for LHBs, Trusts and Primary Care providers.

266. **Basic all staff awareness training – NHS directly employed:** To embed a basic level of knowledge and understanding of the duty of candour for all NHS staff, and to create a culture of openness where staff feel safe and supported to raise concerns, a basic level of awareness training will be required. This would include building on the principles of being open found in the Putting Things Right Guidance²⁰ for when something goes wrong. Being open involves:

- acknowledging, apologising and explaining when things go wrong;
- conducting a thorough review into the incident and reassuring patients, their families and carers that lessons learned will help prevent the incident recurring;
- providing support for those involved to cope with any physical and psychological consequences of what happened; and
- ensure the organisation has effective systems in place to support staff so, when a member of staff is involved in an investigation, support mechanisms are available.

267. Current training for all NHS staff in regards to openness and transparency when an incident occurs is mainly delivered by the Putting Things Right e-learning tool, available on the NHS training portal. As such Welsh Government would look to redesign the e-learning tool to refresh the current content and include a module on the duty of candour.

268. **Basic all staff awareness training – primary care:** The Putting Things Right e-learning tool is also applicable to primary care, but it is envisaged that an additional module will be included which will be specifically tailored to better reflect likely scenarios within a primary care setting. Where primary care practices are unable to access the NHS e-learning portal arrangements will be made to identify platforms from which training can be accessed e.g. through existing professional training routes.

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

270. It is intended this training will build upon the approach developed when 'Being Open'⁶⁵ was introduced in 2005, and subsequently reinforced via the introduction of Putting Things Right in 2011²⁰. This required organisations to identify clinical, nursing and managerial opinion leaders to champion the 'Being Open' approach. These champions were to mentor and support fellow clinicians; develop and implement a strategy for training staff; and provide ongoing organisational support. It is therefore anticipated advanced awareness training would provide 'Organisational Champions', with the necessary knowledge and skills to provide advice and support to other staff within their organisations.

271. It is anticipated this can be delivered via the creation of an additional component, to the e-learning tool described above. It is then expected when the new training is developed it could be promoted at no cost via existing NHS networks, for example the Service User Experience Network and Patient Experience Network, encouraging the development of a wider cohort of staff.
272. **Concerns team training:** To enable providers of NHS services to ensure the duty is being enacted appropriately and to prepare an annual report on the duty of candour, the concerns teams within LHBs and Trusts are likely to be those responsible for collecting the required data as well as monitoring and assuring its quality. This is consistent with the work these teams currently undertake when a body deals with a concern (as explained below). To support concern teams in considering the implications of the duty, for example the data required to be collected and how current processes and procedures may need to change, training will be required.
273. Individuals in the concerns teams already receive job specific training with regards their current role in collecting and monitoring data about concerns. It is anticipated this can be delivered via the creation of an additional module, specifically for concerns teams, to the e-learning tool described above.
274. **Primary care practice managers/ complaints leads:** to support primary care practices in implementing the duty it is proposed that face to face workshops for primary care practice managers/ complaints leads will be provided and delivered at venues across Wales. This is to ensure the practice leads are given the tools needed to help achieve the changes required in their practices.
275. **Board level training:** To support and embed the principles of being open and transparent within providers of NHS services; to support staff in delivering against the duty; and to support the wider leadership, cultural and behavioural changes needed to implement the duty, Board Members will need training. This training will ensure Board Members are confident in their ability to seek assurance their organisation is doing enough to learn from patient incidents and they are using this learning to improve services.
276. It is envisaged this training would be delivered face to face.
277. **Legal and Risk Services training:** To support key individuals within providers of NHS services to understand the implications of duty in relation to the NHS (Wales) Redress Measure 2008⁶⁸ and the 2011 Regulations²⁶ including how LHBs and Trusts handle investigations into concerns raised by patients, their families and staff, expert training will be required. The Legal and Risk team within the NHS Wales Shared Service Partnership currently provide advice and assistance to NHS bodies in relation to redress and Putting Things Right²⁰ and would be expected to deliver this training.

⁶⁸ NHS Redress (Wales) Measure 2008. <http://www.legislation.gov.uk/mwa/2008/1/introduction>

278. It is envisaged this training would be delivered face to face by a lawyer from Legal and Risk.

iii. Development of Statutory Guidance:

279. To support providers of NHS services understand how they discharge their duty, statutory guidance will be prepared by Welsh Government. In particular there will be a need to define and develop scenarios which clarify when the duty should be triggered. The guidance will also include advice on how the duty should be reported on. Therefore due to its clinical and technical nature, it is intended that the Welsh Government will establish workshops, which will include clinicians and lay representatives, to aid the guidance's development as to ensure it is clear to providers of NHS services and service users when the duty of candour applies and what actions then need to be taken. It is the intention guidance will link to the current Putting Things Right²⁰ guidance.

280. **Costs** – the three areas are costed in turn below:

281. The costs, unless indicated otherwise, are anticipated to be incurred in 2020-21. Time, where stated, refers to the number of working days.

282. Due to the specialist nature of this work, unless stated otherwise, it is anticipated 0.5 of a FTE secondee from the NHS will be required to develop the content of the public awareness campaign, the materials to support organisational awareness and the statutory guidance. Additionally the secondee will be required to deliver the training. The work is anticipated to take no longer than 12 months, and be delivered by a member of staff at an appropriate level - estimated to be at a grade equivalent to a Welsh Government Executive Band 2 (EB2). The cost to Welsh Government of the NHS secondee is approximately:

Table 14 – NHS secondee

Costs for EB2 equivalent NHS secondee		
EB2 Annual Average Cost	Estimated time required	Cost
£76,300*	0.5 FTE	£38,200

*provided by the Welsh Government, Central Services & Administration Main Expenditure Group Team based on Average Gross Salary Rates for Non-SCS Pay Bands 2018/19.

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

i. Public Awareness Campaign:

Table 15 – Development of public awareness campaign

Activity	Grade	Time	Cost
Publicity campaign	-	-	£10,000 ⁽ⁱ⁾
Opportunity cost - Welsh translation and proof reading ⁽ⁱⁱ⁾	Management Band 2	0.5 days	£100
Opportunity cost – Design and typesetting ⁽ⁱⁱ⁾	Management Band 3	4hrs	£100
Translation, proofreading and typesetting into 16 minority languages ⁽ⁱⁱⁱ⁾	-	-	£3,300
Production and mastering audio and Braille guides ⁽ⁱⁱⁱ⁾	-	-	£1,000
Print costs, including easy read, children's version ⁽ⁱⁱⁱ⁾	-	-	£6,200
Dispatch ^(iv)	-	-	£2,000
Total			£22,700

⁽ⁱ⁾ Similar to the public communication campaign costs associated with the introduction of the special procedures element of the Public Health (Wales) Act 2017⁶⁹.

⁽ⁱⁱ⁾ Based on the translation, design and typesetting of Putting Things Right leaflet²⁰ – approximately 600 words.

⁽ⁱⁱⁱ⁾ Based on the redesign costs of Putting Things Right leaflet²⁰ in 2017, which included the production of ten audio disks, ten braille copies, easy read and children's versions.

^(iv) Based on the cost of dispatching 106,700 Putting Things Right leaflets²⁰ in 2017.

284. The staff costs to the Welsh Government for developing the public awareness campaign are included in the resource at table 14.

ii. Staff awareness and training:

285. To develop the e-learning module required to support the basic awareness training for all NHS and primary care staff (revising the current PTR module), and separately creating the additional e-learning modules required to support the enhanced training for primary care, concerns teams and advanced specialised staff, there is an opportunity cost for Welsh Government associated with the translation of this material:

⁶⁹Welsh Government. Explanatory Memorandum - Public Health (Wales) Bill. 2018.

Table 16 – development of training e-learning modules:

Activity	Grade	Time	Cost
Opportunity cost - Translation of the e-learning material ⁽ⁱ⁾	Management Band 2	9 days	£1,600

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

286. 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.

287. For the 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 a NHS Band 8b solicitor. The opportunity cost for Legal and Risk Services associated with this is estimated to be:

Table 17 – development and delivery of Legal and Risk Services training

Activity	Training days (2 days per provider of NHS services)	Mean hourly rate (based on top of Band 8b)	27% uplift representing 'on costs'	Total Annual Cost
Opportunity cost – Legal and Risk – development and delivery of training	20 days	£31.80	£6.36	£5,700

288. Additionally, our 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.

Development of Statutory Guidance

289. In developing the statutory guidance, there would be a cost to the Welsh Government associated with the planned workshops with key stakeholders. It is anticipated there would be no more than four workshops held across Wales, at Welsh Government offices or other venues which could be used free of charge. However costs will arise to cover the costs of health professionals attending, these include travel, subsistence, and where applicable locum cover for primary care providers. These rates will be paid in line with the Welsh Government's health statutory committee policy for the reimbursement of member costs. It is estimated the cost associated with holding the four events are:

Table 18 –workshops to develop statutory guidance

Activity	Cost	Number of attendees ⁽ⁱⁱ⁾	Total cost
Locum cover ⁽ⁱ⁾	£400	8	£3,200
Travel and subsistence	£100	8	£800
Total			£4,000

⁽ⁱ⁾ £400 being the average amount paid by Welsh Government in 2018 for a full day locum cover for primary care providers attending statutory health committees.

⁽ⁱⁱ⁾ approximately 8 attending primary care staff attending the events (two Dentists, GPs, Pharmacists and Optometrists).

290. To develop the statutory guidance, there will be an opportunity cost for Welsh Government associated with the staff time required to translate and proofread, and separately design and typeset the guidance. It is estimated the guidance will be no more than 25,000 words. The estimated opportunity cost associated with the development of the case studies are:

Table 19 – opportunity cost of developing statutory guidance

Activity	Grade	Time	Estimated opportunity cost
Opportunity cost - Translation and proofreading	Management Band 2	15 days	£2,600
Opportunity cost - Design and typesetting	Management Band 3	4 days	£500
Total			£3,100

291. The staff costs to the Welsh Government for developing the guidance are included in the resource at table 14.

292. There would be no costs associated with the distribution of the guidance as only electronic versions of the guidance would be available.

293. The guidance would be refreshed every five years, with the first cost occurring in 2025-26, the estimated opportunity cost associated with this refresh are:

Table 20 – opportunity cost of refreshing statutory guidance

Activity	Grade	Time	Estimated opportunity cost
Opportunity cost - Refreshing guidance	Executive Band 2	10 days	£2,900
Opportunity cost - Design and typesetting ⁽ⁱ⁾	Management Band 3	2 days	£300
Opportunity cost - Translation and proofreading ⁽ⁱ⁾	Management Band 2	7.5 days	£1,300
Total			£4,500

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

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

Opportunity cost of training:

295. There is an opportunity cost associated with staff and Board members undertaking training – these are set out outlined below and calculated in Table 21. The estimated opportunity costs associated with those receiving the training are calculated on the number of staff-hours spent on the training, multiplied by the average cost per hour and are set out in the table below. This does not take into account the fact that if this training was not being undertaken many staff would undertake alternative training of some sort as part of their required continuing professional development.

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

297. **Basic All Staff Awareness Training – NHS directly employed:** It is estimated this training would need to be delivered to approximately 90,800 individuals⁵⁰ (staff directly employed by the NHS in Wales at 30 Sept 2017 and NHS Blood and Transplant staff who may facilitate organ donation within Wales) and the e-learning module would take approximately 30 minutes to complete per person.

298. **Basic all staff awareness training – primary care:** It is estimated the e-learning training would to be delivered to approximately 15,500 individuals and would take approximately one hour to complete per person (which includes the basic all staff awareness training taking approximately 30 minutes).

299. **Advanced Specialist Staff Awareness Training:** It is estimated this training would be delivered to approximately 43 individuals (based on four per LHB/ Trust and three for NHS Blood and Transplant), and this training will take approximately three hours to complete per person.

300. **Concerns team training:** It is estimated this training would need to be delivered to approximately 262 individuals, and this training would take approximately two hours to complete per person.

301. **Primary care practice managers/complaints leads:** It is estimated the workshops for primary care practice managers/complaints leads are delivered to approximately 1,945 individuals and will take approximately four hours to complete per person.

302. **Board Level Training:** This training would need to be delivered to approximately 205 individuals (based on Board membership at January 2019), and this training would take approximately two hours to complete per person.

303. **Legal and Risk Services training:** This training would be delivered annually to approximately 1,955 individuals (based on one member per provider of NHS services), and this training would take two days (15 hours) to complete per person.

Table 21 – opportunity costs organisational awareness and training

Cohort	Staff numbers	Hours of training per person	Mean hourly rate	27% uplift representing 'on costs' ⁽ⁱ⁾	Estimated opportunity cost
Basic all staff awareness training - NHS directly employed:	90,848	0.5	£16.59 ⁽ⁱⁱ⁾	£4.48	£957,100
Basic all staff awareness training - primary care:	15,329 ⁽ⁱⁱⁱ⁾	0.5	£16.59	£4.48	£161,500
Advanced specialist staff awareness training	43	3	£27.13 ^(iv)	£7.33	£4,400
Concerns team training	262 ^(v)	2	£16.59	£4.48	£11,000
Primary care practice managers/complaints leads:	1,945 ^(vi)	4	£16.59	£4.48	£163,900
Board level training	205	2	£57.68 ^(vii)	£15.57	£30,000
Legal and Risk training	1,955	15	£16.59	£4.48	£ 617,900
Total					£1,945,800

(i) As advised by Welsh Government HSS-Finance a percentage uplift of 27% has been included as the available Office for National Statistics figures do not include on costs.

(ii) The Office for National Statistics Annual Survey of Hours and Earnings shows the mean hourly pay (excluding overtime) for those working in human health was £16.59 in 2018;

(iii) The data includes dentists⁷⁰, GP practitioners and locums, GP practice staff⁷¹ and community pharmacists⁷², however this figure does not include other staff working in working in pharmacies, opticians or dentists as this data is not gathered. It may include some staff recorded under the directly employed NHS staff figure.

(iv) 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 £27.13 in 2018;

⁷⁰ NHS dental services [Internet]. Gov.Wales Welsh Government services and information. 2019 [cited 3 April 2019]. Available from: <https://gweddill.gov.wales/statistics-and-research/nhs-dental-services/?skip=1&lang=en>

⁷¹ General medical practitioners (GP)[Internet]. Gov.Wales Welsh Government services and information. 2018 [cited 3 April 2019]. Available from: <https://gweddill.gov.wales/statistics-and-research/general-medical-practitioners/?lang=en>

⁷² Community Pharmacy Services [Internet]. Gov.Wales Welsh Government services and information. 2018 [cited 3 April 2019]. Available from: <https://gweddill.gov.wales/statistics-and-research/community-pharmacy-services/?lang=en>

(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) Based on 716 community pharmacies, 461 dental practices, 416 GP practices and 352 optometry practices in Wales as of 1 April 2019. Pharmacy, dental and GMS figures confirmed by NHS Wales Shared Services Partnership and optometry figures provided by Optometry Wales (via WG Sensory Health Policy Team).

(vii) 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 £57.68 in 2018.

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

Implementation and ongoing operational costs:

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

306. Where possible, the duty builds upon the existing systems and processes underpinning the Being Open principles⁶⁵ and the 2011 Regulations²⁶; which are already well established within the existing organisational policies and procedures.

307. All providers of NHS services will need to develop an implementation plan to ensure the duty is effectively introduced. This will include a review of policies and procedures to ensure the changes required by the introduction of the duty are incorporated, reported upon and adopted through organisational governance arrangements – including the reporting arrangements for primary care providers who are providing care on their behalf. It is anticipated that this will fall to corporate concern teams to lead. The opportunity cost of this for LHB's and Trust's is estimated to be:

Table 22 – opportunity cost for development of an implementation plan

Table 22 – Opportunity cost for development of an implementation plan				
Activity	Number of bodies	Time required	Annual rate ⁽ⁱ⁾	Estimated opportunity cost
Opportunity cost - Develop implementation plan – LHBs & Trusts	10	3 days	£76,300	£8,800
Opportunity cost - Develop implementation plan – Primary care practices	1,945	2 days		£ 1,141,600
Total Cost				£ 1,150,400

⁽ⁱ⁾Table 1 – EB2 equivalent – annual rate provided by the Central Services & Administration Main Expenditure Group Team based on Average Gross Salary Rates for Non-SCS Pay Bands 2018/19.

308. The estimated ongoing costs resulting from the duty's implementation are outlined below.
309. **Service user engagement** - The procedure, which will be set out in regulations, will require the provider to notify the service user or their representative on becoming aware of the incident to inform them what they understood to have happened, explain 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.
310. Providers of NHS services should already be taking some of these steps in complying with the 'Being Open' principles and the 2011 Regulations²⁶. These regulations require:
311. Service user notification:
- Regulation 12(7) outlines the duty currently on NHS bodies to notify the service user or their representatives of a 'concern' (which includes a patient safety incident) where its initial investigation determines. However the aforementioned only applies where an incident is notified to the body i.e. by a staff member or by a service user; and
 - Regulation 12(8) provides for an exception for cases where it would "not be in the interest of the patient to be candid" - however it is only relied on in exceptional circumstances.
312. Support:
- Regulation 22(4)(b) outlines the availability of advocacy and support services which may be of assistance to that person.
313. Explaining what will happen next:
- Regulation 22(4)(a) outlines NHS bodies must discuss with the person who notified the concern the manner in which the investigation of the concern will be handled, including consent to the use of medical records.
314. Separately, Section 9 of the Putting Things Right Guidance for NHS staff⁷³ and Section 6.3 of the Health and Care Standards⁷⁴ currently require providers of NHS services to have systems in place to ensure concerns, when reported, are: acted upon and responded to in an appropriate and timely manner, and are handled and investigated openly, effectively and by those appropriately skilled to do so.

⁷³ Welsh Government. Putting things right - Guidance on dealing with concerns about the NHS from 1 April 2011 [Internet]. Welsh Government; 2013. Available from: <http://www.wales.nhs.uk/sites3/Documents/932/Healthcare%20Quality%20-%20Guidance%20-%20Dealing%20with%20concerns%20about%20the%20NHS%20-%20Version%203%20-%20CLEAN%20VERSION%20-%202020140122.pdf>

⁷⁴ Health and Care Standards [Internet]. NHS Wales. 2019 [cited 3 April 2019]. Available from: <http://www.wales.nhs.uk/governance-emanual/health-and-care-standards>

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

- the duty will require providers of NHS services to be upfront with the service user or their representative when more than minimal harm has or may have occurred and not wait for an initial investigation to determine it's appropriateness - as required under 12(7) within the 2011 Regulations²⁶; and
- the duty will change the nature of the communication to service user or their representatives ensuring to ensure they are supportive and advocating of learning and change.

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

317. The number of NRLS reported patient safety incidents (moderate, severe and death) in in Wales between April 2017 and March 2018 was 7,341 this is broken down per care setting at Appendix A – NRLS is the England and Wales National Reporting and Learning System which is the system to inform national patient safety learning. Such incidents are likely to trigger the duty of candour. Whilst there may some underreporting this is the best available evidence to estimate the costs associated with notifying the service user.

318. We have therefore assumed it takes 30 minutes to make and keep a record of such a conversation, and this is costed on the assumption it is completed by a member of staff on the mean hourly pay (excluding overtime) for those working in human health (calculated as per Table 21, including on costs).

Table 23 – opportunity cost for providers of notifying the service user

Activity	Time required	Frequency	Hourly rate	Estimated opportunity cost
Opportunity cost - Communication to service user or representative	30 minutes	7,341	£21.07 ⁽ⁱ⁾	£77,300

(i) As per table 21 - the mean hourly pay and on costs for those working in human health.

319. **Regulations under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011** - Changes will be made to the 2011 Regulations²⁶. These will be delivered separately to the Bill, and the

cost and benefit of this will be presented in a separate Regulatory Impact Assessment.

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

321. However this arrangement does not create any new burden for LHBs as they must co-operate by the very fact one commissions the other. Additionally, in relation to when something goes wrong Regulation 20 of the 2011 Regulations²⁶ and Section 6 of the Putting Things Right Guidance⁷³ set out the procedure to be followed when a primary care provider requests assistance from a LHB to investigate a concern which has been notified to the primary care provider. LHBs do not keep records on the how often they currently offer support and the associated opportunity cost for LHB staff time and therefore any additional cost associated with this option is unquantifiable and therefore unknown.

322. **Legal advice from Legal and Risk Services** - As explained, the Legal and Risk Services provide advice to NHS bodies in relation to redress and Putting Things Right. It is estimated that in the first year (2020-21) advice requests relating to the Duty of Candour would increase the current costs in respect of chargeable advice sought in respect of Putting Things Right matters by 20% and then 10% in subsequent years. The current sums billed by Legal & Risk Services to NHS bodies in respect of Putting Things Right matters is £30,000. The costs for NHS bodies are estimated to be:

Table 24 - Costs of obtaining legal advice from NWSSP Legal & Risk Services

	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
Cost - Legal costs payable to NWSSP Legal & Risk Services for chargeable work relating to advice requests	£6,000	£3,000	£3,000	£3,000	£3,000	£3,000

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

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

- Data on the number of current patient safety incidents is already collected either via local risk management systems which fed into NRLS, or via reporting directly to NRLS (for those primary care providers who do not have access to local risk management systems). The meaning of “more than minimal” harm which will trigger the duty will be set out in guidance. However, it is expected the thresholds for triggering the duty will be aligned with the NRLS thresholds; therefore this will not require the reporting and collection of any information which is not currently collected.
- The system used to record patient safety incidents will need development to create a field to capture if the duty of candour process has been triggered. In Wales, work is currently being undertaken to develop a ‘Once for Wales’ Concerns Management System – an improved system for capturing, amongst other data, patient safety incidents. This will be available to all NHS Trusts, LHBs and primary care providers. This development will make it easier for primary care providers to have direct access to a local risk management system to record patient safety incidents. Any future developments as a result of the duty can be incorporated within this system and delivered at no cost to Welsh Government or NHS providers.
- Regulation 51 of the 2011 Regulations²⁶ requires NHS bodies to prepare an annual report on information regarding concerns (where concerns is taken to include complaints, patient safety incidents and claims). For primary care providers, this includes sending their report to the LHB with whom they have entered into arrangements with, allowing for collation and publication within a LHBs or Trusts Annual Putting Things Right report, and considered within each organisation’s Annual Quality Statement.

325. Given patient safety incidents data is already collected and, given NHS providers are already required to produce an annual report to meet the requirements of Putting Things Right⁷³, implementing the reporting arrangements required by the duty can be achieved at no additional cost.

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

327. **Claims and complaints** - The introduction of Putting Things Right²⁰ in 2011 ensured the principles of Being Open are at the heart of NHS Wales. It acknowledged when things go wrong patients, service users and their families or carers want to be told what happened, receive an apology and be reassured learning will take place. A duty of candour will further empower staff to be open when things go wrong.

328. As a result of this open and honest approach, as well as the ease of access and fairness to redress. This has led to a reduction of lower value claims for LHBs and NHS Trusts reaching litigation in Wales, with people instead opting to take such claims through the redress process (estimated £5.75m of costs savings between the 2014/15 to 2015/16 financial years)⁷⁵. If an organisation is open and upfront in acknowledging harm, offering redress is less costly compared to litigation which can result in lengthy and sometimes complicated legal proceedings. Therefore, the operation of the Putting Things Right scheme²⁰ has resulted in significant costs savings in lower value cases where costs often outweigh damages. The introduction of state backed indemnity for general practices from April 2019 will enable the extension of NHS Redress⁶⁸ to this element of primary care.

329. By being open it may result in further savings which are associated with the introduction of the duty of candour, as litigation in respect of incidents that result in harm may be further avoided. These cost savings have not been quantified as they are unknown. In the NHS in England⁷⁶, where a duty of candour currently exists, the number of formal litigation in 2017/18 reduced to the lowest recorded level as NHS Resolution mediated more claims in a single year than in its entire history. However the extent to which possible savings may apply are difficult to quantify and could in fact result in more cases being taken through the NHS Redress process⁶⁸ should the subsequent investigation into the incident determine that is appropriate.

330. Although there is a theoretical risk of the possibility of increased candour leading to an increase in litigation costs, the evidence from England suggests the likelihood of it occurring is low.

Healthcare Inspectorate Wales:

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

Regulations under the Care Standards Act:

⁷⁵ NHS Wales Shared Services Partnership. Paper prepared for NHS Directors of Finance Forum, 2016

⁷⁶ NHS Resolution. Annual report and accounts 2017/18 [Internet]. NHS Resolution; 2018. Available from: 9. Health and Care Standards [Internet]. NHS Wales. 2019 [cited 3 April 2019]. Available from: <http://www.wales.nhs.uk/governance-emanual/health-and-care-standards>

332. The aim of creating a formal duty of candour for all NHS bodies is to provide a system wide approach in relation to candour (NHS providers, regulated independent health care providers and regulated social care services). To achieve this for regulated independent health care providers, amendments are required to regulations under the 2000 Act²⁷. This will be delivered separately to the Bill, and the cost and benefit of this will be presented in a separate Regulatory Impact Assessment.

Summary of costs:

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

Table 25 – Cost to Welsh Government

	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26 onwards
NHS Seconded (Table 14)	£ 38,200	£ -	£ -	£ -	£ -	£ -
Public awareness campaign (Table 15)	£ 22,700	£ -	£ -	£ -	£ -	£ -
Training e-learning modules (Table 16)	£1,600	£ -	£ -	£ -	£ -	£ -
Workshops to develop statutory guidance (Table 18)	£ 4,000	£ -	£ -	£ -	£ -	£ -
Opportunity cost of developing statutory guidance (Table 19)	£3,100	£ -	£ -	£ -	£ -	£ -
Opportunity cost of refreshing statutory guidance (Table 20)		£ -	£ -	£ -	£ -	£4,500*
Total	£ 69,600	£ -	£ -	£ -	£ -	£4,500

*cost occurring every five years.

Table 26 – Costs to NHS bodies

	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26 onwards
Opportunity cost - organisational awareness and training (Table 21)	£1,945,800	£ -	£ -	£ -	£ -	£ -
Opportunity cost for development of an implementation plan (Table 22)	£1,150,400	£ -	£ -	£ -	£ -	£ -
Opportunity cost for providers of notifying the service user (Table 23)	£77,300	£77,300	£77,300	£77,300	£77,300	£77,300
Legal advice from Legal and Risk Services (Table 24)	£6,000	£3,000	£3,000	£3,000	£3,000	£3,000
Total	£3,179,500	£80,300	£80,300	£80,300	£80,300	£80,300

Table 27 – Cost to NHS Shared Service Partnership Legal and Risk Services

	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26 onwards
Opportunity cost - Legal and Risk training (Table 17)	£5,700	£ 5,700	£ 5,700	£ 5,700	£ 5,700	£ 5,700

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

Benefits

Welsh Government:

335. Creating a statutory duty of candour for all NHS bodies will help create an integrated and whole system approach to candour – as described in paragraph 47. It will promote a culture of openness and improve the quality of care within the health service by encouraging organisational learning, avoiding future incidents.

336. By placing a duty on NHS bodies which brings the notification to a service user or their representative upfront, and not tied to the outcome of an initial

investigation to determine its appropriateness, the approach takes onus away from a member of staff to initiate a process of being candid and places it on the organisation to do so automatically – achieving cultural change.

337. It will help ensure the known barriers to disclosure will be addressed, for example fear, cultures of secrecy and/or blame, lack of confidence in communication skills, fear people will be upset and doubt the disclosure is effective in improving culture. Additionally, by placing the duty at an organisational level reduces any fear associated with institutional repercussions, legal liability, blame, or lack of accountability. Instead it will support the professional obligations which currently exist.
338. It supports the policy direction of an integrated approach across health and social care, aligning to the aspirations within *A Healthier Wales*⁵. Additionally, the proposed duty addresses the recommendations from the expert reviews and delivers the Government's manifesto commitment²⁴. This option therefore meets the policy intent.

Healthcare Inspectorate Wales:

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

NHS bodies:

340. Placing NHS bodies under a duty of candour strengthens existing systems to support a culture of openness and transparency by changing behaviours - addressing the current barriers which prevent candour. It will help achieve a position of consistent and routine practice whereby openness and transparency with service users in relation to their care and treatment, becomes a normal part of the culture across these bodies in Wales – eliminating fear and dispelling any cultures of secrecy and/or blame.
341. It will ensure patients are consistently informed when adverse events happen – reassuring them the issues that led to the event will be addressed and lessons learnt. It will also help to maintain public and patient trust in the health service and promote accountability for safer systems. It will also improve the quality of services by supporting the development of a learning culture across services and engage staff in improvement efforts.
342. The duty is not intended to be a punitive measure; instead it should be viewed as supportive to both patients and staff and be a further mechanism to drive

organisational learning and improvement. The duty is not intended to imply fault or blame but will improve the way a body responds when things go wrong unintentionally.

343. Nevertheless, bodies may perceive the additional detail required (if the candour procedure has been followed) in their publicly available annual reports to be potentially damaging to their reputation and therefore may focus efforts to ensure fewer avoidable incidences of harm occur. If this occurs, it will act as a mechanism of prevention, as bodies strive to improve quality and learning from mistakes. Additionally, it may lead to bodies to ensure the duty of candour has been triggered when an incident has occurred, helping achieve the desired culture change. Alternatively, it may however lead to bodies not honestly reporting compliance with the duty – something which may be picked up by HIW because, as explained earlier, bodies which are not acting in a candid way are likely to have wider governance issues which would raise concern for possible further investigations.
344. The inclusion of details of the duty within publication of the Annual Putting Things Right reports and Annual Quality Statements will continue to provide a system for continuous improvement across the sector by allowing bodies to learn from others - promoted and considered via existing patient experience networks. This is likely to lead to improved quality of care outcomes delivered by NHS bodies due to improvements in working practices and leading to a reduction in avoidable incidences.
345. Finally, it will provide those health and social services providers who commission care, especially across the border into England, with the benefit of having a duty of candour comparable to that in England. This will allow the comparison of data on incidents reported under the proposed duty, adding to a commissioner's evidence base when considering a suitable location for care.

Health and social care professionals:

346. Although individual health and social care professionals are required by their professional organisations to act openly and honestly, we want to ensure they are always supported to act in this manner by the organisations they work for. Professional obligations are crucial but insufficient by themselves to ensure a culture of candour, hence why the proposed duty is to be placed at an organisational level⁷⁷. This will provide staff with a safe and supportive environment to raise concerns and report incidents, and will separately provide the public with confidence they are being treated with respect and as partners in their own care – especially when things go wrong.
347. This option would therefore strengthen the existing systems in place to support openness and transparency. It would require NHS bodies to take action to

⁷⁷ Francis, R. Freedom to speak up [Internet]. 2015. Available from: NHS Resolution. Annual report and accounts 2017/18 [Internet]. NHS Resolution; 2018. Available from: 9. Health and Care Standards [Internet]. NHS Wales. 2019 [cited 3 April 2019]. Available from: <http://www.wales.nhs.uk/governance-emanual/health-and-care-standards>

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

Public:

348. As explained at paragraph 52, when something goes wrong, the way in which organisations deal with these situations becomes very important and can make a huge difference to people's experience and to their on-going relationship with their care provider. This option would maintain public and patient trust in the health service by ensuring that when an adverse outcome occurs, service users are informed, provided with an apology and offered support, and subsequently provided with feedback on investigations and the steps taken to prevent a recurrence. For the service user, they will experience the benefit of feeling that their concerns and distress have been acknowledged - reducing the trauma felt, confidence in the openness of the communication, and the timeliness and accuracy of the information provided.

349. It will also achieve a system wide approach to candour, as described at paragraph 61, providing a person with the assurance that should something go wrong with their care or treatment they will be dealt with in an open and honest way irrespective of whether they received care from the NHS, from a regulated provider of social care services or from a regulated independent health care provider.

Summary and preferred options

350. **Option 1** proposes no change to the current legislative framework. The introduction of Putting Things Right in 2011²⁰ embedded the principles of 'Being Open' in the Welsh NHS, resulting in a gradual shift towards more a co-productive partnership between patients and professionals. However we know barriers still exist, therefore keeping the status quo would miss out on a real opportunity to build on the success of Putting Things Right. Therefore this option does not meet any of the policy objectives.

351. **Option 2** would create a duty of candour on NHS bodies (LHBs, NHS Trusts, Welsh SHAs (including NHS Blood and Transplant in relation to the functions it exercises in Wales)) and primary care providers) which would:

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

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

353. Although there are costs involved in effectively delivering Option 2, the duty builds upon existing systems and process. For Welsh Government these are in relation to effectively communicating the duty. The main cost identified is for NHS bodies, which is the opportunity cost associated with undertaking the necessary training, however this cost is likely to be occurred irrelevant to the proposed duty as many staff would undertake alternative training of some sort as part of their required continuing professional development. In addition, the costs for NHS bodies are balanced by possible savings as a result of a reduction in the number of litigation claims, but this is difficult to quantify in advance of implementation.

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

CITIZEN VOICE BODY

OPTIONS

355. Two options have been identified and explored:

Option 1: do nothing; and

Option 2: create a new, independent body corporate which will represent the interests of the public in relation to both health and social services.

356. Costs identified within the two options are, where applicable, based on the methodology and assumptions set out within **Appendix B**.

357. The Appendix contains the evidence and calculations used to provide best estimates of costs, which where applicable are rounded to the nearest £100 and have been developed in partnership with key stakeholders. Time, where stated, refers to the number of working days and historic costs (where appropriate) have been uprated to reflect inflation in the intervening period.

Consideration of additional options

358. The option of retaining CHCs, amending their functions and conferring additional functions representing the interests of the public in relation to social services, was not considered a viable option as it would fail to address the fundamental drawbacks built in to the current CHC model as outlined in Option 1 – which includes their establishment as unincorporated associations. To establish them as anything other than unincorporated associations would require their abolition in order for them to be established as a body corporate which links very closely to Option 2. Therefore only two options are considered.

OPTION 1: DO NOTHING

Description

359. There would be no legislative change required under this option.

360. However, the “do nothing” option would not take account of the recommendations in various reports and reviews relating to CHCs which are referenced at paragraphs 92 to 98 which recommended changes to CHCs and included recommendations for a more fundamental review. The Longley Review³⁵ even recognised that any future arrangement that was introduced to replace CHCs could look at “...health services in the wider context of all public services to recognise the inter dependency of such services” which chimes with the recommendations in the Parliamentary Review⁴ and the aims of “A Healthier Wales: our plan for health and social care”⁵ to encourage greater integration of health and social services.

361. Significantly, this option would require the functions of CHCs and the CHC Board to remain as they are at present. Maintaining the current arrangement with CHC functions limited to health services would not be effective in delivering integrated citizen engagement in health and social services and would not meet the recommendations of the Parliamentary Review⁴ nor 'A Healthier Wales'⁵.
362. This option would also not resolve the difficulties that are inherent in the establishment of CHCs as unincorporated associations, unable to employ staff or enter into contracts and which require complex accountability arrangements to preserve their operational independence.
363. If the "Do Nothing" Option were to be followed, the seven CHCs would remain, as would the Board of CHCs and its volunteer members. The CHCs would continue to operate within their annual £3.935million budget (2018/19).
364. A full breakdown of the CHC expenditure for the previous financial year, 2017/18 is contained within their annual report⁷⁸. This budget included:
- CHC staff salaries - £2,915,8484;
 - Accommodation - £350,540;
 - Member expenses and training - £132,870;
 - IT support - £115,559;
 - Powys Teaching Health Board (tHB) hosting (HR and Finance support) - £102,628.

Costs

365. The following section provides a summary of the total costs incurred in the operation of the current CHCs in 2018/19 and provides a baseline against which to compare the relative costs and benefits of the preferred Option 2. A breakdown of the calculations used to determine the costs is included at Appendix B.

Table 28 - cost to Welsh Government for funding the CHC's

Welsh Government	Costs per annum
Annual CHC funding*	£3,934,600
Opportunity cost - staff administration (Table 45)	£89,000
Chair remuneration** (from March 2019)	£21,600
General recruitment costs - Board appointments (Table 46)	£3,000
Opportunity cost – Board appointments (Table 47)	£1,000
General recruitment costs – Volunteer members (Table 49)	£4,900
Opportunity cost - volunteer member recruitment (Table 50)	£9,600
Total	£4,063,700

* To increase in 2019/20 to reflect NHS pay deal – total amount to be confirmed

** Chair is to be remunerated at £150 per day up to a maximum of 12 days a month.

⁷⁸ Board of Community Health Councils. Board of Community Health Councils in Wales Annual Report [Internet]. Board of Community Health Councils; 2018. Available from: <http://www.wales.nhs.uk/sitesplus/documents/899/Board%20CHC%20AR%20English.pdf>

Table 29 – cost to voluntary organisations for recruiting CHC volunteer members

Voluntary organisations	Costs per annum
Opportunity costs – CHC volunteer member interviewing to assist Ministerial volunteer member recruitment (Table 51)	£2,500
Opportunity costs – CHC volunteer member recruitment (Table 53)	£1,800
Total	£4,300

Table 30 – cost to local authorities for recruiting CHC volunteer members

Local Authorities	Costs per annum
Opportunity costs – CHC volunteer member recruitment (Table 52)	£1,800

Benefits

366. This Option retains the status quo, consequently any additional benefits are extremely limited.

Welsh Government:

367. This option is the lowest cost of the two options. The main benefit arising from this option for Welsh Government would be in relation to the curtailment of further expenditure associated with Option 2. The current well understood arrangements for managing CHC appointments and the role of Welsh Government staff in administering the CHCs would continue. The establishment costs associated with creating a new body would not be incurred.

368. However, this option would not address the significant disadvantages, outlined within paragraphs 124 to 128, with maintaining the status quo particularly in relation to meeting the Welsh Government's policy direction in relation to maximising the integration of health and social services.

Community Health Councils:

369. For CHCs, there could be an unquantifiable personal benefit for existing individual members of staff and volunteer members. They would have the certainty of continuing to operate within their current roles and locations. They would continue to follow current well established procedures, and they would not be affected by the organisational change associated with Option 2.

370. This option would not allow for any change to the recruitment process for Ministerial appointments of volunteer members which are undertaken via the Public Appointment Process. The CHCs have reported the current requirements make it difficult to attract members who are sufficiently diverse and representative of the local community.

Local authorities and voluntary organisations:

371. For local authorities and voluntary organisations, the only benefit to retaining the status quo would be in the certainty provided by continuing to operate within the established processes for recruitment of CHC volunteer members.
372. A consequence of continuing current operations would be the inability of local authorities to realise the benefits that would result from Option 2 and the creation of a new Body which represents the voice of users of social services, providing valuable service user feedback, and which would supplement complaints advice and assistance services for adults who wish to use the statutory social services complaints procedure. Additionally, the current cost associated with the recruitment of CHC volunteer members would remain with local authorities and voluntary organisations, in comparison to Option 2 under which they would not incur this cost.

LHBs:

373. For LHBs the benefits arising from this option are the continuation of established working relationships with the CHCs.
374. This option however continues the current challenges associated with individual CHCs finding it difficult, due to their duty to represent the interests of people in the area for which they are established, to consider proposals for changes that have a regional or national impact.

Public:

375. The evidence shows^{35 21} there is a lack of public awareness around CHCs, therefore for the public retaining the status quo would deliver limited additional benefit. Instead the benefits of progressing Option 2 would be lost, in particular the opportunity to strengthen the citizen voice by establishing, for the first time, an independent body which can represent the interests of people nationally, regionally and locally and provide a complaints advice and assistance service across health and social services in an integrated way.

OPTION 2: CREATE A NEW INDEPENDENT BODY WITH A REVISED CONSTITUTION, MEMBERSHIP, AND FUNCTION – ENABLING IT TO OPERATE AT LOCAL, REGIONAL AND NATIONAL LEVELS – ACROSS HEALTH AND SOCIAL SERVICES

Description

376. The proposal is to create a new body ('the Body') which will represent the interests of the public across both health and social services and provide complaints assistance services in relation to both NHS services and certain social services as outlined in paragraph 106.
377. The Body will be a body corporate. The Body will have a board with a Chair and a deputy Chair and at least seven but no more than nine board members who

will all be public appointments made by the Welsh Ministers for a term of up to four years. Board members are eligible to serve a maximum of two terms, which gives a total maximum appointment term of 8 years.

378. The core functions of the Body will be as follows:

- a. to represent the interests of the public in health and social services by seeking the views of the public about health and social services;
- b. to make representations to LHBs, Trusts, Welsh SHAs and LAs about matters connected with the exercise of its functions; and
- c. to provide assistance to individuals with complaints made under existing complaints procedures relating to health and social services (excluding certain complaints relating to children where assistance is already arranged by local authorities).

379. In addition, the Body will be under a duty to promote awareness of its functions and prepare and publish a statement of its policy setting out how it proposes to promote awareness of its functions and how it will seek the views of the public.

380. The Body will set its own standing orders to regulate its internal procedures, employ its own staff and have the ability to lease premises.

381. There will be a duty on LHBs, Trusts, Welsh SHAs and LAs to:

- a. have regard to the representations made by the Body;
- b. promote the activities of the Body; and
- c. supply information to the Body.

Costs

382. In order to arrive at the costs associated with this option, we have worked on the assumption the Body will be established and fully operational from 1 October 2021. The assumptions and the calculations used to arrive at the costs are contained at **Appendix B** with relevant table and paragraph numbers included below for ease of reference.

383. There are three types of cost associated with this Option:

384. **Current CHC costs** - the current costs for Welsh Government, local authorities and voluntary organisations associated with continuing to operate the current CHCs, as set out in Option 1, until 1 October 2021. These would be incurred even if we did not pursue Option 2, but are included to illustrate the total costs during the period under consideration and when the costs will be incurred.

385. **Transition costs** - costs which relate to the resources required to undertake a programme of work to establish the new organisation ('transition costs'), and as such are not costs directly related to the operation of the organisation itself – these

will fall directly to Welsh Government and not be absorbed by the Body as part of any funding provided by Welsh Government.

386. **Operating costs** - any recurring costs incurred after 1 October 2021, both for Welsh Government and the Body, as part of routine business.

387. These costs are summarised below:

Current costs (until 1 October 2021)

Welsh Government:

Table 31 – current CHC cost to Welsh Government for funding the CHCs

Item	2019-20	2020-21	April 2021 - Sept 2021
Cost to Welsh Government (Table 28)	£ 4,063,700	£ 4,063,700	£2,031,900

Voluntary Organisations:

Table 32 – current CHC cost to Voluntary Organisations

Item	2019-20	2020-21	April 2021 - Sept 2021
Voluntary Organisations (Table 29)	£4,300	£4,300	£2,150

Local Authorities:

Table 33 – current CHC cost to Local Authorities

Item	2019-20	2020-21	April 2021 - Sept 2021
Local Authorities (Table 30)	£1,800	£1,800	£900

Welsh Government:

Transition costs (1 April 2019 - 1 October 2021)

Table 34 – transition costs associated with the Body

Item	2019-20	2020-21	April 2021 - Sept 2021
Implementation board (Table 54)	£0	£296,300	£435,300
Board appointments (Tables 56)	£0	£0	£16,600
Opportunity cost – Board appointments* (Table 57)	£0	£0	£9,500
Organisational development (Paragraph 567)	£0	£0	£10,000
Training (Tables 65 & 66)	£0	£0	£100,700
IT costs* (Table 68)	£0	£0	£2,130,000
Marketing (Paragraph 575)	£0	£0	£100,000
Total	£0	£296,300	£2,802,100

*Capital expenditure.

Operating costs (from 1 October 2021)

Table 35 – operating cost for the Body

Item	October 2021-March 2022	2022-23	2023-24 onwards
Opportunity cost - Welsh Government sponsorship (Paragraph 581)	£29,500	£59,000	£59,000
Board Appointments (Tables 56 & 57)	£0	£0	£6,500
Total	£29,500	£59,000	£65,500

The Body:

Table 36 – operating costs of the Body

Item	October 2021- March 2022	2022-23	2023-24 onwards
Chair and Board remuneration (Table 55)	£52,500	£105,000	£105,000
Staffing costs (Tables 58 & 63)	£1,668,900	£3,337,700	£3,337,700
Volunteer member costs (Paragraph 556)	£34,000	£67,900	£67,900
Corporate Services (Table 64)	£76,400	£152,800	£152,800
Training (Table 67)	£46,300	£92,500	£92,500
Accommodation (Paragraph 569)	£175,300	£350,500	£350,500
IT costs* (Table 69)	£260,000	£520,000	£520,000
Marketing (Paragraph 575)	£21,200	£42,300	£42,300
Total	£2,334,600	£4,668,700	£4,668,700

*A mixture of revenue and capital expenditure.

Summary:

388. A summary of the total costs outlined above in relation to this option (Tables 31-36) are broken down below to show a profile of this spend:

Table 37 – summary of costs

	2019-20*	2020-21*	April 2021 - Sept 2021*	October 2021- March 2022**	2022- 23**	2023-24 onwards* *
Welsh Governmen t	£4,063,7 00	£4,360,0 00	£4,834,0 00	£2,364,1 00	£4,727,7 00	£4,734,2 00
Local Authorities	£1,800	£1,800	£900	£0	£0	£0
Voluntary Organisatio ns	£4,300	£4,300	£2,200	£0	£0	£0

*includes the funding cost of the CHCs and the transition costs associated with establishing the Body (Tables 31 and 34) – this is a mixture of revenue and capital.

**includes the cost of funding cost of the Body (tables 35 and 36) and is a mixture of revenue and capital.

The below summary table set outs the additional total costs associated with establishing the Body (this option) compared to the total costs associated with Option 1 – these are broken down below to show a profile of this spend:

Table 38 – summary of additional costs

	2019-20	2020-21	April 2021 -Sept 2021	October 2021- March 2022	2022-23	2023-24 onwards
Welsh Government	£0	£296,300	£2,802,100	£332,300	£664,0000	£670,500
Local Authorities	£0	£0	£0	£-900	£-1,800	£-1,800
Voluntary Organisations	£0	£0	£0	£-2,200	£-4,300	£-4,300

389. The estimated costs stated above should be considered in line with the following caveats:

Recruitment of staff and volunteer members:

390. The Body will have the power to develop its own recruitment strategy and recruit its own staff and members. It will however ultimately be for the Welsh Ministers to approve the terms and conditions of remuneration, expenses, allowances and pensions for employees in accordance with paragraph 6 of Schedule 1 to the Bill. For the purposes of this option, it is assumed staff employed by the Body will, in broad terms be in “no worse a position” than the current CHC staff who are employed by Powys tHB.

Accommodation:

391. Although the costs of accommodation are based on actual costs the CHCs currently spend, the new body is expected to develop its own accommodation strategy and this may include having a network of smaller, more centrally located premises (in town or city centres) and also making use of community hubs and libraries etc. which are easier for members of the public to access. Additionally, new ICT, as described below, will allow for staff to work in a more agile manner, aiding their accessibility to the community. Following such an approach has the potential to generate cost-savings. However, these are decisions that the Body’s implementation board will make once established and it is not possible to pre-empt those decisions at the current time. Therefore, while we believe there is the potential for cost-saving to be made, our best estimate at this stage is that the current accommodation costs will continue. In making this assessment we have taken into consideration the additional staffing requirements outlined at paragraph

546 and we do not consider the increase in staff will necessitate increased office space.

Information and Communications Technology (ICT):

392. The costs for ICT are estimated based on twelve physical locations (the current number of CHC offices) which will require a full ICT refit. However, it is recognised, there are potential opportunities for reducing this cost and achieving significant savings from investing in IT and adopting agile working approaches, for example using community premises (such as Community Hubs) and central shared spaces leading to the Body requiring fewer or smaller permanent offices. It is however difficult to accurately estimate the exact potential for savings as the Body, unlike, CHCs will be able to enter into its own arrangements for premises.
393. The Welsh Government will incur initial capital outlay to set up a new and fit for purpose ICT system. This is necessary expenditure as the current IT system used by CHCs is not fit for purpose and has suffered due to a lack of investment. A paper produced by NHS Wales Informatics Service⁷⁹ in February 2019 into the CHC ICT infrastructure reported “as a minimum” £133,829 would be needed to be spent as a matter of urgency as the majority of the desktops and laptops used by CHCs across Wales have reached their end of life (73% are over 4 years old and 7% are over 10 years old). There are also upgrades needed due to the fact that the CHCs are currently using Office 2010 which will be unsupported by Microsoft from 2020. Therefore, even if we were not to pursue Option 2, it is clear that the current CHC IT system would need significant investment if it is to be fit for purpose in the future.
394. Even though the cost of a new ICT system and hardware is significant, having IT software and hardware that is fit for purpose is crucial to the effective operation of the Body as it is anticipated that the use of technology and an interactive website will allow the Body to reach a greater number of the people across Wales and will allow staff and volunteers from the Body to be able to take real time feedback from the public when attending events.
395. As with all technology, it will eventually become outdated and not fit for purpose. Based on advice from the Chief Information Officer of Abertawe Bro Morgannwg University Health Board, Chair of NHS Wales Assistant Director of Informatics Group, we have assumed a 20% capital technology refresh every 5 years and 25% of the original capital outlay as revenue for update and in-house maintenance of the Customer Relationship Management (CRM) system. Therefore, there will be an ongoing cost for the Body to maintain and, if necessary, replace both its hardware and software over time. This has been included in the forecast operating costs for the Body.

Corporate Services:

⁷⁹ NHS Wales Informatics Service [Internet]. NHS Wales Informatics Service. 2019 [cited 3 April 2019]. Available from: <http://www.wales.nhs.uk/nwis/home>

396. Currently the CHCs receive their annual funding from Welsh Government. This is issued to Powys tHB who provide it directly CHCs. The cost for the Health Board associated with this hosting arrangement is £102,628 and is paid to the Health Board from the CHC budget allocation - this includes providing the CHCs with corporate support for matters such as HR and Finance (including payroll and audit). The new Body will need to secure its own corporate support.
397. The Welsh Government Sponsored Body Unit is considering back office functions for Welsh Government Sponsored Bodies and is in dialogue with current Sponsored Bodies and colleagues to gain quantitative and qualitative efficiencies. Therefore where relevant, the work streams established as part of the implementation board will engage with the relevant parties to ensure the Body benefits from these arrangements. Therefore there may be savings associated with the corporate support costs estimated for the Body. However these costs will not be known until the aforementioned work is complete and are, therefore, currently unknown.

Welsh Government:

398. Based on estimated operating costs, set out in Table 36, the Body from 1 October 2021 is likely to require funding from Welsh Government circa of £4,668,700 per annum. This is an increase of £712,500 compared to the current CHCs operating cost plus the cost of remunerating the Chair of the CHC Board which, as per Table 28, amounted to £3,956,200 in 2018/19. When comparing annual budgets of other similar bodies in the UK, it is clear the Welsh Government already, under current arrangements, spends significantly more per head of population, ensuring the voice of the public is heard, than England, Scotland and Northern Ireland spend on their respective bodies. Spend by Governments in 2017/18 to deliver citizen voice functions are:

Table 39 – comparison of other Government bodies with Citizen Voice functions

	Government Spend 2017/18	Population (Mid year 2017) ⁸⁰	Cost Per Head £
Wales (CHC)	£3.9m	3.1m	£1.26
England (HW)⁸¹	£30.2m*	55.6m	£0.54
Scotland (SHC)⁸²	£2.7m	5.4m	£0.48
N. Ireland (PCC)⁸³	£1.6m	1.9m	£0.84

⁸⁰ National level population estimates by year, age and UK country [Internet]. Stats wales. 2019 [cited 3 April 2019]. Available from: <https://stats.wales.gov.wales/Catalogue/Population-and-Migration/Population/Estimates/nationallevelpopulationestimates-by-year-age-ukcountry>

⁸¹ Information provided by the Department of Health including costs for Healthwatch, Local Healthwatch and Aid allocation to the CQC

⁸² Healthcare Improvement Scotland. Annual Accounts - Financial year ended 31 March 2018 [Internet]. Healthcare Improvement Scotland; 2018. Available from: http://www.healthcareimprovementscotland.org/previous_resources/policy_and_strategy/annual_accounts_2017-18.aspx

⁸³ THE PATIENT AND CLIENT COUNCIL. THE PATIENT AND CLIENT COUNCIL ANNUAL REPORT AND ACCOUNTS FOR THE YEAR ENDED 31 MARCH 2018 [Internet]. THE PATIENT AND CLIENT COUNCIL; 2018. Available from: http://www.patientclientcouncil.hscni.net/uploads/files/585_8zfRvS.pdf

*This figure includes funding provided for Local Healthwatch via the Local Government Settlement and the Local Reform & Community Voices Grant which are part of wider pots of monies, which are not ring-fenced and can therefore fluctuate annually. It also includes monies paid to the Care Quality Commission (£2.6m).

399. Taking into account the projected costs for operating the Body at Table 36, it is anticipated that the cost per head of operating the Body will be £1.45.
400. Although the respective bodies do not exercise the same functions (in particular the Scottish Health Council only exercises functions in relation to Health) there is enough communality of functions between the new Body, the Patient and Client Council and Health Watch, to draw broad comparisons. The functions of the Citizen Voice Bodies in Scotland, N Ireland and England are set out at **Appendix C**.
401. The evidence in Table 39 suggests that considerably greater investment is already being committed in Wales to ensure the citizen voice is heard and represented. Although the implementation of Option 2 will further increase this expenditure, a new Body with revised constitution, membership and functions offers an opportunity to ensure that greater value for money is obtained for the investment.
402. In evaluating the options, taking account of the benefits described below, it is considered that the increased costs that would be incurred with the implementation of Option 2 are justified by the added value that a Citizen Voice Body that exercises functions across health and social services will bring to the public in Wales and to public bodies, such as LHBs, Trusts and local authorities.

LHBs, Trusts and Welsh SHAs

403. The Body will be under a duty to provide complaints advice and assistance to persons who wish to pursue a complaint under the existing NHS complaints procedure. CHCs currently provide complaints advice and assistance to adults and health boards are under a duty to provide or secure the provision of assistance to children who wish to make an NHS complaint.
404. It is not anticipated the creation of the new Body will lead to an increase in the number of complaints as the NHS complaints procedure is already extremely well publicised, the 2011 Regulations²⁶ require LHBs and Trusts to advise all complainants of the availability of complaints advocates to support them in pursuing a complaint and the number of complaints received are driven by factors other than the availability of support to bring a complaint. The Body is also to have the ability to make representations to LHBs, Trusts and Welsh SHAs about matters related to its health related functions. LHBs, Trusts and Welsh SHAs will be placed under a duty to have regard to the representations made by the Body. It is anticipated that this will be cost neutral for LHBs, Trusts and Welsh SHAs as they already engage heavily with the CHCs.
405. LHBs and Trusts already have close working relationships with the individual CHCs in their area and with the CHC Board. Significant amounts of time are spent by health bodies engaging with the CHCs (and vice versa). By way of example,

CHCs often attend Quality and Safety meetings of LHBs to feed back the patient perspective, LHB directors of planning sit as a member of CHCs' service planning committees, LHBs and Trusts engage heavily with CHCs in respect of proposed service change matters and CHCs can already make "representations" to LHBs and Trusts on matters relating to the health service in their area, albeit on a non-statutory basis and without the "duty to have regard" that will be introduced as part of the proposed new arrangement.

406. There is only one SHA in Wales, Health Education and Improvement Wales. It is not anticipated that giving the new Body the power to make representations to Welsh SHAs will increase the amount of time HEIW spends engaging with the Body – when compared to the time it currently spends engaging with the CHCs. HEIW does not provide services directly to service users and is not involved, in for example, service change consultations and so when compared with LHBs and Trusts it is not anticipated that it will have the same level of involvement with the new Body.

407. Even though we anticipate the new Body will have a higher profile than the CHCs, we do not consider that a rise in profile will result in a greater amount of time spent by health bodies interacting with the new Body. Rather, if the new Body has a raised profile and obtains feedback from a broader range of citizens to inform feedback, representations etc. this would simply provide a stronger evidence base for this work and provide even greater legitimacy to any representations that may be made. Therefore, it is not anticipated that placing LHBs, Trusts and Welsh SHAs under a duty to have regard to representations made by the Body will greatly impact on the time these bodies spend engaging with the Body.

408. LHBs, Trusts and Welsh SHAs will be under a duty to promote the activities of the Body. As highlighted at paragraph 575, the Welsh Government will fund a media campaign to launch the Body. It is expected that promotional and awareness raising materials will be developed and maintained by the Body and shared with LHBs, Trusts and Welsh SHAs. These bodies will then use these materials to raise awareness via their existing communication channels, such as their website, twitter feed, posters in public areas and on wards etc. LHBs and Trusts are already under a duty to publicise the NHS complaints procedure under the Putting Things Right arrangements so, for these organisations, this new duty can build on their existing work in this area resulting in no additional cost.

Local Authorities:

409. The establishment of the Body with the power to recruit its own volunteer members would relieve Local Authorities of their duty to undertake the appointment of councillors as CHC volunteer members, meaning a saving of the associated costs – covered in Tables 30 and 38.

410. Separately, the Body will exercise the function of providing complaints advice and assistance to persons in relation to certain social services complaints as set out in paragraph 106. Even though the Body will have the power to provide complaints advice and assistance in relation to these types of social services complaint, the Body will supplement the existing sources of advice and assistance

in keeping with the aim of the 2014 Act² to ensure people have greater voice and control over the care and support they receive by actively involving individuals in decisions about their lives, including when assessing and meeting needs.

411. The Welsh Government wrote to all local authorities asking what arrangements they currently have in place for providing complaints advice and assistance to persons who wish to pursue a complaint under the Social Services Complaints Procedures (Wales) Regulations 2014 and what the cost of those arrangements is. Different local authorities have different arrangements. Some provide complaints advice and assistance through the local authority complaints' officers, others refer persons who require assistance to voluntary organisations (such as Age Cymru) and others enter into arrangements with independent advocacy providers but combine such arrangements with arrangements for independent advocacy services that they are required to secure for children under the 2014 Act². Some local authorities utilise a combination of these approaches to meet the wide ranging needs of persons who ask for assistance in pursuing a complaint. Consequently, when asked, individual local authorities were unable to disaggregate the specific cost of independent complaints advice and assistance services for those utilising the statutory local authority social services complaints procedure.
412. As per the analysis in relation to NHS complaints above, it is not considered that the creation of a Body that will have the ability to provide complaints advice and assistance in relation to certain social services complaints will drive an increase in the number of complaints received by local authorities. The Social Services Complaints procedure is well established and publicised and, as with the NHS complaints procedure, the Social Services Complaints Procedure (Wales) Regulations 2014 requires local authorities to offer guidance and assistance to complainants on following the complaints procedure or on where such guidance might be obtained. There are already bodies which provide such complaints advice and guidance. Again as with the health sector, there are many factors which drive the number of complaints.
413. The Body will have the ability to make representations to local authorities about matters relating to its social services functions. Local authorities will be placed under a duty to have regard to the representations made by the Body. There will be a cost to local authorities associated with this however we have been unable to produce a reliable estimate of this cost. Therefore this cost is unknown.
414. In trying to estimate a cost, consideration was given to other pieces of legislation which contained the power to make 'representations', for example the 2015 Act¹ and the Public Services Ombudsman (Wales) Act 2005. Consideration was given to the regulatory impact assessments associated with these pieces of legislation and discussions were held with relevant Welsh Government policy leads. In addition, contact was made with the Future Generations Commissioner's office, the Welsh Local Government Association, a local authority and the Swansea Public Services Board, seeking their views on the most appropriate way to quantify a realistic cost. The responses received demonstrated a mixture of arrangements across organisations, with no evidence presented which could reliably be extrapolated as an estimated cost for all of the 22 local authorities in Wales. This

was mainly due to the fact that responses indicated that the handling of queries or representations is dependent on their nature and complexity, with the opportunity cost of responding varying significantly from case to case. For example, representation could take anything from one member of staff devoting minutes to a response compared to a more complex case which would require significant work, involving different staff grades. Due to the number of unknowns, a range of costings has not been provided as this would be so broad that it would not provide value and would be misleading.

415. Consideration was also given to mirroring the current costs associated with representations being made by the current CHCs to LHBs and Trusts. However it was considered unrealistic to expect that any such costs could effectively be directly mirrored across the local authorities in any consistent way as although the current CHCs are heavily engaged with LHBs and Trusts these links, which are above their statutory requirements, have developed as a result of long standing relationships. Additionally, LHBs and Trusts have different governance and accountability arrangements.
416. Local Authorities will be under a duty to promote the activities of the Body. However, as set out above in relation to LHBs and Trusts this is not anticipated to be a significant cost. As highlighted at paragraphs 575-577, the Welsh Government will fund a media campaign to launch the Body. Promotional and awareness raising materials will be developed and maintained by the Body and shared with local authorities. Local authorities will then use these materials to raise awareness via their existing communication channels, such as their website, twitter feed, posters in public areas etc. They could also distribute promotional materials to social care providers with whom they enter into arrangements for the provision of social care services.

Voluntary Organisations:

417. The establishment of a new body with the power to recruit its own volunteer members would relieve Voluntary Organisations of their duty to appoint CHC volunteer members, meaning a saving of the associated costs – covered in Tables 29 and 38. It is anticipated many of the current voluntary members will continue to contribute to the work of the Body as voluntary members, but these would need to be recruited by the Body upon its establishment.
418. It is anticipated that some of those who currently receive complaints advice and assistance will in future go to the Body for advice and support and voluntary organisations will have the option of referring people needing advice support to the Body. This has the potential to reduce pressure, on voluntary organisations that currently provide complaints advice and assistance to people wishing to bring a complaint about social services. Additional capacity to deal with social services complaints could be staffed or procured by the Body but, for the purposes of the RIA, we have costed additional capacity on a staffed basis.

Benefits

419. There are a number of significant benefits to creating a new, independent, body corporate which will represent the interests of the public in relation to both health and social services. The principal advantage is that it will provide the public with a body which is able to represent their views across these two key sectors.
420. Under current arrangements, there is no single body dedicated to representing the citizen voice in relation to social services. The CHCs' statutory functions are limited to representing the interests of the population in their district in matters related to the health service. Therefore, they cannot represent the citizen voice in relation to social services.
421. As explained in paragraphs 96-99, we are moving towards a system where health and social care services will increasingly be delivered in an integrated way. The *Parliamentary Review*⁴ recommended seamless integration of health and social care services alongside more integrated citizen engagement, and this is reflected in the aims of *A Healthier Wales*⁵, which sets out the goal of ensuring that citizens are placed at the heart of a whole system approach to health and social care services in Wales.
422. The benefits of this integrated approach were presented at length by the *Parliamentary Review*⁴. In brief, 'joining up' care by organising it effectively around the needs of the service user, reduces the number of assessments and visits to different providers, reduces delays in provision of services, results in better clinical and non-clinical outcomes, and results in greater levels of satisfaction for service users. A key feature of the integrated approach is accessible, integrated care by the right professional with the right skills at the right time, provided closer to home, with access to specialist treatment when necessary. Given the move towards more integrated services, it makes sense for there to be a single body tasked with representing the interests of citizens across integrated health and social care systems.
423. A policy priority for the Welsh Government is to pursue policies to drive the greater integration between health and social services. However policy cannot be developed in isolation and therefore input from the public is crucial. Although NHS staff and social care workers provide an invaluable perspective when considering what constitutes a good quality service, service user engagement is imperative to ensure the needs and expectations of individuals using the services are heard by service providers. It is therefore considered, from a Welsh Government policy perspective, that the Body needs to be adequately funded to enable it to effectively enhance the views and voice of the people of Wales in relation to health services and social services..
424. As set out at Table 36, part of the investment will be to commit funding to enable the Body to publicise the services it offers to ensure that the Body has a higher profile amongst members of the public than the current CHCs. This will be vital to improving access to the Body and encouraging people to feed back their experiences of health and social services. Increased understanding of, access to and use of the Body is key to ensuring that the Body represents value for money

both in terms of services offered to the public and in terms of service improvement effected as a result of feedback to public authorities such as LHBs, Trusts and local authorities that are responsible for the provision of health and social services. A body which is adequately resourced to deliver the aspirations set will ensure it becomes a key, invaluable, source of information in relation to service users' views of the health and social services systems.

425. The Body's core functions require it to represent the interest of the public in respect of health and social services by seeking the views of the public and in turn make representations to LHBs, NHS Trusts and local authorities, and for these bodies to be under a legal duty to "have regard" to the representations made by the Body. CHCs act to gather local intelligence on service user concerns and suggestions in relation to health only. Given the planned greater integration between health and social services, this Option provides a solution by creating a body which has the ability to represent the views of public along pathways of care between health and social services and supporting the statutory partnership boards in assessing the health and social care needs of the population and shaping effective delivery within their boundaries.
426. Establishing the Body with a national remit, but with local representation, will enable the Body to effectively represent views at a local level whilst the national element, using information it has gathered locally and regionally, will enable it to drive thematic, national learning and improvement for the benefit of service users. This can promote good practice and lessons learnt - improving the quality and value for money of services, influencing national strategy, policy and operations.
427. Another of the Body's core functions will be to provide assistance with NHS complaints relating to both adults and children and certain social services complaints. This means the functions of the Body in this key area are strengthened when compared to those currently exercised by the CHCs. For the first time there will be a public body that is able to provide service users with complaints advice and assistance in relation to all NHS complaints and a significant number of social services complaints. It is considered that this is a significant step forward at a time when a greater integration between health and social services is being actively pursued. As set out in paragraph 107, the Body will not provide complaints advice and assistance to children who have a statutory right to complaints assistance under the 2014 Act² in order to avoid duplication.
428. Additionally, maintaining the status quo (Option 1) would mean the continuation of the significant difficulties that are inherent with the current CHCs and would not deliver the potential benefits associated with creating the Body (Option 2). A detailed account of how these benefits are expected to be achieved and who is expected to benefit is provided below but, in brief, these benefits include:
- Establishment - removing any perceived conflict of interest associated with being hosted by Powys tHB, ensuring it can operate with independence;
 - Public representation - removing restrictions to allow the Body to deliver its functions in an integrated way across both health and social services;

- Functions - refocusing the positioning of a Citizen Voice Body to remove any duplication of functions (such as inspection) that are present in the current healthcare system; and
- Member recruitment - removing the current restrictions and burdens associated with the recruitment of volunteer members.

Establishment:

429. As highlighted in paragraph 90, CHCs are established as unincorporated associations, meaning they do not have the powers associated with being established as legal bodies in their own right which has required them to be “hosted” by Powys tHB. In practice this means:

- CHCs are unable to employ staff. Consequently all CHC staff are employed by Powys tHB;
- backroom services such as finance, HR, IT etc. are provided to CHCs by Powys tHB, meaning the CHCs are required to use the NHS jobs site for recruiting staff, and the CHCs’ websites are hosted by the NHS which is disadvantageous in terms of the public’s perception of their independence;
- they are unable to enter into contracts for goods or services, which has again necessitated all such contracts being entered into on their behalf by the NHS;
- all leases for the Board and local CHC accommodation are negotiated on behalf of the CHCs by the NHS and the contracts are entered into by the Welsh Ministers; and
- due to their hosted status, complex accountability arrangements have been required to enable CHCs and the Board to perform their functions and operate independently of their host organisation and the Welsh Government.

430. When the CHCs were established, over 40 years ago, it was considered acceptable for them to be established as unincorporated associations; dependent upon a “host” body to be able to operate. However, given the increased importance and emphasis that is now placed on citizen voice and citizen engagement, it is considered a body representing the interests of the public needs to be independent and should not be hosted by a NHS body (or any other public body) as the potential for conflicts of interest are too high. Consequently, when viewed in light of current expectations it is considered an unincorporated association model is no longer appropriate.

431. Option 2 would address these difficulties by creating a Body which is an Executive Welsh Government Sponsored Body (“WGSB”) – described at **Appendix D**. By establishing the Body as a WGSB it will ensure the Body is as independent as possible from the Welsh Ministers. It will not be ‘hosted’ by another organisation, nullifying any concerns regarding conflicts of interest when an organisation acts as host to a body that is charged with representing the interests of the public in the delivery of its own functions. It will also mean that the Body will be a ‘body corporate’, removing the practical difficulties associated with the way in which CHCs are currently established and operate.

432. The Body’s Chief Executive will be appointed as its “Accounting Officer” (as set out in Schedule 1 of The Bill). This will encourage the Body to work

autonomously in making corporate decisions and managing the operation and resources of the body in delivering its objectives.

433. As is the case with all Welsh Government Sponsored Bodies, Ministers will set out the remit of the Body, including priorities to be pursued by the body during the coming year, and establish a reporting framework for the Body.

Public representation:

434. The legislation that establishes CHCs requires them to represent the public's interest in the health service "in their district", which is not reflective of an increasingly integrated approach to service delivery. The CHCs' legal duty to represent the interests of people in their geographical area causes challenges when cross boundary working or service change is proposed as, constrained by the current legislative framework, it can be difficult to look at regional and national issues.

435. This Option, resolves this issue by creating a national body which will help to ensure consistency in the arrangements and services provided locally across Wales and facilitate cross-boundary working.

436. The Body will be established so LHBs, Trusts and Local Authorities must have regard to the representations made by the Body i.e. they must have regard to representations made by the Body on matters such as proposed changes to services. This will ensure the citizen voice is brought to the attention of those public bodies that provide or commission health and social services and the citizen's voice is at the heart of a whole system approach to health and social services in line with the aims of 'A Healthier Wales'⁵. This gives the public a major voice in identifying issues that are important to them, issues of concern but also in identifying areas of good practice.

Functions:

437. As explained in paragraphs 92 to 98, a number of reports and reviews into CHCs have been undertaken on how best the citizen voice may be represented more widely in Wales in relation to health. This option presents an opportunity to consider what functions a Citizen Voice Body needs to be able to perform to be an effective voice for the public in relation to both health and social services and to remove any duplication of functions that is present in the current system.

438. The creation of the Body, with revised functions to those of the existing CHCs, will help focus activities on representing the citizen voice, changing the focus away from inspection to one of engagement allowing for the creation of a higher public profile. This reflects the recommendations of the OECD Review¹¹ which provided:

'The potential for CHCs to engage with the local communities and advocate for patients around their concerns seems clear. The value of some of their other functions, notably inspections and onsite scrutiny of health care is less clear. It would seem more effective for the CHCs to focus their activities on reflecting the patient voice and engaging with other scrutiny bodies in Wales....'

439. The Body will also be able to provide assurance and impetus for LHBs, Trusts and local authorities to improve the way they engage with, and work in partnership with, citizens in the planning and delivery of services.

Member recruitment:

440. For Welsh Government, the recruitment of CHC volunteer members has grown increasingly unstable in recent years as it has become difficult to attract sufficient people to the role. Anecdotal feedback relayed to Welsh Government and the CHCs suggests many people find the public appointments process off-putting, and it difficult to commit to the required 3-5 days per month. The current system is entirely reliant on the recruitment processes undertaken by third parties, namely the Welsh Ministers, local authorities and voluntary organisations and the retention of these volunteer members.
441. Additionally, whilst CHC volunteer members are appointed on the basis of their skills and their ability to represent patients, the membership is not diverse or representative of local communities. This is despite concerted efforts in recent years from all involved in the recruitment process, including the CHCs themselves, to encourage applications from underrepresented groups.
442. This option addresses these drawbacks, and creates a Body which has the power to recruit its own volunteer members, not relying on others, and free of the constraints presented by the public appointments system. It provides the Body with flexibility allowing it to act in a manner which will attract a greater number of potential volunteer members, helping to create a diverse profile which is more representative of users of health and social services - allowing the Body to gain better informed citizen system wide views.

Care Inspectorate Wales and Healthcare Inspectorate Wales:

443. There was broad consensus following the White Paper consultation²⁵ that the inspectorates and the citizen voice body should not form part of one single body. However, CHCs have the function of inspecting premises where NHS services are provided. There was broad agreement following the White Paper consultation²⁵ a potential new Body should not have this function as it duplicates the role of Healthcare Inspectorate Wales³⁹ and neither the staff nor the volunteer members of the CHCs (who would transfer across to the Body) are trained inspectors.
444. However, it is recognised even though the new Body and the inspectorates (CIW³⁸ and HIW³⁹) will exercise different functions, their functions are complementary and there will be benefits to them working together.
445. It is considered the development of a MOU to shape the relationship between the inspectorates and the new Body would be an appropriate mechanism to set out collaborative working arrangements and to maximise opportunities for a strong citizen /lay involvement going forward and to ensure there is a mechanism for feeding the citizen voice into the inspectorates. This collaborative approach will help focus resources within the respective bodies, allowing for a comprehensive,

evidence based, picture of the citizen experience. This will be of benefit to the new Body and to the inspectorates.

LHBs and Trusts:

446. This Option creates benefits for LHBs and Trusts. Firstly, it would help the NHS respond to the Parliamentary Review⁴, which states *“New models of care must be co-designed and co-developed with the public and users of care alongside front-line health and social care professionals,....”*
447. Secondly, establishing the Body as WGSB (as opposed to the CHC unincorporated association model) will ensure it is as independent as possible from the Welsh Ministers, LHBs, Trusts and local authorities which leads to fewer potential conflicts of interests when the Body is representing the views of the public.

Local Authorities:

448. These proposals build on the principles of the 2014 Act² to place individuals and their needs at the centre of their care, giving individuals a voice in, and control over, achieving their well-being outcomes; and to encourage individuals to become more involved in the design and delivery of services through co-production. The 2014 Act², together with the 2016 Act⁹, reinforce the importance of the voice of individuals in supporting the use of effective evidence, to inform the continuing cycle of service improvement through planning, commissioning and delivery of health and social care services including requirement to formally and routinely engage with citizens.
449. The Citizen Voice Body, in discharging its functions, will amass feedback and opinions about both health and social services across Wales. This information will form part of the suite of evidence local authorities and local health boards consider as part of their statutory duties to assess the health and social care needs of their population. This in turn supports the process of putting people at the centre of service provision and building services around the citizen.

Public Service Boards:

450. CHCs have the status of “other partners” on Public Services Boards³⁶ (PSBs) under the 2015 Act¹. There is a PSB for each local authority area and consists of the relevant local authority, local health board, fire and rescue authority for the area as well as the Natural Resources Body for Wales. PSBs must seek the advice of their “other partners” and involve them in the activities of the Board as it considers appropriate.
451. The Body will replace CHCs as one of the “other partners” to the PSB. There are benefits arising from this option for PSBs, in that it would have a new body which would be able to provide comments on Public Service Board Action Plans from both a health and social services perspective, adding to a greater integrated focus. There is also a benefit to the Body as it is a valuable forum for ensuring the views of the citizen in relation to matters relating to health and social services are made known to the PSBs when they exercise their functions.

Regional Partnership Boards:

452. The purpose of RPBs is to drive the effective delivery of seamless care services between social services, health, the third sector and other partners.
453. Boards have been required to produce population assessments to identify the level of care and support needs in their regions and area plans to respond to that need (under sections 14 and 14A of the 2014 Act²). It is proposed to amend the Care and Support (Area Planning) (Wales) Regulations 2017 and the Care and Support (Population Assessments) (Wales) Regulations 2015 to require partnership boards to consult with the Citizen Voice Body in the preparation of these assessments and plans.
454. The Body will have a key role in supporting the RPBs by ensuring the population assessments are continually informed by information gathered by the Body on the views of the public.

Voluntary organisations:

455. As explained in paragraph 418, the Body may choose to procure additional capacity to deliver services that voluntary organisations may wish to bid for. Whilst this will have the obvious benefit of increasing a voluntary organisation's revenue and help sustain the voluntary sector, it could also potentially provide wider benefits for both the Body and the voluntary organisations, for example, by discovering a wider network of volunteers, promoting its work to help to create a sustainable, more diverse and possibly higher quality pool of volunteer members for both parties.

Public:

456. The Body will strengthen the current arrangements for the benefit of people by ensuring a whole system approach when inputting the public's views. Creating a single, dedicated, national body that operates in relation to both health and social services and at national and local levels will create a stronger voice for the citizen in issues that apply across geographic and organisational boundaries. It will remove artificial barriers and recognises the increasing integration in the way services are delivered.
457. The creation of a Body, which is recognised by and engaged with the public, provides the opportunity to refresh the offer in terms of public involvement with the development and delivery of health and social services. Through its diverse volunteer membership it will be able to respond to the widest possible range of views and experiences, enabling it to listen to and in turn accurately represent the local community leading to patient centred services, more closely aligned to the needs of those who use them.

SUMMARY AND PREFERRED OPTION

458. Whilst the costs for Option 2 are greater than those for Option 1, so are the benefits.
459. Creating a new, independent body would fully meet the policy objective of creating a citizen voice body which is 'fit for the future', that has responsibility for representing the citizen voice in both health and social services across Wales and which meets both the recommendations of the Parliamentary Review⁴ and the aims set out in A Healthier Wales⁵. The refocussing of the functions of the new Body away from inspection and onsite scrutiny of services removes duplication that is inherent in the current arrangements and takes account of the views expressed by the OECD¹¹ in their Review of Health Care Quality in the United Kingdom.
460. Consequently, it is considered the increased costs associated with the implementation of Option 2 are justified by the added value a Citizen Voice Body that exercises functions across health and social services would bring.
461. Option 1 proposes no change to current arrangements, with CHCs having no remit to represent the voice of the public in social services. It is therefore clear this option does not deliver the policy intent of having a single body that can represent the citizen voice across health and social services. Keeping the status quo with Option 1 also means CHCs continue as unincorporated associations hosted by a NHS body which, as set out earlier, is now considered to be an outdated model as current thinking is that a body that represents the voice of citizens should not be hosted by a body which provides public services. Therefore Option 1 means we would lose the opportunity to reform part of the health and social services system where it is generally agreed change is needed.
462. Option 2, the preferred option, would however allow for the representation of the citizen voice to be provided in a more integrated fashion, aiming to provide a seamless, person centred experience, along a pathway which encompasses health and social services.

NHS VICE CHAIRS

463. Two options have been identified and explored in the development of this Bill:

Option 1: Do nothing;

Option 2: Amend the NHS (Wales) Act 2006 to mirror the position of Vice Chairs for LHBs for NHS Trusts, enabling the Welsh Ministers, if they consider it appropriate, to appoint a Vice Chair to the board of an NHS Trust.

Option 1 – Do nothing

Description

464. This option would involve the continuation of the existing position under which NHS Trusts have the power to appoint a Vice Chair from the existing Independent Board members to allow the proceedings of the Trust to be conducted in the absence of the Chair. This differs from the position for Local Health Boards (LHBs). The Welsh Ministers have powers to appoint a Vice Chair to a LHB with LHB Vice Chairs having responsibilities beyond deputising in the absence of the Chair.

Costs

465. There are no new or additional costs attached to this option.

466. NHS Trusts are currently required to pay Chairs and Independent Members remuneration and allowances at an amount determined by the Welsh Ministers. As set out above, currently the Vice Chair role is undertaken by an existing Independent Member. Below is a list of the current rates of remuneration for independent members on the NHS Trusts Boards.

Table 40 – Current rates of remuneration for Independent Members on NHS Trust Boards.

Remuneration for NHS Trust Independent Members			
NHS TRUST	POST	REMUNERATION	TIME COMMITMENT
Public Health Wales	Independent Member	£9,360	4 days per month
Velindre	Independent Member	£9,360	4 days per month
Welsh Ambulance Services	Independent Member	£9,360	4 days per month

Benefits

467. Doing nothing would change nothing. Currently NHS Trusts have the power to appoint a Vice Chair to the board from the existing Independent board membership, but this results in an increase in nominal time commitments on an existing Independent Board Member. By doing nothing this would continue and may negatively impact on the Independent Member undertaking the role as well as undermine the benefits of a separate Vice Chair position on the board.
468. Doing nothing would not involve additional costs, whereas the alternative option would require additional remuneration to be paid by NHS Trusts to a Vice Chair role on the board. This would need to be balanced against the benefits of option 2.

Option 2 – Amend the NHS (Wales) Act 2006 to enable the Welsh Ministers, if they consider it appropriate, to appoint a Vice Chair to the board of an NHS Trust

Description

469. This option will enable the Welsh Ministers, if they consider it appropriate, to appoint a Vice Chair to an NHS Trust. The most straightforward way of achieving this option is to amend the NHS (Wales) Act 2006 so that NHS Trusts are placed in the same position as LHBs.

Costs

470. If a Vice Chair is appointed to the board, an NHS Trust will be required to pay the Vice Chair remuneration and allowances of an amount determined by the Welsh Ministers.
471. If Option 2 is selected, there are two potential ways of implementing it - either by the Vice Chair replacing one of the existing Independent Board Members or as an additional Independent Member appointment. If the introduction of a Vice Chair post were to replace an existing Independent Member post, the remuneration level of the new post would be partly offset against the remuneration level of the previous post. In engaging with NHS Trusts on the rates and time commitment, they did set out a preference for the Vice Chair role being an additional appointment. Should a decision in the future be made for the Vice Chair role to be in addition to the existing number of Independent Members, the costs would be a recurring additional cost for NHS Trusts. Both scenario costs are reflected in Table 42. Any changes to the size of NHS boards, however, needs to be considered on a whole system basis and proposals would be subject to further consultation and require amendments to the National Health Service Trusts (Membership and Procedure) Regulations 1990.
472. Any appointment by the Welsh Ministers of a Vice Chair to a NHS Trust would be comparable to appointment of a Vice Chair to a LHB. Below is a list of the current tenures, remuneration rates, and time commitments relating to the Vice Chair role across the seven LHBs in Wales.

Table 41 – Current Vice Chair tenures, remuneration rates, and time commitments relating to the Vice Chair role across the 7 LHBs in Wales.

Remuneration rates for Local Health Board Vice Chairs				
HEALTH BOARD	TENURE	REMUNE- RATION	TIME COMMITMENT	SPECIFIC RESPONSIBILITIES
Swansea Bay University Health Board – Vice Chair	4 years (maximum 8 years)	£56,316 per annum (band 4)	13 days per month	<ul style="list-style-type: none"> • Deputise for the Chair in their absence. • Provide strong, effective and visible leadership, across primary, community, mental health and learning disability services. • Chair the Mental Health Act Committee of the Board. • Work effectively with community and professional partners. • Support the Health Board's performance management processes. • Undertake an external ambassador role.
Aneurin Bevan University Health Board – Vice Chair	4 years (maximum 8 years)	£56,316 per annum (band 4)	13 days per month	
Betsi Cadwaladr University Health Board – Vice Chair	4 years (maximum 8 years)	£56,316 per annum (band 4)	13 days per month	
Cardiff and Vale University Health Board	4 years (maximum 8 years)	£56,316 per annum (band 4)	13 days per month	
Cwm Taf Morgannwg University Health Board	4 years (maximum 8 years)	£47, 736 per annum (band 3)	13 days per month	
Hywel Dda University Health Board	4 years (maximum 8 years)	£47,736 per annum (band 3)	13 days per month	
Powys Teaching Health Board	4 years (maximum 8 years)	£30 – 35k per annum (band 2)	13 days per month	

473. Remuneration rates are determined by the Welsh Ministers. The current remuneration rates for Vice Chairs on LHB Boards in the NHS in Wales are banded, providing rates between £34,788-56,316 for a time commitment of 13 days per month. Members are regarded as holders of an office for tax and National Insurance purposes. All remuneration relating to the appointment is taxable and Pay As You Earn (PAYE) in respect of income tax and National Insurance Contributions will be deducted at source. This appointment is non-pensionable.

474. Currently, the NHS Trusts Chair and Independent Members receive band 2 level remuneration. In a Vice Chair role this would be equivalent to the Vice Chair role at Powys, receiving £30 – 35k per annum.

475. Responses to the consultation from NHS Trusts suggested a nominal time

commitment of 8 days for Vice Chairs of NHS Trusts, with remuneration paid on a pro-rata basis. At band 2, this would result in remuneration of approximately £18,461. However, it is envisaged that NHS Trusts will be provided the option of recruiting up to a time commitment of 13 days, in order to provide flexibility, when necessary, to balance resources against contemporary requirements of the NHS Trust board.

476. The public appointments of Chairs, Vice Chairs, and Independent Members are governed by Regulations, which provide that each appointment must last no longer than four years⁸⁴, with a maximum period of any one person holding the same role for a maximum of eight years⁸⁵. The cost of advertising a post under the public appointments process is estimated to be at £750. Six of the Independent Members posts across the three Trusts (two in each) end four year tenures in Spring 2020. Should the Vice Chair role replace an existing Independent Member role, the overall costs of running the public appointments process would not be impacted/ would remain the same.

477. Below is an illustration of the potential costs for taking forward this option.

⁸⁴ The National Health Service Trusts (Membership and Procedure) Regulations 1990, Regulation (7)(1)

⁸⁵ The Public Health Wales National Health Service Trust (Membership and Procedure) Regulations 2009, Regulation (14)(3)

Table 42 – Potential costs associated with option 2

Option 2 – Cost Summary			
ACTIVITY	NEW & RECURRING COSTS	TIMING	BUDGET HOLDER
Remuneration Levels should Vice Chair role replace an existing Independent Member	<p>Band 2 level remuneration at 13 days time commitment = £30-35,000</p> <p>£30-35,000 offset against £9,400 (IM remuneration replacement) = £20,600-£25,600</p> <p>Pro-rata on basis of 8 days time commitment = £18,500)</p> <p>£18,500 offset against £9,400 (IM remuneration replacement) = new recurring costs of £9100</p> <p>New and recurring costs could fluctuate between approximately £9,100 and £25,600, for each NHS Trust, according to the nominal time commitment. Across all three NHS Trusts costs would range from £27,300 and £76,900.</p>	Annually.	NHS Trusts
Remuneration Levels should Vice Chair form an additional board member	<p>Band 2 level remuneration at 13 days time commitment = £30-35,000</p> <p>Band 2 level remuneration at 8 days time commitment = £18,500-21,500</p> <p>New and recurring costs could fluctuate between approximately £18,500 and £35,000 for each Trust, according to the nominal time commitment. Across all three Trusts costs would range from £55,500 to £105,000.</p>	Annually	NHS Trusts

Benefits

478. The main benefit this option would have over option 1 is that it would remove the limitations of the current position which only enables a NHS Trust to appoint a Vice Chair from its existing Independent Members. The current position is reliant on the existing Independent Members having the available time to fulfil the role of Vice Chair and the appropriate skills to deputise for the Chair.

479. The Welsh Government recognises the importance of the Vice Chair role as

separate to that of the Chair and the influence this has on a board's organisational effectiveness and governance, by having a Vice Chair:

- Playing a full and active role in the governance of an organisation, providing opinion and challenge and support to the board on key issues;
- Contributing to the work of the board based upon independence, past experience and knowledge, and ability to stand back from operational management;
- Contributing and accepting corporate decisions to ensure a joined up, robust and transparent decision making process by the board;
- Further strengthen the Independent Membership capability and act as sounding board for the Chair.

480. Additionally, appointment to a position with a defined role and greater time commitment may lead to widening the application pool and interest from candidates with Ministers able to clarify a different and more appropriate skill set within the job description.

481. The benefits of a Vice Chair position on a board has been demonstrated in respect of LHBs where Vice Chairs have specific roles and responsibilities beyond that of deputising in the Chair's absence. Currently, the Vice Chairs of LHBs meet as a group on a monthly basis, and hold quarterly meetings with Welsh Ministers. Extending the Vice Chair role to NHS Trusts will thus enable further collaboration between boards and enhance dialogue and shared-learning on a national scale.

SUMMARY AND PREFERRED OPTION

482. Option 2 is the preferred option as this will enable the Welsh Ministers, where appropriate, to appoint a Vice Chair to an NHS Trust. This will require amendment of the NHS (Wales) Act 2006. Although this will result in a cost increase this will allow for a defined role for Vice Chairs and for responsibilities to be shared between Chairs and Vice Chairs. This clarity will improve the governance arrangements for NHS Trusts, leading to efficiencies in leadership, with a view to impacting positively on service quality standards and improvements for patient experience.

483. While option 2 makes provision for a power to enable the Welsh Ministers to appoint a Vice Chair of NHS Trusts, it will under current arrangements replace an existing independent member. As noted in paragraph 471 changes to overall board size and composition of NHS bodies needs to be considered on a whole system basis. A wider review of NHS Board membership and composition is being undertaken and changes to the regulations under secondary legislation will be subject to its own, separate, Explanatory Memorandum and Regulatory Impact Assessment. However, the costs included in the summary costs for this RIA (at Table 43) illustrate the full range of costs including the scenario of a Vice Chair forming a new additional board member.

SUMMARY OF COST ESTIMATES

The below table contains a summary of the preceding analysis and cost estimates together to show the cost to the different parties of the Bill as a whole:

Table 43 – summary of estimated costs

Costs	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
Welsh Ministers						
Duty of Quality	£200	£0	£0	£0	£0	£0
Welsh Government						
Duty of Quality	£59,500	£1,900	£1,900	£1,900	£1,900	£10,200
Duty of Candour	£69,600	£0	£0	£0	£0	£4,500
Citizen Voice Body	£296,300	£3,134,400	£664,000	£670,500	£670,500	£670,500
Total - Welsh Government	£425,400	£3,136,300	£665,900	£672,400	£672,400	£685,200
NHS Bodies						
Duty of Quality	£992,200	£0	£0	£0	£0	£0
Duty of Candour	£3,179,500	£80,300	£80,300	£80,300	£80,300	£80,300
Duty of Candour – Legal and Risk	£5,700	£5,700	£5,700	£5,700	£5,700	£5,700
Vice Chair - Minimum	£27,300	£27,300	£27,300	£27,300	£27,300	£27,300
Vice Chair - Maximum	£105,000	£105,000	£105,000	£105,000	£105,000	£105,000
Total - NHS Bodies - Minimum	£4,204,700	£113,300	£113,300	£113,300	£113,300	£113,300
Total - NHS Bodies - Maximum	£4,282,400	£191,000	£191,000	£191,000	£191,000	£191,000
Other bodies						
Voluntary Organisations	£0	£-2,200	£-4,300	£-4,300	£-4,300	£-4,300
Local Authorities	£0	£-900	£-1,800	£-1,800	£-1,800	£-1,800
Total – Other bodies	£0	£-3,100	£-6,100	£-6,100	£-6,100	£-6,100
Total – Minimum						
Total – Minimum	£4,630,300	£3,246,500	£773,100	£779,600	£779,600	£792,400
Total – Maximum						
Total – Maximum	£4,708,000	£3,324,200	£850,800	£857,300	£857,300	£870,100
Present Value of cost - Minimum						
Present Value of cost - Minimum	£4,473,700	£3,030,600	£697,300	£679,400	£656,400	£644,600
Present Value of cost - Maximum						
Present Value of cost - Maximum	£4,548,800	£3,103,200	£767,400	£747,100	£721,800	£707,800

Appendix A

Reported Incidents By Degree Of Harm, By Care Setting, Wales: Apr 2017 - Mar 2018

Table 44 - Reported Incidents By Degree Of Harm

Care setting	Number of incidents					
Acute / general hospitals	No Harm	Low	Moderate	Severe	Death	Total
Community nursing, medical and therapy services (incl. community hospital)	37,289	12,986	3,571	185	7	54,038
Mental health services	8,727	8,160	2,809	72	9	19,777
General practices	6,464	2,380	399	18	8	9,269
Ambulance services	897	253	202	10	0	1,362
Learning disabilities services	723	138	6	1	1	869
Community pharmacy	435	195	14	1	0	645
Community and general dental services	268	19	14	2	0	303
Community optometry / optician services	142	57	12	0	0	211
Total	54,945	24,188	7,027	289	25	86,474

NB Incidents for which degree of harm was not reported are excluded.

Costing the Options

OPTION 1:

Welsh Government staff administration

484. Currently the Welsh Government exercises its role in holding the Board of CHCs to account, through its independent chair, for the performance of the CHC Board's strategy, plans and functions. Staff time spent by Welsh Government on all aspects of CHC work is estimated to cost:

Table 45 – breakdown of Welsh Government staff administration cost

Grade	WTE	Cost Per Annum
Management Band 2	0.4	£18,300
Management Band 1	0.4	£23,200
Executive Band 2	0.5	£38,200
Executive Band 1	0.1	£9,300
Total		£89,000

485. Costs for Welsh Government staff are based on Average Gross Salary Rates for Non-Senior Civil Staff (SCS) Pay Bands 2018/19.

Board appointments

486. There are costs incurred by Welsh Government in appointing the Chair and the two independent board members to the CHC Board through the Public Appointments process. In addition, there are opportunity costs for Welsh Government policy staff involved in the process.

487. The estimated cost of the above is based on the recruitment of the new CHC Chair of the Board of CHCs during October – December 2018:

Table 46 – cost for recruiting CHC chair and board members

Expenditure type	Estimated cost
Advertising	£9,700
Travel and Subsistence for independent panel members	£900
OCPA approved panel member	£1,400
Total	£12,000

488. To determine the cost of recruiting three board members the following assumptions have been made:

- the recruitment is undertaken at the same time, once every four years (as they are recruited on a fixed four year term);
- advertising costs remain the same – the same advert could be used for the three posts (Chair and the two Independent Board Members);
- the OCPA approved panel member is only needed for the Chair appointment;

- Travel and Subsistence for an independent panel member is multiplied by three to represent the posts.

489. Based on the above, the cost is proportioned per annum and is estimated to be (£12,000 divided by 4 = £3,000).

490. In addition to the above, the process also involved a total of six Welsh Government staff at varying levels. The opportunity costs associated with these are estimated below:

Table 47 – Welsh Government staff opportunity cost for recruiting board members

Welsh Government staff time per grade	Average gross cost per annum	Days required	Cost
Welsh Government administration cost			
Deputy Director	£107,313	3	£1,200
Executive Band 2	£76,308	2	£600
Management Band 1	£57,977	2	£400
Management Band 2	£45,644	3	£500
Welsh Government appointments unit			
Executive Band 2	£76,308	2	£600
Management Band 2	£45,644	3	£500
Total		15	£3,800

491. Based on the above, the cost is proportioned per annum and is estimated to be (£3,800 divided by four = £1,000).

Chair remuneration

492. From March 2019 the Chair of the Board will be remunerated £150 per day for a total of 12 days per month funded by Welsh Government through Powys tHB. This equates to an annual cost of approximately £21,600. The other members of the board are not remunerated.

Cost of CHC volunteer member recruitment

493. The current recruitment requirements, as set out in regulation 3 of and Schedule 1 of the 2010 Regulations³⁴, require the following total number of volunteer members to be appointed to membership of a Council by the relevant appointing bodies (276). This option would not change these regulations.

Table 48 – number of CHC appointments

Name of Community Health Council	Total number of volunteer members to be appointed by the Welsh Ministers	Total number of volunteer members to be appointed by relevant local authorities	Total number of volunteer members to be appointed by voluntary organisations
Aneurin Bevan CHC	30	15	15
Abertawe Bro Morgannwg CHC	12	6	6
Betsi Cadwaladr CHC	36	18	18
Cardiff and Vale of Glamorgan CHC	12	6	6
Cwm Taf CHC	18	9	9
Hywel Dda CHC	18	9	9
Brecknock and Radnor CHC	6	3	3
Montgomeryshire CHC	6	3	3
Total	138	69	69

494. Volunteer members are recruited on a fixed four year term. Subject to a satisfactory performance appraisal, a member may be re-appointed for a second term.

495. On average, a CHC ministerial member recruitment round is undertaken once a year as there is a constant turnover of volunteer members who reach the end of their fixed term appointments or resign.

The CHC Ministerial volunteer member recruitment:

496. The Welsh Government held a recruitment exercise through the public appointments process in 2018 to fill the Welsh Minister appointed vacancies on the seven CHCs across Wales. The cost to the Welsh Government of recruiting 55 CHC ministerial volunteer members was £4,900. This cost is broken down as follows:

Table 49 - General recruitment costs

Activity	Cost
Advertising	£4,400
Travel and Subsistence for independent panel members	£200
Translation services	£200
Room hire	£100
Total	£4,900

497. In addition to the above, the process also involved a total of nine Welsh Government staff at varying levels participating on interview panels, and the involvement of the Welsh Government's Public Appointments Unit. The opportunity costs associated with these are estimated below:

Table 50 - Opportunity cost for Welsh Government for CHC member recruitment

Pay Band	Average Annual Gross Cost	Estimated number of days	Cost £ per day	Total cost
Welsh Government – administrative				
Executive Band 2	£76,308	2	£293.49	£600
Management Band 1	£57,977	1	£223.06	£200
Management Band 2	£45,644	4	£175.55	£700
Management Band 3	£35,080	5	£134.92	£700
Public Appointments Unit – administrative				
Executive Band 2	£76,308	3	£293.49	£900
Management Band 2	£45,644	3	£175.55	£500
Sift				
Executive Band 2	£76,308	3	£293.49	£900
Management Band 2	£45,644	2	£175.55	£400
Interview process				
Deputy Director	£107,313	2	£412.74	£800
Executive Band 2	£76,308	8	£293.49	£2,300
Management Band 1	£57,977	4	£223.06	£900
Management Band 2	£45,644	2	£175.55	£400
Management Band 3	£35,080	2	£134.92	£300
Total		41		£9,600

498. Additionally, this exercise incurred costs for existing CHC volunteer members and voluntary organisations, who participated in sifting and interviewing new volunteer members on behalf of the Welsh Ministers – which included eight interviewing panels. The opportunity costs associated with these are calculated below:

Table 51 - Opportunity cost for CHC volunteer members and voluntary organisations

Organisation	Cost per annum
CHC Members	No costs as volunteer members are unpaid
Voluntary organisations	£2,500*

*Based on opportunity costs from VCS Cymru who participated in two panels from the last recruitment exercise – proportioned accordingly.

499. The annual cost for recruiting volunteer members for Ministerial appointments is estimated at £14,500. This is higher than those for local authorities and voluntary organisations due to the requirement to follow the public appointments process which incurs a greater cost, for example the requirement to advertise posts.

Local Authority CHC member recruitment:

500. The costs associated with the recruitment to appoint 69 CHC local authority volunteer members have been calculated in liaison with the Welsh Local Government Association, and are estimated to be:

Table 52 – Cost to Local Authorities to recruit CHC volunteer members

Expenditure type	Estimated cost per annum
Total	£1,800

Voluntary organisation CHC member recruitment:

501. The costs associated with the recruitment to appoint 69 CHC voluntary organisation CHC volunteer members have been calculated in liaison with the Welsh Council for Voluntary Action, and are estimated to be:

Table 53 - Cost to voluntary organisations to recruit CHC volunteer members

Expenditure type	Estimated cost per annum
Total	£1,800

OPTION 2:

Establishment of a new organisation

502. Costs have been calculated on the basis the organisation will be established approximately 14 months after Royal Assent (June 2020). Therefore it is assumed the Body's functions, the Board, members of staff, and office fit-out and infrastructure installation, will be completed in time for an establishment date of 1 October 2021.

Status of the new organisation

503. The new organisation will be a body corporate and will become an Executive Welsh Government Sponsored Body (WGSB).

Operating climate

504. It has been assumed no crises or significant changes will occur to the health and social services systems in Wales during the period of costing, and therefore the level of funding granted is likely to remain the same.

Implementation board

505. Responsibility for establishing the new body will sit with a dedicated Welsh Government implementation board for 14 months. The implementation board will comprise of a range of work streams, which will mainly be staffed by Welsh Government, Powys tHB, and when appointed the Chair, Board and CEO of the new Body.

506. In addition to the above, there will be a cost for ad-hoc support provided by wider Welsh Government leads in the delivery of the relevant work streams and the current CHC staff. For example, staff from procurement or communications may attend meetings as necessary to give advice on specific matters. However this cost cannot be calculated on the basis that the number of work streams, the frequency of meetings, and the exact nature of the support required cannot be determined until further policy work is completed.
507. Therefore staff numbers and ad-hoc project running costs are broadly based on information provided by the project team established to support the implementation of Health Education Improvement Wales (HEIW⁴⁰), with staff numbers increasing as work streams develop. These costs will fall to Welsh Government between July 2020 and September 2021.

Table 54 – Implementation board cost to Welsh Government

Resource	2020/21 (8 months)	April 2021 - Sept 2021 (6 months)	Source/ assumption
Welsh Government:			Average gross salary rates for Non-SCS Welsh Government pay bands 2018/19.
1 x Programme Director	£62,200	£46,700	1 x EB1 x 14 months
2 x Heads of Transition	£59,900	£38,200	1 x EB2 x 14 months
	£0	£38,200	1 x EB2 x 6 months
2 x Programme Managers	£38,700	£29,000	1 x MB1 x 14 months
	£0	£29,000	1 x MB1 x 6 months
4 x Programme Officers	£30,400	£22,800	1 x MB2 x 14 months
	£22,800	£22,800	1 x MB2 x 12 months
	£0	£45,600	2 x MB2 x 6 months
New Body:			Remuneration rates for Board members calculated in Table 55.
Chair	£10,300	£7,700	1 x 14 months
Deputy Chair	£5,700	£6,800	1 x 11 months
Board Members	£0	£38,000	8 x 6 months
Chief Executive	£0	£59,500	1 x 6 months - based on current CHC CEO salary per annum £118,900 (including on-costs).
Support from Powys tHB	£61,300	£46,000	1 x NHS Wales band 8c x 14 months (including on-costs).
Ad-hoc project running costs	£5,000	£5,000	To secure additional specialist external advice as required – figure based on ad-hoc cost incurred by HEIW.
Total	£296,300	£435,300	

508. Once the body has been established the implementation board will be disbanded and oversight responsibilities will be transferred to the sponsor team.

Remuneration of the Board

509. The Body will require a Board to be established.

510. The Board members will be remunerated. The estimated remuneration has been calculated based on a Band 2 level as set by the Welsh Government's Public Bodies Unit and an estimate of the number of days the various members will be required to work.

Table 55 – remuneration rates

Type	Number of posts	Remuneration per day £	Number of days worked per annum	Total cost per annum £
Chair	1	£256	60	£15,400
Deputy Chair	1	£226	60	£13,600
Board Member	8*	£198	48	£76,000
Total				£105,000

*The Board will have between seven to nine members; therefore for the purpose of this calculation eight posts have been used.

511. This is an ongoing operating cost to Welsh Government.

512. As a comparison, the current chair of the Board of CHCs is remunerated but the other board members are not.

Board recruitment costs for appointments

513. There will be a cost for Welsh Government associated with Board member appointments; this is calculated based on the current cost to the Welsh Government as outlined in Option 1 - Tables 46 and 47 associated with appointing three independent members to the Board of CHCs.

514. In the first year all members will be recruited in one campaign with the costs being incurred by Welsh Government in April – September 2021. To estimate this cost the costs contained in Tables 46 and 47 are multiplied by three (representing the appointment of 9 members) except for the advertising cost in Table 46 and the opportunity cost for the Welsh Government appointments unit in Table 47 as these will only be incurred once.

Table 56 – cost for recruiting nine board members

Expenditure type	Estimated cost
Advertising	£9,700
Travel and Subsistence for independent panel members	£2,700
OCPA approved panel member	£4,200
Total	£16,600

Table 57 – Welsh Government staff opportunity cost for recruiting nine board members

Welsh Government staff time per grade	Average gross cost per annum	Days required	Cost
Welsh Government administration cost			
Deputy Director	£107,313	9	£3,700
Executive Band 2	£76,308	6	£1,800
Management Band 1	£57,977	6	£1,300
Management Band 2	£45,644	9	£1,600
Welsh Government appointments unit			
Executive Band 2	£76,308	2	£600
Management Band 2	£45,644	3	£500
Total		35	£9,500

515. To determine the cost per annum, it is assumed that the recruitment is undertaken at the same time, once every four years (as the Chair, Deputy Chair and Board members are recruited on a fixed four year term).

516. Based on the above, the cost is proportioned per annum and is estimated to be (£26,100 divided by four = £6,500). This cost is likely to be incurred from 2023/24 onwards as it assumed unlikely that a recruitment exercise is to take place within the first 18 months of the body being established.

Staffing costs

517. With the creation of any new body and the subsequent transfer of staff, a workforce structure will need to be developed and a job matching exercise will need to be completed. This may identify the need for changes to the current roles held by CHC staff. It is a matter for the new Body and the Implementation Project Board to determine staff structures, but it is anticipated that the staffing structure would need to be organised along a regional footprint, linked to RPB areas. This would ensure strong regional and local representation and an ability to work across health and social services.

518. For the purposes of this document, the total estimated staffing costs are based on the transfer of current 73wte CHC staff, employed by Powys tHB, and the additional staff estimated in table below for the performance of the extended complaints advice and assistance functions the new Body will perform.

519. Save for the additional specialist staff identified below to perform the extended complaints advice and assistance functions of the Body, it is not considered the new Body will require additional staff to perform its other core functions. In reaching this conclusion, we have considered the staffing ratio of full time equivalent staff: per head of population (included in Table 39) of the Patient and Client Council in Northern Ireland and Health Watch in England.

520. The Patient and Client Council in Northern Ireland has 26 staff⁸⁶ to perform all of its functions (including its complaints advice and assistance functions across health and social services) for a population of 1.9 million (a staffing ratio of 1:73,077 per head of population). Health Watch employed an estimated 408 full time equivalent staff in 2017/18⁸⁷ to perform all of its functions for a population of 55.6 million (a staffing ratio of 1:136,275 per head of population).

521. Even taking into account the fact that the functions of the different citizen voice bodies do vary, for example local Health Watch only directly provide health complaints advice and assistance functions in approximately one fifth of local Health Watch organisations (the rest is contracted out) and do not provide complaints advice in relation to social services complaints, it is clear that per head of population the Body will have significantly more staff than equivalent bodies in England and N Ireland.

522. Taking into account current staffing levels of CHCs set out in Table 58 and the estimated additional staff needed to perform the extended complaints advice and assistance functions of the Body set out in Table 62 the estimated ratio is 1:40,260 per head of population.

523. Subject to the staffing structure of the new Body and the requirement for a TUPE style exercise to manage staff transfers, solely for the purposes of the RIA it is assumed that the current CHC staff will transfer to the new Body and at the same pay rate. Current CHC staff costs are set out below.

Table 58 – staffing cost for current CHC staff who will transfer to the Body

Type	Number of wte staff	Total	Source/ Assumption
Staff costs - Pay	73	£2,915,800	Based on CHC staff costs 2018/19.
Staff non pay - Expenses	73	£129,100	
Total		£3,044,900	

524. These costs will be absorbed by the Body as part of its ongoing operating costs.

Recruitment of additional Staff

525. Notwithstanding the general observations made above in relation to current staffing levels of the CHCs compared to other Citizen Voice bodies in the UK, it is considered that additional staff will be required to enable the Body to perform its complaints advice and assistance functions.

526. Unlike CHCs, the new Body will provide a complaints advice and assistance service to:

- i. children who wish to complain about NHS services;

⁸⁶ Officials contacted the Patient and Client Council to determine the number of staff employed.

⁸⁷ What Matters Most Health Watch Annual Report 2017/18, p.44.

- ii. persons who wish to complain about the social services functions of local authorities (apart from complaints made by children who are entitled to complaints advice and assistance from local authorities pursuant to section 178(1)(a));
- iii. persons who wish to make a complaint to a provider of a service regulated under section 2 of the Regulation and Inspection of Social Care (Wales) Act 2016⁹; and
- iv. persons who wish to make a complaint to the Public Services Ombudsman for Wales in relation to a local authority's social services functions, a care home provider or a domiciliary care provider.

527. Complaints advice and assistance is a specialist service that needs to be offered by appropriately skilled and trained staff. Unlike the other functions of the Body, this is not a function where volunteer members can undertake or assist in undertaking work. The resourcing of the CHCs' complaints advice and assistance function accounts for a significant proportion of the current overall CHC staffing costs: £878,000 out of a total staffing cost of £2,826,000 for 2018/19.

528. In order to determine how many additional complaints advice and assistance staff will be required to undertake these additional functions, an assessment has been undertaken of (i) the number of NHS complaints (across primary and secondary care) for the three years between 2015/16 and 2017/18; (ii) the number of complaints in which the CHCs have provided complaints advice and assistance across the same time frame; and (iii) the number of staff employed in the CHCs by Powys tHB in the provision of complaints advice and assistance services.

529. This gives an indication of:

- a) the percentage of complaints made where complainants sought assistance from the CHC; and
- b) the number of staff needed to deal with these complaints.

Table 59 – Number of complaints dealt with by CHCs compared to the total number of NHS complaints (including primary and secondary care).

	2015/16	2016/17	2017/18
Total number of NHS complaints	11,823	9,308	9,347
Total number of complaints dealt with by the CHC	1561	1503	1305
% of complaints where CHC provided complaints assistance	13.2%	16.1%	13.96%

530. In 2018/2019 across all of the CHCs there were a total of 24.04 WTE staff employed to carry out the complaints advice and assistance function. This is split between complaints advocates, of which there were 14.36 WTE equivalents in May 2018⁸⁸, with the remainder being comprised of complaints managers and

⁸⁸ Confirmed by CHC Board Human Resources Manager on 16 May 2018.

complaints support assistants many of whom have a dual complaints support/general administrative role.

531. The average number of NHS complaints for the three year period from 2015/16 to 2017/18 is 10,159. The average number of complaints that the CHC assisted with over the same three year period is 1456. Consequently, in percentage terms, CHCs assist with 14.33% of all NHS complaints. To determine the likely need for additional complaints staffing, the assumption is that for the additional complaints functions that the Body will undertake, the same percentage of cases will require complaints advice and assistance from the Body.

(i) Provision of complaints advice and assistance to children who wish to bring a complaint about a NHS service.

532. Contact was made with all LHBs and Trusts to determine how many complaints had been made in relation to children during 2017/2018. Six out of seven LHBs were able to provide us with figures for the number of complaints relating to children (covering complaints that had been made by children themselves, parents on behalf of a child or a third party). Adjusting the numbers upwards to account for the fact one LHB did not keep this data; the responses indicated that during that timeframe 720 complaints had been made by or on behalf of children. Of these, the vast majority had been made by parents on behalf of their child.

533. LHBs collect data from primary care providers on the number of complaints received during each financial year. However, this data is not broken down into the number of “adult” and “child” complaints. Therefore, it has been necessary to estimate the number of complaints relating to children made to primary care providers. Taking the total number of complaints in Table 62, across that three year period an average of 71% of cases related to secondary care. Therefore, assuming the same percentage of children submit complaints in relation to primary and secondary care, it is estimated that 294 complaints (29%) in relation to children are dealt with by primary care providers per annum. This gives an estimated total of 1014 complaints per annum that relate to children.

ii) Provision of complaints advice and assistance to persons who wish to complain about the social services functions of local authorities.

534. We contacted all 22 local authorities in Wales to ask how many complaints they consider under the Social Services Complaints Procedure (Wales) Regulations 2014. We indicated that we did not require details of the number of complaints made under the Representations (Procedures) Wales Regulations 2014 as the Body will not be providing complaints advice and assistance to children who have existing statutory rights under the 2014 Act². We received a response from 20 local authorities. The figures in Table 60 below have been adjusted upwards to take account of the two missing responses.

535. There is variation in the way that local authorities collate their complaints data. However, the following provides the best estimate of the number of complaints that are dealt with by local authorities in relation to their social services functions, but excluding complaints in relation to children who have existing statutory rights

under the 2014 Act ²(and in relation to which the Body will not provide assistance).

Table 60 – Number of complaints made to local authorities under the Social Services Complaints Procedure (Wales) Regulations 2014.

	2015/16	2016/17	2017/18
Number of complaints made by adults in relation to local authorities social services functions.	1,261	1,181	1,302

536. The average across the three year period is 1248 complaints.

iii) Complaints advice and assistance to persons who wish to make a complaint to a provider of a regulated service under the 2016 Act.

537. There is no data on the number of complaints that are made to providers of regulated services. Local Authorities do not collect this data nor do CIW or the Welsh Ministers. However, the 2017 Regulations¹⁰ specify that providers of regulated services must submit an annual return to CIW. The annual return will include details of the number of formal complaints made and the number upheld. The first annual return is due to be submitted in 2020. Consequently, prior to the establishment of the Body, it will not be possible to determine how many complaints per annum are made in relation to these types of services.

538. For the purposes of the RIA, it is estimated that the number of complaints made to providers of regulated services will be the same as the number of complaints made to local authorities in the exercise of their social services functions. In reality it is considered that this is a significant overestimate based on the limited information that was provided by a small number of local authorities when we approached them for this data. A more accurate estimate will be calculated once the relevant complaints data is available from CIW in 2020.

iv) Complaints to the Public Services Ombudsman for Wales in relation to local authority social services functions, care home providers and domiciliary care providers.

539. The office of the Public Services Ombudsman for Wales (“PSOW”) has confirmed the number of complaints that have been made to his office relating to social services complaints (both adult and children) and complaints against care homes and providers of domiciliary care.

540. In Table 61 below we have only accounted for the complaints made in relation to adult social services as the Body is not to have the ability to provide complaints advice and assistance to children who have a statutory right to an advocate under the 2014 Act². Those children, who have a statutory right to an advocate under the 2014 Act², are able to use their advocate to pursue a complaint with the PSOW.

Table 61- Complaints made to the PSOW

Nature of complaint	2015/16	2016/17	2017/18
Adult social services	68	81	74
Care homes	1	5	0
Domiciliary Care	1	3	1
Total	70	89	75

541. The average number of complaints received per annum by the PSOW across all three areas during the period 2015/16 to 2017/18 is 78.

542. A summary of the total estimated number of complaints that may be made to the NHS, local authorities, 2016 Act regulated providers and the PSOW in relation to the additional complaints functions that the Body will have the power to provide assistance in relation to (but which CHCs cannot) is as follows:

Table 62 - Summary of the estimated number of additional complaints that fall within the scope of the Body's complaints functions

Type of complaint	Number per annum
NHS complaints relating to children	1014
Complaints to local authorities under the Social Services Complaints Procedures (Wales) Regulations 2014	1248
Complaints to providers of 2016 Act regulated services	1248
Adult social services complaints to the PSOW	78
Total	3,588

543. As set out above, in relation to NHS complaints, CHCs currently provide complaints advice and assistance in relation to 14% of complaints. It is considered reasonable to proceed on the assumption that, in relation to the new mainly social services complaints that may be dealt with by the Body, a similar percentage of complainants will come to the Body for assistance. It is considered that this is a reasonable assumption for the purpose of costing additional staff that may be required by the Body as, in the absence of a public body that has had the function of providing advice and assistance to complainants in relation to Social Services matters, local authority complaints staff, as well as providing help and assistance themselves, have signposted complainants to voluntary organisations and Citizens' Advice for help and assistance. These organisations will continue to be able to provide help and support to complainants going forward and so the percentage of social services complaints dealt with by the Body may, in fact, be less than 14%.

544. Also, as set out in paragraph 412 above, there are many factors that influence the number of complaints. It is also true that under both the NHS and Social Services complaints procedures, the organisation complained about is already under a duty to advise complainants of sources of help and advice for navigating the respective complaints procedures. Therefore, for the complaints advice and assistance function it is not anticipated that the higher profile that the Body will have (compared to CHCs) will impact on the percentage of overall complaints that are received by it for advice and assistance.

545. Consequently, it is estimated that the number of additional complaints that will be dealt with by the Body as a result of its complaints advice and assistance functions being broader than those of the CHCs is estimated at 502 (i.e.14% of 3588 complaints)

546. The estimated staffing costs, to include on costs, are as follows: for an average number of 1456 complaints per annum CHCs have a staffing complement of 24 WTE staff. This is comprised of 14.36 WTE advocates supported by complaints managers and advocacy support assistants who, in many cases, have a dual advocacy support/general administrative role. To deal with an estimated additional 502 complaints per annum an estimated additional eight WTE members of staff would be required to supplement the complaints advice and assistance function. These additional members of staff would support the current 24 members in the current CHC staffing structure whose roles involve a complaints advice and assistance.

547. The cost of these additional staff is estimated as follows.

Table 63 – Estimated additional complaints staff costs for the Body

Type	Average CHC cost for a staff member	Number of additional staff	Total	Source/ Assumption
Staff costs – Pay	£35,900	8	£287,200	Based on average CHC staff costs in 2018/19 for individuals employed to carry out complaints advice and assistance functions. Includes on costs.
Staff non pay - Expenses	£700	8	£5,600	
Total			£292,800	

548. The total staffing costs for the Body are estimated to be (Tables 58 and 63):
£3,337,700

Pensions and TUPE

549. The RIA assumes remuneration costs and pension costs for staff in the Body are broadly in line with the current salary and pension arrangements of CHC staff. The Welsh Government complies with the “Fair Deal” principles for staff pensions.⁸⁹

Volunteer member costs

550. The Body will be able to use volunteer members to support the delivery of its functions. However unlike the current CHC model there will be no limits set on

⁸⁹ HM Treasury. Fair Deal for staff pensions: staff transfer from central government. HM Treasury; 2013.

the number of volunteer members, the maximum time a volunteer member may serve the Body, nor will there be a requirement for third parties to appoint members.

551. As outlined in Table 48, CHCs can have a maximum of 276 volunteer members. As the Body will exercise functions across health and social services, it is anticipated that the Body will require additional members. It will be up to the Body to determine how it wishes to operate to best perform its functions and it will have the freedom to establish a volunteer membership model that best meets its needs. It may follow the example of the Patient and Client Council, which has a cohort of members who provide services “in person” for the Council and a larger number of online members. However, it is anticipated that the Body will build strong links with the Inspectorates and voluntary organisations to share and utilise intelligence and possibly lay members.
552. One of the main criticisms of the CHCs’ current membership is their lack of diversity. The implementation programme that will be set up to support the establishment of the Body will devise strategies to help the Body attract the best possible volunteer members and a more diverse membership that is representative of the users of health and social services. This will be supported by a modern website, the cost of which is incorporated in Table 68 below which details the ICT investment, which will allow the Body to engage with citizens and seek their views. An interactive website will also allow the body to reach a large audience of prospective volunteer members and will make it easier for people to express their views and to provide services to the Body as volunteer member. This, coupled with the move away from the public appointments process and the minimum time commitment needed currently to be a CHC member, should make it easier to attract a more diverse volunteer base.
553. The Body will also be encouraged to establish networks across health and social care increasing its visibility and audience. It is also hoped that many of those who are current CHC volunteer members will continue to support the Body.
554. It is difficult to estimate how many volunteer members the Body will require as this will be dependent on numerous factors such as location, skill set of volunteers and the time commitment offered. As set out above, the volunteer membership model adopted may include volunteer members providing services “in person”, complemented by a larger “online” membership that will respond to consultations, express views on proposals relating to service change, provide contributions to requests for topics for thematic reviews etc. However, for the purpose of this document it is assumed the Body will continue to have 276 volunteer members providing services “in person” working to the current CHC time commitment and who will require training.
555. Currently each volunteer member is committed to support the CHCs at least 3-5 days per month. The volunteer members are not paid, however they do receive training and reimbursement of travel costs.
556. In 2017/18 the CHCs spent £67,900 on travel and subsistence for its volunteer members. This cost will be absorbed by the Body as part of its ongoing

operating costs. Separately, the body spent £55,200 on training for volunteer members; this is covered in Table 67.

557. It is important to note that, unlike the Welsh Ministers, the Body will not be required to follow the formal Public Appointments process which abides by the recruitment guidelines and advertising requirements as set out by the Office of the Commissioner for Public Appointments. Opportunity costs associated with the recruitment of staff by the Body are expected to be incorporated within the corporate services function outlined below. Costs associated with “paid” advertising to attract volunteer members to the Body will be met from the marketing budget of £42,300 that is identified below.

Corporate Services

558. The Body, once established will need to establish a corporate support service to provide HR, finance, and audit support (an executive WGPB is required to have an internal audit service) as these services are currently provided to the CHCs via Powys tHB. Therefore no staff from the existing CHCs will be transferred to undertake these roles. We would anticipate the staff and systems will be put in place by the shadow board, ahead of the Body’s commencement. The cost of delivering this service is estimated to be:

Table 64 – Corporate services cost for new body

Item	Estimated cost per annum	Source/ Assumption
HR support	£56,400	Based on costs contained within the Regulatory Impact Assessment for Qualification Wales ⁹⁰ - a Body with a similar number of wte staff.
Finance support	£56,400	
Internal audit	£20,000	Based on advice from Welsh Government Audit, Assurance and Counter Fraud Division – regarding costs relating to other Welsh Government Public Sponsored Bodies.
External audit	£20,000	
Total	£152,800	

559. This cost is deemed an ongoing operating cost for the Body.

Training costs - establishment

560. There is an assumption that as part of the transitional costs associated with the establishment of the new Body, the Welsh Government will fund training to ensure staff and volunteer members are appropriately skilled to undertake the work of the Body. This cost is deemed to be for Welsh Government in the first six months of operation (October 2021 – April 2022).

561. Due to the specialist nature of this work it is anticipated that specialist support will be required.

⁹⁰ Welsh Government. Explanatory Memorandum Qualifications Wales Bill 2015.

562. It is anticipated that a WTE secondee who has experience of the NHS and social services will be required to develop induction training resources (toolkit/workbook) for both staff and those volunteer members who undertake tasks that require them to be trained. These resources will be utilised for staff and volunteers who join the Body upon establishment and in the future. This resource will be made available electronically so it can be accessed remotely by staff and volunteer members, and in a format which can routinely be updated by the Body. It is anticipated the induction training will cover the following headline topics:

- health and social services sectors and functions;
- the law and health and social services;
- values and principles underpinning health and social services; and
- role of the new Body.

563. This work is anticipated to take no longer than six months, and be delivered by a member of staff at an appropriate level - estimated to be at a grade equivalent to a Welsh Government Executive Band 2 (EB2). The cost to Welsh Government of the secondee is:

Table 65 - Secondee

Costs for EB2 equivalent NHS secondee		
EB2 Annual Average Cost	Estimated time required	Cost
£76,300*	0.5	£38,200

*provided by the Welsh Government Central Services & Administration Main Expenditure Group Team based on Average Gross Salary Rates for Non-SCS Pay Bands 2018/19.

564. Those staff who have the specific role of providing complaints advice and assistance in the new Body will require expert training. New staff who are recruited to assist in performing the Body's complaints advice and assistance functions will undergo training in relation to both the health and social services complaints systems. Existing staff who are employed to undertake a complaints advice and assistance role will only undergo training in relation to social services complaints. For training on the landscape in social services, Social Care Wales has estimated that providing bespoke training for 25 advocates would attract a training fee of £6,800 (£272 per person). For health services, the current CHCs spend £250 per person on training fees to obtain similar training. It is anticipated that Welsh Government would meet the cost of this specialist training within the first six months of the Body being established, after which point it would be for the body to incorporate as part of its annual training budget.

565. The total cost for Welsh Government in April 2021 - September 2022 is estimated as:

Table 66 – Training costs for Welsh Government

Item	Cost per item	Number of staff involved in delivering the complaints function	Total cost
Seconded	£45,800	1	£45,800
Complaints training – Health service	£250	32*	£8,000
Complaints training – Social services	£272	32*	£8,700
Total			£62,500

*represents the current number of CHCs staff who have a role in the provision of complaints advice and assistance (24) and the additional staff required for the Body to supplement this function (8).

Training costs – operational

566. The new Body will require a training budget. Using data provided by the current CHCs for 2017/18, the CHCs budgeted £33,650 for training of its 73.24 wte staff (£460 per wte staff head) and £65,200 for training of its 276 volunteer members (£200 per volunteer member head). Based on the estimated number of staff and volunteer members the Body will require, the Body is likely to incur an ongoing operating cost which is estimated to be:

Table 67 – Training budget for the Body

Item	Cost per head	Number of staff/ volunteer members	Cost per annum
Staff	£460	81*	£37,300
Volunteer members	£200	276**	£55,200
Total			£92,500

*77 staff is the current 73 wte staff, plus the additional 4 staff as calculated in Table 63.

**As explained at paragraph 551, for the purpose of this document 276 volunteer members is based on the current number who are providing services “in person” are used as the basis to determine the number of volunteer members that will require training. However it will ultimately be for the Body to determine the level of training provided to its volunteer members.

Organisational Development

567. Successful Boards contain a healthy combination of knowledge, skills and attributes accumulated through experience and frequent exposure to new ideas and different ways of delivering success. To assist the new Board on its passage to high performance, development opportunities are available from Academi Wales⁹¹. Academi Wales, is the centre for excellence in leadership and management for public services in Wales, offering a range of cost effective leadership development programmes and interventions, (many of which are available free of charge) funded by the Welsh Government to public sector organisations. Key development areas include: good governance, high performing boards, healthy boards, diagnostics to enhance effective

⁹¹ Academi Wales [Internet]. Academi Wales. 2019 [cited 3 April 2019]. Available from: <https://academiwales.gov.wales/>

relationships, engagement and challenge to improve individual and collective performance.

568. Academi Wales have advised a supporting budget of £10,000 would supplement the aforementioned 'off the shelf development interventions', through the creation of a be-spoke package of interventions to address any additional organisational development needs which may subsequently be identified. This cost is to be incurred by Welsh Government between April – September 2021 when the Board and Chief Executive are in place.

Accommodation

569. The cost of accommodation is estimated as £350,500, this is based on the actual CHC spend in 2018/19 on its twelve offices. This cost is deemed an ongoing operating cost for the Body.

ICT costs

570. To ensure the new body can operate seamlessly, being accessible to people across Wales, it is necessary to provide ICT which is fit for purpose and which will allow staff the flexibility to operate remotely. This is important for all staff, but is particularly important for those members of staff who offer complaints advice and assistance as it is envisaged that if they are ICT enabled they will be able to offer drop in centres at community hubs etc. to make the service they provide more accessible.

571. The estimated costs are caveated as the precise costs will vary dependent upon:

- product selection and potential volume discounts subject to the procurement exercise and detailed specification; and
- the chosen model of working, number of sites where the new body is responsible for infrastructure, the location of those sites, the building types, the building design, the building condition and specifics of the refit.

572. The Welsh Government will incur the initial capital outlay to set up a new and fit for purpose ICT system; this cost is deemed to be for Welsh Government in April – September 2021. The costs associated with these elements are presented below as a range, however the lowest cost point has been used as we feel this is a more accurate estimate based on the caveats provided in paragraphs 394-397. These costs are estimated to be:

Establishment costs – Welsh Government:

Table 68 – ICT establishment cost

Description	Cost April 2021 - Sept 2021	Source/ Assumption
End User Hardware for approx. 100 users*	£200-£300k Capital cost	A review of the implementation documents from several comparable projects including: - Qualifications Wales (QLW); - Health and Education Improvement Wales (HEIW); - NHS Wales Shared Services Partnership (NWSSP); - Welsh Government Corporate Digital Team.
Purchase of a commercial of-the-shelf customer relationship management (CRM) system for approx. 100 users* and development of an interactive website.	£130k-£180k Capital cost	
Infrastructure and Telephony for approx. 12 physical locations	£1.8m-£2.64m Capital cost	
Total	£2,130,000	

*Estimated for the purpose of procurement – subject to Body determining staff and volunteer member needs.

Ongoing operating costs – the Body:

573. There will be an ongoing operating cost for the Body, this will be a mixture of revenue and capital outlay and is estimated to be:

Table 69 – Ongoing operating ICT costs

Description	Cost Sept 2021 – April 2022	Ongoing annual cost	Source/ Assumption
Hardware replacement costs*	£25k-£38k Capital cost	£50k-£75k Capital cost	Advice from the NHS Informatics Directorate/ ABMUHB Chief Information Officer - 25% replacement cost per annum.
Annual CRM maintenance and licencing costs**	£10k-£15k Revenue cost	£20k-£30k Revenue cost	An average of quotes received in response to the NHS Wales Shared Services Partnership (NWSSP) CRM procurement exercise. Advice from the NHS Informatics Directorate/ ABMUHB Chief Information Officer - 20% replacement cost per annum.
Annual IT and telephony maintenance and licencing costs**	£225k-£330k Revenue cost	£450k-£660k Revenue cost	A review of the implementation documents from several comparable projects including: - Qualifications Wales (QLW); - Health and Education Improvement Wales (HEIW); - NHS Wales Shared Services Partnership (NWSSP); - Advice from the NHS Informatics Directorate/ ABMUHB Chief Information Officer - 20% replacement cost per annum.
Total	£260,000	£520,000	

*25% of the initial capital outlay per annum has been allocated as an average for callouts, in-house support, maintenance and replacement costs related to ICT hardware, ongoing website maintenance and vulnerability testing, and telephony.

****20% of the initial outlay has been allocated as an average for the need to develop a new/refreshed system every 5 years.**

574. Further revision may be required once the model of operation has been established and any new premises identified. However the system is costed to hold 'level 4' data appropriate for holding sensitive personal data (which is the relevant level to allow the Body to hold personal and medical information which it is likely to hold in connection with its complaints advice and assistance function) to enable to Body to comply with GDPR requirements.

Marketing – Welsh Government

575. There is an assumption that as part of the transitional costs associated with the establishment of the new Body, the Welsh Government will fund an awareness campaign to inform the population of Wales that a new Citizen Voice Body for Wales has been created. The campaign will also aim to raise awareness of the scope of the Body's functions and support the call for volunteers.

576. A reasonable estimate for the cost of an awareness campaign for the six month period leading up to the Body's establishment can be based on the Welsh Government's communication campaign for the Public Health (Minimum Price for Alcohol) (Wales) Act 2018. The campaign budget during six months in 2018-19 was £100,000. This included a mix of traditional media, digital media, out-of-home adverts, direct mail and hard copy communication materials for stakeholders. This cost is expected to be incurred by Welsh Government between April - September 2021.

577. On an ongoing basis, to ensure the work of the Body is publicised and for it to remain in the consciousness of users of health and social services, the Body will incur an operating cost associated with marketing. This is estimated to be £42,300 per annum. This cost is estimated on the basis of the average funding provided by Welsh Government to the MEIC project (£50,000), the Welsh Language Commissioner⁹² (£32,000) and the Public Services Ombudsman for Wales ⁹³(£45,000) in 2017/18.

Insurance

578. As advised by Welsh Government Corporate Governance Unit it will not be possible to provide an estimate of insurance costs for the new body until the operating model of the body has been established. The new body will be required to carry out an assessment of risk once their model of operation has been

⁹²Welsh Language commissioner. 2017-18 Annual Report [Internet]. Welsh Language commissioner; 2018. Available from: <http://www.comisiynyddygymraeg.cymru/English/Publications%20List/Adroddiad%20Blynyddol%202017-18%20Annual%20Report.pdf>

⁹³ [Public Services Ombudsman for Wales. Public Services Ombudsman for Wales anual reports and accounts 2017/18 \[Internet\]. the Public Services Ombudsman for Wales; 2018. Available from: https://www.ombudsman.wales/wp-content/uploads/2018/07/PSOW-Annual-Report-and-Accounts-2017-2018.pdf](https://www.ombudsman.wales/wp-content/uploads/2018/07/PSOW-Annual-Report-and-Accounts-2017-2018.pdf)

determined by the Executive during the shadow period before the new body becomes operational. This assessment will inform if there are any areas where the new body is legally required to have insurance (such as if the body will hire/own any vehicles or if vehicles owned by volunteers will need insurance for business use). Where there is no statutory requirement for insurance, if it would be more cost effective, the Government can cover any liability for risk as opposed to purchasing commercial insurances. This may include such areas as employer's liability, public liability and insurance for assets.

Transition of assets and liabilities

579. Any assets, rights and liabilities of Powys tHB (as host organisation), any NHS organisation that enters into contracts on behalf of CHCs and the Welsh Ministers (who enter into leases on behalf of the CHC) will be transferred to the new Body and therefore it is assumed this is cost neutral.

Welsh Government sponsorship

580. The new body would receive all of its funding directly from the Welsh Ministers, via the Welsh Government as a Welsh Government Sponsored Body (WGSB). With a WGSB there is a governance framework which sets out, amongst other things, the planning and reporting arrangements with its sponsor division in Welsh Government.

581. There will be recurring opportunity cost for Welsh Government associated with the ongoing sponsorship of a WGSB. The average staff cost of sponsorship for a 'small' WGSPB (a body whose budget is under £5m⁹⁴) is estimated to be 1.6wte staff at a cost of £59,000.

⁹⁴ *Welsh Government report 'Delivering Together: Strengthening the Welsh Government's Sponsorship of Arms-length Bodies (2017)*

Roles and Responsibilities of the Citizen Voice Bodies in the UK

England

582. Healthwatch England was established in accordance with section 181 of the Health and Social Care Act 2008⁹⁵ (as amended by the Health and Social Care Act 2012)⁹⁵ and is a statutory committee of the Care Quality Commission (CQC).
583. Its functions are set out in section 45A of the Health and Social Care Act 2008 and include providing general advice and assistance to the local Healthwatch⁹⁶ organisations, making general recommendations to English local authorities about the making of arrangements for public and patient involvement in health and social care contained in section 221 of the Local Government and Public Involvement in Health Act 2007⁹⁷, giving English local authorities written notice if they are of the view their arrangements under section 221(2) of that Act are not being carried on properly, and giving information and advice to the Secretary of State, and other named public bodies on the views of the public on their need for and experience of health and social services and views on the standard of health and social services.
584. Local Healthwatch organisations are established in every local authority area in England. Their functions include, for each local authority area:
- promoting and supporting the involvement of local people in the commissioning, provision and scrutiny of local health and social services;
 - obtaining the views of local people about their needs for and experience of local health and social services, making such views known and making reports and recommendations about how local health and social services could be improved;
 - providing advice and information about access to local health and social services;
 - enabling local people to monitor the commissioning and provision of health and social services for the purposes of considering the standard of these services and whether and how such services could or ought to be improved.
585. Some local Healthwatch organisations provide complaints advice and assistance in relation to NHS complaints, in other areas local authorities commission private providers to provide complaints advice and assistance. The complaints advice and assistance does not extend to social services complaints. Healthwatch England does not provide complaints advice and assistance and offers signposting instead.

⁹⁵ **Health and Social Care Act 2012**. London: HMSO

⁹⁶ Local Healthwatch [Internet]. Napp.org.uk. 2019 [cited 4 April 2019]. Available from: <https://www.napp.org.uk/healthwatch.html>

⁹⁷ **Local Government and Public Involvement in Health Act 2007**. London: HMSO

Scotland

586. The Scottish Health Council (SHC) was established by the Scottish Executive in April 2005 to promote Patient Focus and Public Involvement in the NHS in Scotland. It is a committee of Healthcare Improvement Scotland.

587. In addition to a national office, which sets the overall strategic direction of the organisation, it has a network of 14 regional offices – one in each Health Board area.

588. Following an extensive engagement and consultation process a set of proposals have been developed to refocus the Scottish Health Council Directorate to take account of the integration of health and social care, and also to ensure that its efforts are focused on the areas where it can make the most impact on strengthening the engagement of people and of communities. Detail of the new proposals will be published in 2019.

589. However, the current functions of the Scottish Health Council are as set out below. The overarching objective is to promote **Patient Focus and Public Involvement** in the NHS in Scotland. A key aspect of their role is to support NHS Boards and monitor how they carry out their statutory duty to involve patients and the public in the planning and delivery of NHS services.

590. The core functions relate to:

- Community Engagement and Improvement Support – providing proactive and tailored support for local health and care services and community groups
- Performance & Planning – reviewing and evaluating NHS Boards' approaches to involvement through the Participation Standard
- Service Change – supporting NHS Boards to meet the requirement to involve people when planning or changing local services
- Participation Network – a centre for the exchange of knowledge, support, development and ideas
- Volunteering in NHS Scotland Programme - supporting NHS Boards to develop sustainable volunteering programmes.

591. Complaints advice and assistance is not provided by the body but is the responsibility of the Patient Advice and Support Service, delivered by the Scottish Citizens Advice Bureaux⁹⁸.

592. In addition to the Scottish health councils, the Scottish Government funds Care Opinion Scotland, which is used to enable patients and the public to provide online feedback on the services they receive.

⁹⁸ Patient Advice & Support Service [Internet]. Citizens Advice Scotland. 2019 [cited 3 April 2019]. Available from: <https://www.cas.org.uk/pass>

Northern Ireland

593. The Patient and Client Council (PCC) was established on the 1st April 2009. It has a Board which is made up of a Chair and sixteen non-executive directors, recruited from across Northern Ireland under the Public Appointments Process. The Board is responsible for setting the policy and direction for the PCC and for monitoring progress and performance.

594. The PCC's functions (in relation to health and social care) include⁹⁹:

- representing the interests of the public;
- promoting involvement of the public;
- providing assistance (by way of representation or otherwise) to individuals making or intending to make a complaint relating to health and social care (as defined in the Act); and
- promoting the provision of advice and information to the public about the design, commissioning and delivery of health and social care.

⁹⁹ **Health and Social Care (Reform) Act (Northern Ireland)** 2009. London: HMSO

Characteristics of WGSB

595. A WGSB, by definition, is a “body which has a role in the process of national government but is neither a government department nor part of one, and which accordingly operates to a greater or lesser extent at arm’s length from the Welsh Ministers”. The body, as an executive body, will be established to exercise functions in its own right using public money however the degree of independence and autonomy, coupled with the fact the body is funded from public money, mean that a Welsh Government sponsoring department will exercise a certain degree of control and supervision, particularly in relation to their performance and their use of, and accountability for, public funds.

596. The key characteristics of an Executive WGSB are as follows:

- Executive WGSBs are usually established under statute, although a small number have been established by Royal Warrant or Royal Charter.
- They are not part of The Crown but have their own legal personality.
- They carry out a wide range of administrative, commercial, executive and regulatory or technical functions which are considered to be better delivered at arms length from WG.
- Their degree of autonomy or independence from the Welsh Ministers varies but all operate within a strategic framework determined by WMs.
- Through their accounting officer, they are directly accountable to the NAW and Parliament although Ministers are ultimately accountable for their performance and their continued existence.
- They are headed by Boards (or occasionally an office-holder) whose members are appointed by Ministers. Some members may be Crown Appointments on the advice of Ministers or appointments may be made by the body itself.
- The Board appoints the CEO, usually with the agreement of the WM.
- CEO and staff are not civil servants but employed by the body itself.
- The CEO is usually designated as the Accounting Officer.
- They produce their own accounts and annual report.
- AGW is the external auditor in the vast majority of cases.

- Funding is delivered through grant or, more commonly, grant-in-aid although some may generate additional income through other sources.
- Appointments to the Board of WGSBs are regulated by the Commissioner for Public Appointments and must be made in compliance with the Code of Governance.

8. Impact Assessments

597. Alongside the costs and benefits presented in the RIA, a number of other potential impacts have been considered and an integrated impact assessment carried out. A summary of the findings of this process is provided below and the full impact assessment has been published on the Welsh Government Internet: <https://gov.wales/health-and-social-care-quality-and-engagement-wales-bill-impact-assessment> .

598. In addition to the consideration given during the development of the Bill, if the Bill is passed, we will continue to work with the relevant policy teams and stakeholders to monitor the potential impacts of the legislation and determine any processes or guidance which may need to be put in place to secure the anticipated positive impacts and mitigate against any unintended consequences.

Children's Rights Impact Assessment (CRIA)

599. The CRIA considers the intended positive impacts on children and young people, together with possible negative impacts and mitigations of those impacts. The CRIA concludes the Bill will not have a direct role in promoting the rights of a child or young person and is not expected to have any significant negative impacts.

600. The CRIA outlines areas where some consequential positive impacts may be realised, such as those which may result from the Citizen Voice Body providing complaints advice and assistance to those children and young people who do not currently have a statutory right to an advocate under the 2014 Act².

Equalities Impact Assessment (EIA)

601. The EIA explores the potential impact of the Bill on people in protected groups and those living in low income households. The proposals are intended to benefit the health and well-being of the population of Wales as a whole; an assessment of the different components of the Bill found a net positive impact for those citizens in vulnerable and protected groups.

602. A communication and engagement strategy will be developed to ensure all stakeholders are informed, engaged and supported to maximise the benefits of the new ways of working. Additionally, the Welsh Ministers and NHS bodies will regularly assess – and respond to – any potential negative impact of any decisions with a view to improving the quality of care and achieving the best possible outcome for the individual.

Rural Proofing Impact Assessment (RPIA)

603. The RPIA considered the impact of the Bill on rural communities and individuals living within those communities. It found, overall, the proposals will have a minor net positive impact on people who live in rural areas; with the Citizen Voice Body having the potential to strengthen the voice of rural

communities in designing the services they receive and the duty of quality ensuring those services are evaluated based on a broadened definition of quality which includes patient experience.

604. The RPIA also highlighted some potential negative impacts around access to services in local areas and recommended some thought would be needed to consider mitigation of these risks when deciding on the model of operation for the new body.

Privacy Impact Assessment (PIA)

605. A PIA has been conducted in relation to the Bill. The duty of quality, duty of candour, and power to appoint Vice Chairs in Trusts will not require any new personal data to be held or processed by the relevant bodies. The creation of the Citizen Voice Body as a body corporate will require it to handle data which was previously held within NHS systems.

606. The PIA has considered the implications of this change and, in mitigation against the possible risks, the proposed implementation team established to introduce the Body will consider what data needs to be transferred to enable the new body to meet its obligations, and what measures will be required to ensure continued compliance with statutory obligations and best practice in relation to data handling.

Welsh Language Impact Assessment (WLIA)

607. The WLIA explores the potential impacts of the proposed legislation on the Welsh Language and it is not expected the provisions of the Bill will have any negative impact on the use of Welsh Language or on Welsh Language communities. Specific proposals, such as the Duty of Quality requiring patient experience be considered during the planning and evaluation of services, and the intention for the Citizen Voice Body to recruit volunteers from the local population to support a representative demographic, are likely to support patients receiving care in the language of their choice and within their communities.

Biodiversity Impact Assessment

608. The impact of the Bill on biodiversity and the habitat regulations were considered and it was agreed that there will be no direct impact on either; therefore, a Strategic Environmental Assessment and an Impact Assessment on Carbon Budgets were considered not to be required for the Bill.

Climate Change Impact Assessment

609. We have considered the impact of the Bill on greenhouse gas emissions and have concluded there is no direct link, either positive or negative. We have also concluded there is no direct link between the Bill and adapting to the effects of climate change.

Natural Resources Impact Assessment

610. We have considered the impact of the Bill on the National Priorities in the Natural Resources Policy and opportunities for the sustainable management of natural resources. We have concluded there is no direct link, either positive or negative.

Health Impact Assessment (HIA)

611. The HIA evaluated the anticipated impacts of enacting the legislation as drafted and determined, placing quality at the heart of decision making will result in improved health outcomes for the people of Wales and will make an overall positive contribution to reducing health inequalities in Wales.

612. The HIA highlighted the need for the policy to be reviewed periodically to maximise the potential positive benefits from the policy and to wherever possible eliminate or mitigate any negative impacts or unintended consequences, which may be identified ahead of and following implementation

Justice Impact Assessment (JIA)

613. The potential impacts on the justice system of the proposals have been considered, including on:

- a. courts (criminal and civil);
- b. non-devolved tribunals;
- c. devolved tribunals;
- d. legal aid;
- e. the judiciary;
- f. prosecuting bodies; and
- g. prisons, youth justice and probation services.

The Bill does not create any new, or modify any existing offences, sanctions or penalties and the duties that it introduces are placed on public bodies or bodies carrying out functions on their behalf meaning that enforcement will be a matter of public record, through publicly available annual reports on quality and candour, rather than through specific sanctions. Based on similar schemes that operate in England, we believe that the likelihood of civil claims arising from the new duties to be low. The likely impact on the justice system of the proposals in the Health and Social Care (Quality and Engagement) (Wales) Bill is therefore minimal or nil.

9. Post implementation review

614. The Bill is multi-faceted and will provide a legislative framework to enable action in a number of interlinked areas to drive learning and improvement and prevent healthcare associated harm.
615. The implementation approach outlined in the RIA builds, where possible, on existing planning and reporting processes to deliver an effective framework for demonstrating outcomes and impacts without excessive additional burden. This approach will underpin the monitoring and evaluation associated with the Bill, making use of routinely collected administrative and survey data, complemented with qualitative evidence from key stakeholders and service recipients.
616. A programme of monitoring and evaluation activity will be developed to correspond with key activities and a range of research and evaluation methods will be considered, depending on the nature of the data required. Given the multiple outcomes anticipated as a result of the legislation, it is important to note that some elements of the approach will have relevance across the different issues being addressed by the Bill.
617. While the specific evaluation methodology cannot be finalised until the detail of the implementation of the different areas of the bill has been agreed, and while routine health data will provide an essential information source, it must be noted that a number of the issues addressed in the Bill are also being addressed by other forms of action. For example, the provisions in the Bill relating to the establishment of the Citizen Voice Body could ultimately improve service user satisfaction and contribute to a more sustainable NHS if feedback from the general public is more routinely informing service improvements. However, given the wider political and financial environment that the NHS currently operates in, it would be unrealistic to assume there would be no other factors influencing public/service user satisfaction during and post implementation. It will therefore be difficult to fully attribute certain population level trends (as may be identified through this type of data) to the effects of the Bill.

Health data and statistics

618. Activity to monitor the implementation of the Bill will wherever possible be aligned to other relevant work. Data provided through surveys routinely undertaken by Welsh Government and partners will therefore be utilised in the monitoring and evaluation of the legislation. At the same time consideration may need to be given to new data collections as necessary.
619. Examples of possible data sources include the National Survey for Wales¹⁰⁰ and NHS staff survey, which includes an engagement score¹⁰¹.

¹⁰⁰ National Survey for Wales: background information [Internet]. GOV.WALES Welsh Government services and information. 2019 [cited 3 April 2019]. Available from: <https://gov.wales/national-survey-wales-background-information>

¹⁰¹ 2018 NHS Wales Staff Survey [Internet]. Myonlinesurvey.co.uk. 2019 [cited 3 April 2019]. Available from: <http://www.myonlinesurvey.co.uk/ws18/ws18efaq/>

Administrative data

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

- Data on the number of current patient safety incidents, currently collected via the National Reporting and Learning System (NRLS)¹⁰² and ‘Once for Wales’ Concerns Management System, currently under development; and,
- PROMs (Patient Reported Outcome Measures) and PREMs (Patient Reported Experience Measures)¹⁰³.
- Findings from inspections and reviews undertaken by Healthcare Inspectorate Wales.

Reviewing the implementation process

621. The multi-faceted approach outlined above will focus on the extent to which the legislation has contributed to delivering change across the range of outcomes where it would be expected to make a difference. This will include, as recommended by the Finance Committee in their 2017 ‘Inquiry into the financial estimates accompanying legislation¹⁰⁴,’ consideration of the accuracy of the estimated costs, savings, benefits and dis-benefits included in the RIA.

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

623. Taking the example of the proposed Citizen’s Voice Body, the overall approach to monitoring and evaluation will be consistent with the requirement to monitor and review the performance of Welsh Government sponsored bodies (WGSBs) against their remit letter and operational plan, including a probation period of two years from inception.

624. Costing monitoring and evaluation without detail on scope and methods to be used is problematic. At this stage, based on costs associated with similar evaluations and reviews conducted previously – including the Public Health (Minimum Price for Alcohol) (Wales) Act 2018 and Human Transplantation (Wales) Act 2013 – costs are estimated at £250,000 to £300,000 spread over five

¹⁰² Patient safety Welsh Government services and information [Internet]. GOV.WALES. 2019 [cited 3 April 2019]. Available from: <https://gov.wales/patient-safety>

¹⁰³ Health in Wales | PROMs, PREMs and Efficiency Programme [Internet]. NHS Wales. [cited 3 April 2019]. Available from: <http://www.wales.nhs.uk/promspremsandefficiencyprogramme>

¹⁰⁴ <http://senedd.assembly.wales/documents/s70559/Welsh%20Government%20response.pdf>

years. It is important to note the total cost of this work will inevitably depend on the balance of using and analysing routinely-available and bespoke data and research about the implementation and enforcement of the legislation.

These notes refer to the Health and Social Care (Quality and Engagement) (Wales) Bill which was introduced into the National Assembly for Wales on 17 June 2019

Annex 1

HEALTH AND SOCIAL CARE (QUALITY AND ENGAGEMENT) (WALES) BILL

EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes are for the Health and Social Care (Quality and Engagement) (Wales) Bill which was introduced to the National Assembly for Wales on 17 June 2019. They have been prepared by the Health and Social Services Department of the Welsh Government to assist the reader of the Bill.
2. The Explanatory Notes are not meant to be a comprehensive description of the contents of the Bill. Where an individual provision of the Bill does not seem to require any explanation or comment, none is given.

SUMMARY AND BACKGROUND

3. The Bill makes provision about a number of interrelated proposals relating to quality and public engagement in health and social care.
 - a. Part 1 provides an overview of the main provisions of the Bill.
 - b. Part 2 imposes a duty relating to improvement in the quality of health services on the Welsh Ministers and NHS bodies.
 - c. Part 3 makes provision for and about a duty of candour in respect of health services.
 - d. Part 4 establishes, and makes provision about the functions of, the Citizen Voice Body for Health and Social Care, Wales whose function is to represent the interests of the public in respect of health and social care and to provide advocacy services in respect of complaints. It also abolishes Community Health Councils and the Board of Community Health Councils.
 - e. Part 5 makes provision about vice-chairs of NHS Trusts, for minor and consequential amendments to other legislation and contains supplementary provisions about the Bill including provision in relation to the making of regulations and arrangements for bringing the Bill into force.
4. The Bill forms part of the Welsh Government's agenda for improving quality and public engagement in health and social care.
5. The Welsh Government's Green Paper *Our Health, Our Health Service* and White Paper *Services Fit for the Future* sought views on measures relating to quality, governance and

These notes refer to the Health and Social Care (Quality and Engagement) (Wales) Bill which was introduced into the National Assembly for Wales on 17 June 2019

citizen engagement across health and social care. The responses to both consultations were taken into account in developing the Bill for introduction.

6. The *Parliamentary Review of Health and Social Care in Wales* also set out a number of recommendations relating to health and social care, including recommendations relating to improvement in the quality of services and the integration of health and social care services. The Welsh Government set out its response in *A Healthier Wales: our Plan for Health and Social Care*.

COMMENTARY ON SECTIONS

Part 2: Improvement in health services

Section 2 – Quality in the provision of health services

7. This section imposes new duties on the Welsh Ministers and NHS bodies relating to improving the quality of health services.
8. The provision will, in respect of NHS bodies, replace that in section 45(1) of the Health and Social Care (Community Health and Standards) Act 2003. Section 45(1) imposes a duty on NHS bodies (local health boards, NHS trusts and Welsh special health authorities) to ensure that appropriate arrangements are in place to monitor and improve the quality of health care provided by or for those bodies. The new provision will replace section 45(1) and will, additionally, apply to the Welsh Ministers.
9. New section 1A of the National Health Service (Wales) Act 2006, as inserted by subsection (1), will require the Welsh Ministers to exercise their functions in relation to the health service with a view to securing improvement in the quality of health services. This duty will apply when the Welsh Ministers exercise *any* of their functions that relate to the health service, including functions relating to the health service that sit outside the National Health Service (Wales) Act 2006 such as, for example, the Welsh Ministers' function of reviewing and investigating health care under Chapter 4 of Part 2 of the Health and Social Care (Community Health and Standards) Act 2003.
10. Under section 1A(3) and (5), the Welsh Ministers will be required to publish an annual report on the duty to secure improvement and lay the report before the National Assembly for Wales. The report must include an assessment of the extent of any improvement in outcomes achieved as a result of steps taken to comply with the duty. The kinds of outcomes that may be assessed in the report may include, for example, the extent of any improvement in patient experience, or in the early detection and treatment of sepsis or the extent of any improvement in reducing the incidence of hospital acquired infections.
11. New sections 12A, 20A and 24A of the National Health Service (Wales) Act 2006, as inserted by the subsequent subsections of section 2, will impose a corresponding duty on local health boards, NHS trusts and Welsh special health authorities ("NHS bodies"). NHS bodies will be required to exercise all of their functions with a view to securing improvement in the quality of health services. The duty, therefore, differs to that in section 45(1) in that it applies to the exercise of all functions. In discharging the

duty, an NHS body will not only be required to consider how it might improve a service it provides directly, but also how it might act in a way that will contribute to an improvement in the quality of another part of the health service. For example, the provision of an electronic medicines prescribing and discharge system may improve the quality of the service experienced by service users across the health service as a whole.

12. When discharging the duty NHS bodies will be required to take into account any standards set by the Welsh Ministers under section 47 of the Health and Social Care (Community Health and Standards) Act 2003. The current standards are the *Health and Care Standards* (April 2015). The Welsh Ministers will also have the function of conducting reviews of the arrangements made by NHS bodies for the purpose of discharging their duty under section 12A, 20A or 24A. These elements are provided for by amendments made by Part 1 of Schedule 3 to the Bill.

Part 3: Duty of candour

Section 3 – When the duty of candour applies

13. This section explains when the duty of candour in Part 3 will apply. When the duty applies, an NHS body must take certain steps in accordance with a procedure set out in regulations made under section 4.
14. For the purpose of this Part an NHS body is a local health board, an NHS trust, a Welsh special health authority and a primary care provider. A primary care provider is a person who provides general medical services (GP services), general dental services, general ophthalmic services or pharmaceutical services on behalf of a local health board. The application of the duty to special health authorities includes NHS Blood and Transplant in respect of the exercise of its functions in Wales.
15. The duty of candour procedure will have to be followed where the two conditions in subsections (2) and (3) are met.
16. The first condition is that the service user to whom health care is being or has been provided by the NHS body has suffered an adverse outcome. A service user is treated as having suffered an adverse outcome if the service user experiences, or if the circumstances are such that the service user could experience, any unexpected or unintended harm that is more than minimal. The meaning of “more than minimal harm” will be set out in guidance issued by the Welsh Ministers under section 10 of the Bill. The guidance will be developed having regard to existing definitions of harm, such as those used in the National Reporting and Learning System which is the existing system for reporting adverse patient safety incidents in the NHS. For the purpose of the duty of candour, harm includes psychological harm.
17. The duty is triggered not only when harm is known to have occurred but in cases where harm could occur in the future; for example, where an error in the administration of medication may cause an adverse outcome at a future point. The duty may be triggered by an action taken by an NHS body during the provision of health care or by a failure to take action. The harm must be unintended or unexpected

These notes refer to the Health and Social Care (Quality and Engagement) (Wales) Bill which was introduced into the National Assembly for Wales on 17 June 2019

which means that the duty does not apply where undesirable outcomes occur as a result of a medical condition.

18. The second condition is that the provision of the health care was or may have been a factor in the service user suffering the outcome. The outcome must therefore relate to the provision of the care by the NHS body rather than being solely attributable to the person's illness or underlying condition. It need not, however, be certain that the health care caused the harm; it is sufficient that the health care may have been a factor. The application of the duty does not indicate that the NHS body has acted negligently.

Section 4 - Duty of candour procedure

19. This section requires the Welsh Ministers to provide in regulations for a procedure to be followed by an NHS body when the duty of candour applies to the body. The procedure will set out actions to be taken by NHS bodies when the duty applies.
20. Subsections (2) and (3) give detail as to what the regulations must make provision about. The regulations must, for example, require the NHS Body to notify the service user or their representative that the duty of candour has come into effect, to provide information about any further enquiries that will be carried out, and make provision about support and an apology.

Section 5 - Primary care providers: duty to prepare report

21. This section requires a primary care provider to prepare an annual report on whether the duty of candour has come into effect in relation to health care provided by the provider. The section sets out what information the report must contain (but it can include other information).
22. Where a primary care provider has provided health care on behalf of two or more local health boards in a particular financial year, this section will require the provider to prepare a separate report in respect of each local health board.

Section 6 - Supply of report under section 5

23. This section requires a primary care provider, as soon as practicable after the end of a financial year, to send the annual report prepared under section 5 to the local health board to which the report relates.
24. A local health board must prepare a summary of the reports it has received from the primary care providers under subsection (1).

Section 7 - Local Health Board, NHS Trust and Special Health Authority: reporting requirements

25. This section requires local health boards, NHS trusts and Welsh special health authorities (including NHS Blood and Transplant in relation to the exercise of its functions in Wales), as soon as practicable after the end of each financial year, to prepare an annual report on the duty of candour. It also makes provision about what that report must contain (but it can include other information).

Section 8 – Publication of section 6 summary and section 7 report

26. This section requires NHS bodies subject to the duty in section 7 to publish the reports prepared under that section.
27. In the case of a local health board, the report must include the summary prepared under section 6 of the reports provided to the local health board by primary care providers providing services on its behalf. The local health board will therefore be responsible for publishing information relevant to the duty of candour in respect of its own services and the services provided by primary care services for its area. This will mean that all of the information about the duty of candour in respect of a local health board area will be published together.

Section 9 – Confidentiality

28. Subsection (1) of this section provides that a report published under section 8 by an NHS body may not name certain individuals. The individuals are: any person to whom health care is being or has been provided by or on behalf of the body; and any person acting on such a person's behalf. In addition, subsection (2) requires an NHS body, when determining what information to include in a section 8 report, to have regard to the need to avoid including any information which, even though it does not actually give an individual's name, is in the circumstances likely to enable the identification of that individual. Such a circumstance might arise, for example, where the details of a particular patient's care have received media attention. The purpose of this provision is to protect confidentiality.

Section 10 – Guidance given by the Welsh Ministers

29. This section requires NHS bodies, in exercising functions relating to the duty of candour, to have regard to any guidance issued by the Welsh Ministers.

Section 11 – Interpretation of “health care” and other terms

30. This section makes provision about the interpretation of terms used in Part 3 including the meaning of “health care”, “illness” and “NHS body”.
31. By virtue of subsection (5), where health care is provided as part of a contract, agreement or arrangement between two NHS bodies, the care is deemed as having been provided by the body providing the care rather than the body which arranged for the care to be provided on its behalf. This means that in relation to such an arrangement, the duty of candour, if engaged, would apply to the provider of the care only. This includes health care provided on behalf of the NHS body by a primary care provider.
32. Under subsection (6), where health care is provided on an NHS body's behalf by a body that is not an NHS body, the duty of candour, if engaged in relation to the health care in question, will apply to the NHS body, not the body which provided the care.

Part 4: The Citizen Voice Body for Health and Social Care

Section 12 - Establishment of Citizen Voice Body

These notes refer to the Health and Social Care (Quality and Engagement) (Wales) Bill which was introduced into the National Assembly for Wales on 17 June 2019

33. This section establishes the Citizen Voice Body for Health and Social Care, Wales (the “Citizen Voice Body”) as a body corporate (a legal entity in its own right) whose general objective will be to represent the interests of the public in health and social care. It will also provide complaints advocacy service in respect of health and social care. The Citizen Voice Body will be a national body that will replace the 7 Community Health Councils in Wales which operate at local levels and the Board of Community Health Councils which oversees the local Councils.
34. Provision about the Citizen Voice Body’s membership, constitution and operational arrangements is made in Schedule 1. It will have at least 7 but no more than 9 members, plus a chairing member and a deputy chairing member, who will be appointed by the Welsh Ministers.
35. The Citizen Voice Body will be required to appoint a chief executive and may appoint other staff. The Body will have the power to establish committees and sub-committees and will be required to make rules regulating its procedure and the procedure of any of its committees or sub-committees.

Section 13 – General objective

36. This section provides that the Citizen Voice Body’s general objective, in carrying out its functions, is to represent the interests of the public in respect of health services and social services. “Health services” mean NHS services and “social services” mean the services provided by local authorities in exercise of their social services functions.
37. Subsection (2) requires the Citizen Voice Body, for the purpose of achieving its general objective, to seek the views of the public. It may do so in whatever way it considers appropriate. For example, the Body may hold events, conduct online surveys polls and online discussion groups, distribute feedback forms and maintain a social media presence. Section 15 enables the Body to make representations to a local health board, NHS trust, Welsh special health authority or local authority which will enable it to convey to those bodies the views it has sought from the public.
38. The Citizen Voice Body will also have a role where local health boards or NHS trusts plan services or propose changes to them. Under section 183 of the National Health Service (Wales) Act 2006 and section 242 of the National Health Service Act 2006 local health boards and NHS trusts have a duty make arrangements to consult the public or their representatives when they plan their services, develop proposals for changing how their services are provided or make decisions affecting the operation of their services. In the exercise of its function of representing the public’s interests, the Citizen Voice Body may be involved in consultations carried out by local health boards in the discharge of these duties. Local health boards, and NHS trusts may consult the Body directly but the Body may also instigate its own contribution to consultations. The local health board, or trust must take any representation made by the Body into account (see section 15). The Body may also make contributions to any consultation carried out by a local authority about its social services functions. The local authority must take any representation made by the Body into account (see section 15).

Section 14 – Public awareness and statement of policy

39. This section places the Citizen Voice Body under a duty to promote public awareness of its general objective and functions. It must also prepare and publish a statement of its policy setting out how it proposes to promote awareness of its functions and how it will seek the views of the public for the purpose of its general objective.

Section 15 – Representations to public bodies

40. This section enables the Citizen Voice Body to make representations to a local health board, NHS trust, Welsh special health authority or local authority about anything it considers relevant to provision of a health service or social services. This enables it to make known any views it has sought from the public and represent those views to the bodies responsible for providing and arranging health and social services, whether in response to consultation or at its own instigation.
41. A local health board, NHS trust, Welsh special health authority or local authority must have regard to the representation when exercising any function to which that representation relates.

Section 16 - Advocacy services etc. in respect of complaints about services

42. This section gives functions to the Citizen Voice Body in relation to complaints. Under this section the Citizen Voice Body may provide assistance to individuals with complaints relating to health and social services including social care services regulated under the Regulation and Inspection of Social Care (Wales) Act 2016.
43. Assistance may be given by, for example, providing information and support to allow a service user to pursue a complaint themselves or by providing the support to a complainant at meetings where a complaint is discussed.
44. Subsection (2) sets out the complaints relating to health services in respect of which the Citizen Voice Body may give assistance. They are the complaints in respect of which by virtue of section 187 of the National Health Service (Wales) Act 2006 the Welsh Ministers are required to arrange for the provision of independent advocacy services. These include complaints about—
- a. the exercise of any of the functions of an NHS body (a local health board, an NHS trust or Welsh special health authority),
 - b. the provision of health care by an NHS body including care provided on their behalf by another person or body,
 - c. the provision of redress by or for an NHS body under the NHS Redress (Wales) Measure 2008.
45. It also includes complaints made to the Public Services Ombudsman for Wales relating to NHS services.
46. Subsections (3) to (6) set out the other complaints in respect of which the Citizens Voice Body may provide assistance. These include—
- a. complaints made to a local authority about the exercise of its social services functions,
 - b. complaints made to a local authority about the provision of services by another person or body under arrangements with the local authority,

These notes refer to the Health and Social Care (Quality and Engagement) (Wales) Bill which was introduced into the National Assembly for Wales on 17 June 2019

- c. complaints made to a provider of a regulated social care service (within the meaning of the Regulation and Inspection of Social Care (Wales) Act 2016) such as a care home service or domiciliary support service.
- 47. It also includes complaints made to the Public Services Ombudsman for Wales about a local authority's social services functions or about care home services and domiciliary care services.
- 48. Subsection (7) excludes from the Body's functions assistance with complaints to a local authority by children and other specified individuals where complaints assistance is already arranged by local authorities by virtue of their duties under Part 10 of the Social Services and Well-being (Wales) Act 2014.

Section 17 – Duty to promote awareness of activities of Citizen Voice Body

- 49. This section imposes a duty on local health boards, NHS trusts, Welsh special health authorities and local authorities to promote awareness of the activities of the Citizen Voice Body.

Section 18 - Duty to supply information to Citizen Voice Body

- 50. This section imposes a duty on local health boards, NHS trusts, Welsh special health authorities and local authorities to supply such information to the Citizen Voice Body as it may reasonably request for the purpose of its functions. This will enable it to obtain information about the services provided by or arranged by the body or its proposals for developments, for example. The information excludes information that is protected from disclosure by other legislation or other rule of law. A request for information could not, for example, override prohibitions on disclosure contained in data protection legislation.

Section 19 and 20– Meaning of health services, social services and other terms

- 51. These sections make provision about the interpretation of the terms used in Part 4 including the meaning of “health services” and “social services”.

Section 21 – Abolition of Community Health Councils, and connected matters

- 52. This section abolishes Community Health Councils and the Board of Community Health Councils in Wales by the repeal of section 182 of and Schedule 10 to the National Health Service (Wales) Act 2006. Community Health Councils were established under section 182 of the National Health Service (Wales) Act 2006 to represent the interests of the public in the health service. They also provide independent advocacy services, by virtue of arrangements made with the Welsh Ministers under section 187 of the National Health Service (Wales) Act 2006. These functions will be exercised by the Citizen Voice Body with the addition of function relating to social care.
- 53. Part 2 of Schedule 3 makes consequential amendments related to the abolition of the Community Health Councils and the Board of Community Health Councils and creation of the Citizen Voice Body. The Community Health Councils were initially established in 1974 in England and Wales and continued in existence in Wales by virtue of section 182 of the National Health Service (Wales) Act 2006. A number of Acts of Parliament such as the Public Bodies (Admission to Meetings) Act 1960, the

These notes refer to the Health and Social Care (Quality and Engagement) (Wales) Bill which was introduced into the National Assembly for Wales on 17 June 2019

Freedom of Information Act 2000 and the Equality Act 2010 refer to Community Health Councils, as do a number of Welsh Acts, such as the Well-being of Future Generations (Wales) Act 2015 and the Regulation and Inspection of Social Care (Wales) Act 2016. This Part of the Schedule removes references to the Community Health Council and Board of Community Health Councils in Wales and, where appropriate, adds a reference to the Citizen Voice Body.

54. This section also introduces Schedule 2 to the Act which enables the Welsh Ministers to transfer property, rights and liabilities which currently exist in relation to Community Health Councils to the Citizen Voice Body. The Welsh Ministers must lay any scheme before the National Assembly for Wales, as provided in paragraph 1(6).

Part 5: Miscellaneous and general

Section 22 – Vice-chairs of boards of directors of NHS Trusts

55. This section amends Part 1 of Schedule 3 to the National Health Service (Wales) Act 2006 to enable the Welsh Ministers, if they consider it appropriate, to appoint a vice-chair to the board of an NHS Trust.
56. Subsections (3) and (4) make consequential amendments in connection with the main proposition in subsection (2). In the case of subsection (3), these amendments are necessary to allow the Welsh Ministers to make regulations about the qualifications and tenure of office of a vice chair (including the circumstances in which they cease to hold office or may be removed or suspended). The amendments made by subsection (4) are necessary to require an NHS Trust to pay remuneration and other allowances to a vice-chair.

Section 23 – Regulations

57. This section explains that powers to make regulations are to be exercised by statutory instrument (which means that certain procedural and other requirements contained in the Statutory Instruments Act 1946 apply in relation to the regulations).
58. Subsection (3) provides that the affirmative procedure will apply to regulations made under section 26 if the regulations amend or repeal any enactment contained in primary legislation (section 26 contains a power to make transitional etc. provision necessary for the purposes of the Bill). This means that any such regulations are subject to the express approval of the National Assembly for Wales.
59. Subsection (4) provides that all other regulations are subject to annulment in pursuance of a resolution of the National Assembly for Wales, including regulations made under section 26 that do not amend or repeal primary legislation.

Section 24 – Interpretation

60. This section defines key terms used in the Bill, including “regulations”, “Local Health Board”, and “NHS Trust”.

Section 25– Minor and consequential amendments

61. This section introduces Schedule 3 which sets out minor and consequential amendments relating to the duty of quality and the Citizen Voice Body.

These notes refer to the Health and Social Care (Quality and Engagement) (Wales) Bill which was introduced into the National Assembly for Wales on 17 June 2019

62. Part 2 of Schedule 3 sets out consequential amendments related to the abolition of the Community Health Councils and the Board of Community Health Councils in Wales and creation of the Citizen Voice Body.

Section 26 – Power to make transitional etc. provision

63. This section enables the Welsh Ministers to make regulations to provide for any consequential, supplementary or incidental provision, or any transitional, transitory or saving provisions in the circumstances set out in subsection (1).

Section 27 – Coming into force

64. This section makes provision about when and how the Bill comes into force.
65. Subsection (1) provides that this section and section 28 will come into force one day after the Bill receives Royal Assent.
66. The other provisions of the Bill will come into force on a day specified in a commencement order (or orders) made by the Welsh Ministers under subsection (2). By virtue of subsection (2), the Welsh Ministers will have power to specify different dates for different purposes and include transitional, transitory and savings provision in any commencement order.

Annex 2

Index of Standing Order requirements

Table 70

Standing order		Section	pages/ paragraphs
26.6(i)	Statement the provisions of the Bill would be within the legislative competence of the Assembly	Member's declaration	Page 1
26.6(ii)	Set out the policy objectives of the Bill	Chapter 3 - Purpose and intended effect of the legislation	Page 10
26.6(iii)	Set out whether alternative ways of achieving the policy objectives were considered and, if so, why the approach taken in the Bill was adopted	Part 2 – Regulatory Impact Assessment	Page 47
26.6(iv)	Set out the consultation, if any, which was undertaken on: (a) the policy objectives of the Bill and the ways of meeting them; (b) the detail of the Bill, and (c) a draft Bill, either in full or in part (and if in part, which parts)	Chapter 4 – Consultation	Page 41 Paras 149 to 158
26.6(v)	Set out a summary of the outcome of that consultation, including how and why any draft Bill has been amended	Chapter 4 – Consultation	Page 42 Para 153
26.6(vi)	If the bill, or part of the Bill, was not previously published as a draft, state	Chapter 4 – Consultation	Page 43

Standing order		Section	pages/ paragraphs
	the reasons for that decision		Para 158
26.6(vii)	Summarise objectively what each of the provisions of the Bill is intended to do (to the extent that it requires explanation or comment) and give other information necessary to explain the effect of the Bill	Annex 1 – Explanatory Notes	Page 158
26.6(viii)	Set out the best estimates of: <ul style="list-style-type: none"> (a) the gross administrative, compliance and other costs to which the provisions of the Bill would give rise; (b) the administrative savings arising from the Bill; (c) net administrative costs of the Bill’s provisions; (d) the timescales over which such costs and savings would be expected to arise; and (e) on whom the costs would fall 	Part 2 – Regulatory Impact Assessment	Page 47
26.6(ix)	Any environmental and social benefits and dis-benefits arising from the Bill that cannot be quantified financially	Part 2 – Regulatory Impact Assessment	Page 47
26.6(x)	Where the Bill contains any provision conferring power to make subordinate legislation, set out, in relation to each such provision: <ul style="list-style-type: none"> (a) the person upon whom, or the body upon which, the power is conferred and the form in which the power is to be exercised; (b) why it is considered appropriate to delegate the power; and 	Chapter 5 - Power to make subordinate legislation	Page 44 Paras 159 to 160

Standing order		Section	pages/ paragraphs
	(c) the Assembly procedure (if any) to which the subordinate legislation made or to be made in the exercise of the power is to be subject, and why it was considered appropriate to make it subject to that procedure (and not to make it subject to any other procedure);		
26.6(xi)	Where the Bill contains any provision charging expenditure on the Welsh Consolidated Fund, incorporate a report of the Auditor General setting out his or her views on whether the charge is appropriate	The requirement of Standing Order 26.6(xi) does not apply to this Bill	not applicable
26.6(xii)	Set out the potential impact (if any) on the justice system in England and Wales of the provisions of the Bill (a “justice impact assessment”), in accordance with section 110A of the Act.	Part 2 – Regulatory Impact Assessment	Page 154 Para 613
26.6B	Where provisions of the Bill are derived from existing primary legislation, whether for the purposes of amendment or consolidation, the Explanatory Memorandum must be accompanied by a table of derivations that explain clearly how the Bill relates to the existing legal framework.	The requirement in Standing Order 26.6B for a Table of Derivations is not applicable to this Bill as the Bill is a standalone piece of legislation and does not derive from existing primary legislation for the purposes of amendment or consolidation	not applicable
26.6C	Where the Bill proposes to significantly amend existing primary legislation, the Explanatory Memorandum must be accompanied by a schedule setting out the wording of existing legislation amended by the Bill, and setting out clearly how that wording is amended by the Bill.	Annex 4 – Schedule of Amendments	Page 171

Annex 3

Schedule of amendments

National Health Service (Wales) Act 2006

AMENDMENTS TO BE MADE BY THE HEALTH AND SOCIAL CARE (QUALITY AND ENGAGEMENT) (WALES) BILL

This document is intended to show how the provisions of the National Health Service (Wales) Act 2006 as they applied in relation to Wales would look on 04 March 2019 as amended by the Health and Social Care (Quality and Engagement) (Wales) Bill (if enacted as introduced on 17 June 2019).

Material to be deleted by the Health and Social Care (Quality and Engagement) (Wales) Bill is in strikethrough, e.g. ~~omitted material looks like this~~. Material to be added by the Health and Social Care (Quality and Engagement) (Wales) Bill is underlined, e.g. added material looks like this. References to the relevant amending provisions of the Bill are provided in the right hand column on each page.

A number of related provisions from the Act, although not being amended, are included to aid understanding of the proposed amendments.

Warning

This text has been prepared by officials of the Department for Health and Social Services of the Welsh Government. Although efforts have been taken to ensure that it is accurate, it should not be relied on as a definitive text of the Act or the Bill.

It has been produced solely to help people understand the effect of the Health and Social Care (Quality and Engagement) (Wales) Bill. It is not intended for use in any other context.

National Health Service (Wales) Act 2006

*Amending
section of the
Health and
Social Care
(Quality and
Engagement)
(Wales) Bill*

<p>1 Welsh Ministers' duty to promote health service</p> <p>(1) The Welsh Ministers must continue the promotion in Wales of a comprehensive health service designed to secure improvement—</p> <p>(a) in the physical and mental health of the people of Wales, and</p> <p>(b) in the prevention, diagnosis and treatment of illness.</p> <p>(2) The Welsh Ministers must for that purpose provide or secure the provision of services in accordance with this Act.</p> <p><u>1A</u> Welsh Ministers' duty to secure quality in health services</p> <p>(1) <u>The Welsh Ministers must exercise their functions in relation to the health service with a view to securing improvement in the quality of health services.</u></p> <p>(2) <u>For the purposes of this section—</u></p> <p><u>“health services” means any services provided or secured in accordance with this Act;</u></p> <p><u>“quality” includes, but is not limited to, quality in terms of—</u></p> <p>(a) <u>the effectiveness of health services,</u></p> <p>(b) <u>the safety of health services, and</u></p> <p>(c) <u>the experience of individuals to whom health services are provided.</u></p> <p>(3) <u>The Welsh Ministers must publish an annual report on the steps they have taken to comply with the duty in subsection (1).</u></p> <p>(4) <u>The report must include an assessment of the extent of any improvement in outcomes achieved by virtue of those steps.</u></p> <p>(5) <u>The Welsh Ministers must lay a copy of the report before the National Assembly for Wales.</u></p>	<p>Section 2(2)</p>
<p>12 Functions of Local Health Boards</p> <p>(1) The Welsh Ministers may direct a Local Health Board to exercise in</p>	<p>Section 2(3)</p>

<p>relation to its area—</p> <p>(a) functions which were transferred to the National Assembly for Wales by the Health Authorities (Transfer of Functions, Staff, Property, Rights and Liabilities and Abolition) (Wales) Order 2003 (S.I. 2003/813 (W.98)),</p> <p>(b) such other of their functions relating to the health service as are specified in the direction.</p> <p>(2) The functions which may be specified in directions under subsection (1) include functions under enactments relating to mental health and care homes.</p> <p>(3) The Welsh Ministers may give directions to a Local Health Board about its exercise of any functions.</p> <p><u>12A Local Health Boards' duty to secure quality in health services</u></p> <p>(1) <u>Each Local Health Board must exercise its functions with a view to securing improvement in the quality of health services.</u></p> <p>(2) <u>For the purposes this section—</u></p> <p><u>“health services” means any services provided or secured in accordance with this Act;</u></p> <p><u>“quality” includes, but is not limited to, quality in terms of—</u></p> <p><u>(a) the effectiveness of health services,</u></p> <p><u>(b) the safety of health services, and</u></p> <p><u>(c) the experience of individuals to whom health services are provided.</u></p> <p>(3) <u>Each Local Health Board must publish an annual report on the steps it has taken to comply with the duty in subsection (1).</u></p> <p>(4) <u>The report must include an assessment of the extent of any improvement in outcomes achieved by virtue of those steps.</u></p>	
<p>20 General duty of NHS trusts</p> <p>An NHS trust must exercise its functions effectively, efficiently and economically.</p> <p><u>20A Duty of NHS trusts to secure quality in health services</u></p> <p>(1) Each NHS trust must exercise its functions with a view to securing</p>	<p>Section 2(4)</p>

<p><u>improvement in the quality of health services.</u></p> <p>(2) <u>For the purposes of this section—</u></p> <p><u>“health services” means any services provided or secured in accordance with this Act;</u></p> <p><u>“quality” includes, but is not limited to, quality in terms of—</u></p> <p><u>(a) the effectiveness of health services,</u></p> <p><u>(b) the safety of health services, and</u></p> <p><u>(c) the experience of individuals to whom health services are provided.</u></p> <p>(3) <u>Each NHS trust must publish an annual report on the steps it has taken to comply with the duty in subsection (1).</u></p> <p>(4) <u>The report must include an assessment of the extent of any improvement in outcomes achieved by virtue of those steps.”</u></p>	
<p>24 Exercise of health service functions by Special Health Authorities</p> <p>(1) The Welsh Ministers may direct a Special Health Authority to exercise any of the functions of the Welsh Ministers relating to the health service which are specified in the directions.</p> <p>(2) Subsection (1) does not apply to the functions of the Welsh Ministers in relation to pilot schemes.</p> <p>(3) The functions which may be specified in directions include functions under enactments relating to mental health and care homes.</p> <p><u>24A Duty of Special Health Authorities to secure quality in health services</u></p> <p>(1) <u>Each Special Health Authority must exercise its functions with a view to securing improvement in the quality of health services.</u></p> <p>(2) <u>For the purposes of this section—</u></p> <p><u>“health services” means any services provided or secured in accordance with this Act;</u></p> <p><u>“quality” includes, but is not limited to, quality in terms of—</u></p> <p><u>(a) the effectiveness of health services,</u></p> <p><u>(b) the safety of health services, and</u></p>	<p>Section 2(5)</p>

<p><u>(c) the experience of individuals to whom health services are provided.</u></p> <p><u>(3) Each Special Health Authority must publish an annual report on the steps it has taken to comply with the duty in subsection (1).</u></p> <p><u>(4) The report must include an assessment of the extent of any improvement in outcomes achieved by virtue of those steps.</u></p> <p><u>(5) References in this section to a Special Health Authority do not include references to a cross-border Special Health Authority (within the meaning of section 8A(5))."</u></p>	
<p style="text-align: center;">CHAPTER 1 COMMUNITY HEALTH COUNCILS</p> <p>182 Community Health Councils</p> <p>(1) The Community Health Councils established for areas in Wales continue in existence.</p> <p>(2) But the Welsh Ministers may by order—</p> <p style="padding-left: 40px;">(a) provide for Community Health Councils to be known by a different name,</p> <p style="padding-left: 40px;">(b) vary the area in Wales for which a Community Health Council is established,</p> <p style="padding-left: 40px;">(c) abolish a Community Health Council, or</p> <p style="padding-left: 40px;">(d) establish a new Community Health Council for an area in Wales.</p> <p>(3) The Welsh Ministers must act under this section to ensure—</p> <p style="padding-left: 40px;">(a) that the areas for which Community Health Councils are at any time established together comprise the whole of Wales,</p> <p style="padding-left: 40px;">(b) that no part of an area for which a Community Health Council is established is separated from the rest of it by a territory not included in the area.</p> <p>(4) Schedule 10 makes further provision about Community Health Councils continued in existence or established under this section.</p>	Section 21(1)
<p style="text-align: center;">SCHEDULE 10 FURTHER PROVISION ABOUT COMMUNITY HEALTH COUNCILS</p>	Section 21(2)

1— ~~Each Community Health Council must—~~

- ~~(a) represent the interests in the health service of the public in its district, and~~
- ~~(b) perform such other functions as may be conferred on it by regulations under paragraph 2.~~

2— ~~Regulations may make provision about—~~

- ~~(a) the membership of Councils,~~
- ~~(b) the proceedings of Councils,~~
- ~~(c) the staff, premises and expenses of Councils,~~
- ~~(d) the discharge of any function of a Council by a committee of the Council or by a joint committee appointed with another Council,~~
- ~~(e) the appointment, as members of a committee or joint committee, of persons who are not members of the Council or Councils concerned,~~
- ~~(f) the consultation of Councils by Local Health Boards and NHS trusts with respect to such matters, and on such occasions, as may be prescribed,~~
- ~~(g) the consideration by Councils of matters relating to the operation of the health service within their districts, and the giving of advice by Councils to Local Health Boards and NHS trusts on such matters,~~
- ~~(h) the preparation and publication of reports by Councils,~~
- ~~(i) matters to be included in any such report,~~
- ~~(j) the furnishing and publication by Local Health Boards and NHS trusts of comments on reports of Councils,~~
- ~~(k) the provision of information (including descriptions of information which are or are not to be provided) to Councils by Local Health Boards,~~
- ~~(l) the provision of information (including descriptions of information which are or are not to be provided) by Councils to other persons (including other Councils),~~
- ~~(m) the provision by Councils on behalf of the Welsh Ministers of the independent advocacy services required to be provided under section 187,~~
- ~~(n) the functions to be exercised by Councils in addition to those~~

<p style="text-align: center;">exercisable otherwise than by virtue of this Schedule.</p> <p>2A Regulations made under paragraph 2(a) may make provision about—</p> <ul style="list-style-type: none"> (a) the election by members of a Council of a member to chair the Council, and (b) the appointment by the Welsh Ministers of a member to chair the Council on an interim basis in cases where the member so elected is removed or suspended from office.] <p>3 (1) The Welsh Ministers may make regulations requiring—</p> <ul style="list-style-type: none"> (a) Local Health Boards, (d) NHS trusts, (e) local authorities, (f) persons providing primary medical services, primary dental services or pharmaceutical services under this Act or the National Health Service Act 2006 (c. 41), (g) persons providing general ophthalmic services under this Act, or (h) persons providing piloted services (within the meaning of section 92(7) of this Act or section 134(7) of the National Health Service Act 2006 (c. 41)) or LP services (within the meaning of paragraph 1(7) of Schedule 7 to this Act or paragraph 1(7) of Schedule 12 to that Act), <p>to allow members of a Council authorised by or under the regulations to enter and inspect, for the purposes of any of the Council's functions, premises owned or controlled by those referred to in paragraphs (a) to (h).</p> <p>—(2) The Welsh Ministers may also make regulations requiring any other person who owns or controls premises where services are provided as mentioned in sub-paragraph (1)(f), (g) or (h) to allow members of a Council authorised by or under the regulations to enter and inspect the premises for the purposes of any of the Council's functions.</p> <p>—(3) The regulations may in particular make provision as to—</p> <ul style="list-style-type: none"> (a) cases and circumstances in which access must be permitted, (b) limitations or conditions to which access must be subject. <p>4 The Welsh Ministers may by regulations—</p>	
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<p>(a) — provide for the establishment of a body —</p> <p>(i) — to advise Councils with respect to the performance of their functions, and to assist Councils in the performance of their functions, and</p> <p>(ii) — to perform such other functions as may be prescribed, and</p> <p>(b) — provide for the membership, proceedings, staff, premises and expenses of that body.</p> <p>5 — The Welsh Ministers may pay to members of Councils and any body established under paragraph 4 such travelling and other allowances (including compensation for loss of remunerative time) as the Welsh Ministers may determine.</p>	
<p style="text-align: center;">Part 1 of Schedule 3 <i>Board of directors</i></p> <p>3 (1) Each NHS trust has a board of directors consisting of—</p> <p style="padding-left: 40px;">(a) a chairman appointed by the Welsh Ministers, and</p> <p style="padding-left: 40px;"><u>(aa) if the Welsh Ministers consider it appropriate, a vice-chair appointed by them, and</u></p> <p style="padding-left: 40px;">(b) executive and non-executive directors.</p> <p>(2) Sub-paragraph (1)(b) is subject to paragraph 7(2).</p> <p>(3) An executive director is a director who is an employee of the NHS trust, and a non-executive director is a director who is not an employee of the NHS trust.</p> <p>(4) Sub-paragraph (3) is subject to any provision made by regulations under paragraph 4(1)(d).</p>	Section 22(2)
<p style="text-align: center;"><i>Regulations</i></p> <p>4 (1) The Welsh Ministers may by regulations make provision with respect to—</p> <p style="padding-left: 40px;">(a) the qualifications for and the tenure of office of the chairman, <u>the vice-chair</u> and directors of an NHS trust (including the circumstances in which they cease to hold, or may be removed from, office or may be suspended from performing the functions of the office),</p> <p style="padding-left: 40px;">(b) the persons by whom the directors and any of the officers</p>	Section 22(3)

	<p>must be appointed and the manner of their appointment,</p> <p>(c) the maximum and minimum numbers of the directors,</p> <p>(d) the circumstances in which a person who is not an employee of the NHS trust is nevertheless, on appointment as a director, to be regarded as an executive rather than a non-executive director,</p> <p>(e) the proceedings of the NHS trust (including the validation of proceedings in the event of a vacancy or defect in appointment), and</p> <p>(f) the appointment, constitution and exercise of functions by committees and sub-committees of the NHS trust (whether or not consisting of or including any members of the board).</p> <p>(2) Regulations under sub-paragraph (1) may, in particular, make provision to deal with cases where the post of any officer of an NHS trust is held jointly by two or more persons or where the functions of such an officer are in any other way performed by more than one person.</p>	
11	<p style="text-align: center;"><i>Pay and allowances</i></p> <p>(1) An NHS trust must pay—</p> <p>(a) to the chairman, <u>the vice-chair (if any)</u> and any non-executive director of the NHS trust remuneration of an amount determined by the Welsh Ministers,</p> <p>(b) to the chairman, <u>the vice-chair (if any)</u> and any non-executive director of the NHS trust such travelling and other allowances as may be determined by the Welsh Ministers,</p> <p>(c) to any member of a committee or sub-committee of the NHS trust who is not also a director such travelling and other allowances as may be determined by the Welsh Ministers.</p> <p>(2) If an NHS trust so determines in the case of a person who is or has been a chairman of the NHS trust, the NHS trust must pay such pension, allowances or gratuities to or in respect of him as may be determined by the Welsh Ministers.</p> <p>(3) A determination under sub-paragraph (2), so far as it relates to pensions, may be made only with the approval of the Treasury.</p>	Section 22(4)

<p>(4) Different determinations may be made under sub-paragraph (1) or sub-paragraph (2) in relation to different cases or descriptions of cases.</p>	
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Health and Social Care (Community Health and Standards) Act 2003

AMENDMENTS TO BE MADE BY THE HEALTH AND SOCIAL CARE (QUALITY AND ENGAGEMENT) (WALES) BILL

This document is intended to show how the provisions of the Health and Social Care (Community Health and Standards) Act 2003⁷ as they applied in relation to Wales would look on 04 March 2019 as amended by the Health and Social Care (Quality and Engagement) (Wales) Bill (if enacted as introduced on 17 June 2019).

Material to be deleted by the Health and Social Care (Quality and Engagement) (Wales) Bill is in strikethrough, e.g. ~~omitted material looks like this~~. Material to be added by the Health and Social Care (Quality and Engagement) (Wales) Bill is underlined, e.g. added material looks like this. References to the relevant amending provisions of the Bill are provided in the right hand column on each page.

A number of related provisions from the Act, although not being amended, are included to aid understanding of the proposed amendments.

Warning

This text has been prepared by officials of the Department for Health and Social Services of the Welsh Government. Although efforts have been taken to ensure that it is accurate, it should not be relied on as a definitive text of the Act or the Bill.

It has been produced solely to help people understand the effect of the Health and Social Care (Quality and Engagement) (Wales) Bill. It is not intended for use in any other context.

**Health and Social Care (Community Health and Standards)
Act 2003**

*Amending
section of the
Health and
Social Care
(Quality and
Engagement
) (Wales) Bill*

<p>CHAPTER 2 NHS HEALTH CARE: INTRODUCTORY</p>	
<p>45 Quality in health care</p> <p>(1) — It is the duty of each Welsh NHS body to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care provided by and for that body.</p> <p>(2) In this Part “health care” means—</p> <p> (a) services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness; and</p> <p> (b) the promotion and protection of public health.</p> <p>(3) In subsection (2)(a), “illness” has the meaning given by section 275 of the 2006 Act.</p> <p>(4) In this Chapter references to the provision of health care for a body include in the case of an English NHS body references to the provision of health care in respect of which direct payments are made by that body under section 12A(1), or under regulations under section 12A(4), of the National Health Service Act 2006.</p>	<p><i>Schedule 3 Part 1 Para 2</i></p>
<p>47 Standards set by Assembly</p> <p>(1) The Assembly may prepare and publish statements of standards in relation to the provision of health care by and for Welsh NHS bodies.</p> <p>(2) The Assembly must keep the standards under review and may publish amended statements whenever it considers it appropriate.</p> <p>(3) The Assembly must consult such persons as it considers appropriate—</p> <p> (a) before publishing a statement under this section;</p> <p> (b) before publishing an amended statement under this section which in the opinion of the Assembly effects a substantial change in the standards.</p> <p>(4) The standards set out in statements under this section are to be taken into account by every Welsh NHS body in discharging its duty under</p>	<p><i>Schedule 3 Part 1 Para 3</i></p>

~~section 45~~ a Welsh NHS body in discharging a duty under section 12A(1), 20A(1), or 24A(1) of the National Health Service (Wales) Act 2006 (duties to secure quality in the provision of health services).

CHAPTER 4

NHS HEALTH CARE: FUNCTIONS OF NATIONAL ASSEMBLY FOR WALES

Reviews and investigations

70 Reviews and investigations relating to Wales

- (1) The Assembly has the function of conducting reviews of, and investigations into, the provision of health care by and for Welsh NHS bodies.
- (2) The Assembly may in particular under this section conduct—
 - (a) a review of the overall provision of health care by and for Welsh NHS bodies;
 - (b) a review of the overall provision of a particular kind of health care by and for Welsh NHS bodies;
 - (c) a review of, or investigation into, the provision of any health care by or for a particular Welsh NHS body.
- (3) The Assembly has the function of conducting reviews of the ~~arrangements made by Welsh NHS bodies for the purpose of discharging their duty under section 45—~~ steps taken by a Welsh NHS body for the purpose of discharging a duty under section 12A(1), 20A(1), or 24A(1) of the National Health Service (Wales) Act 2006 (duties to secure quality in the provision of health services).
- (3A) Before conducting a review under this section the Assembly must—
 - (a) consult the Auditor General for Wales, and
 - (b) take into account any relevant work done or being done by the Auditor General for Wales.
- (4) In exercising its functions under this section in relation to any health care the Assembly shall be concerned in particular with—
 - (a) the availability of, and access to, the health care;
 - (b) the quality and effectiveness of the health care;
 - (c) the financial or other management of the health care and the economy and efficiency of its provision;

*Schedule 3
Part 1 Para 4*

<p>(d) the availability and quality of information provided to the public about the health care;</p> <p>(e) the need to safeguard and promote the rights and welfare of children; and</p> <p>(f) the effectiveness of measures taken for the purpose specified in paragraph (e) by the body in question and any person who provides, or is to provide, health care for that body,</p> <p>and must take into account the standards set out in statements published under section 47.</p> <p>(5) For the purposes of this section the Assembly may carry out an inspection of—</p> <p>(a) any Welsh NHS body;</p> <p>(b) any other person who provides, or is to provide, health care for a Welsh NHS body (in Wales or elsewhere).</p> <p>(6) Where the Assembly conducts a review under this section it must publish a report.</p>	
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